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

9-04
15 December 2004

INITIAL ASSESSMENT REPORT

PROPOSAL P291

REVIEW OF NOVEL FOOD STANDARD

DEADLINE FOR PUBLIC SUBMISSIONS: **6pm (Canberra time) 2 March 2005**
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

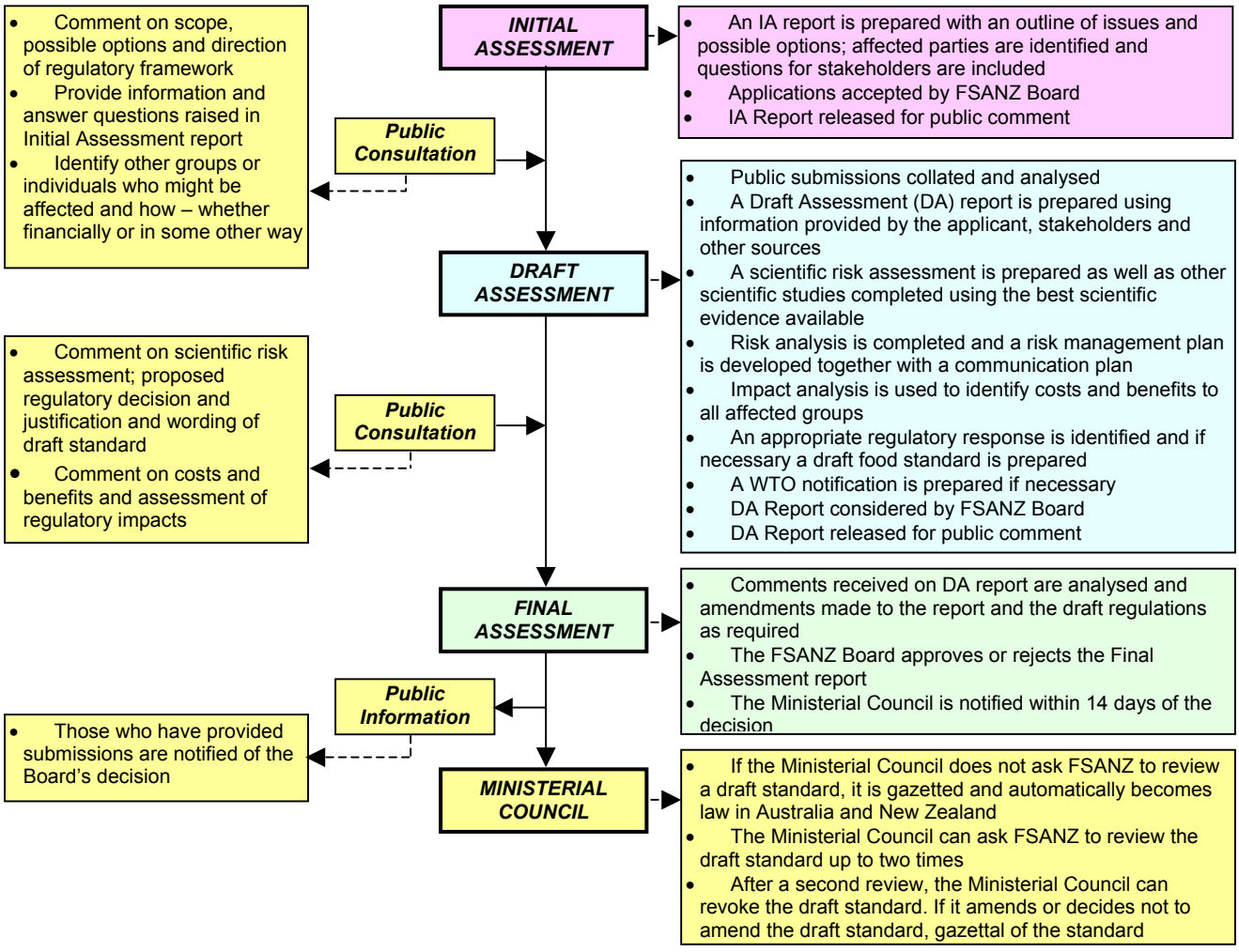
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 an Initial Assessment Report of Proposal P291, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report 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 Draft 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) 2 March 2005**.

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

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 such, FSANZ has raised this Proposal to review the regulation for novel foods and the mechanism for making determinations as to novelty. In accordance with the policy guidance, FSANZ has established a Standard Development Advisory Committee (SDAC) to assist FSANZ during the review of novel foods. The role of the SDAC is to provide advice to FSANZ on matters related to the review, rather than to endorse any regulatory option.

The current Novel Foods Standard requires that all novel foods or novel food ingredients undergo a risk-based pre-market safety assessment before they can be offered for retail sale for direct human consumption in Australia and New Zealand. Novel foods are defined as a subset of non-traditional foods. Novel foods must comply with any conditions of use that are specified as a result of their pre-market safety assessment. The determination as to whether or not a food or food ingredient is novel is made in accordance with the definitions for 'non-traditional' and 'novel' in the Standard and 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).

A number of issues have been identified in this Report in relation to the current Standard and were discussed with SDAC members at the first meeting. Questions are asked of submitters in relation to all of the issues identified. The issues for which a detailed discussion is presented in this Report include:

- The general history and operation of the Standard, including determinations with respect to novelty and proposed decision-making mechanisms.
- The purpose of the Standard, including the reasons for introducing the Standard and the wording in the purpose clause of the Standard.
- The definitions for 'non-traditional food' and 'novel food' and the difficulties associated with these definitions, particularly for enforcement agencies.
- The scope of the Standard to include food produced using new technologies and/or specific categories of novel foods.
- Data requirements for the assessment of novel foods and the assessment process itself.
- Inter-relationships with other standards, other projects and the foods-therapeutic goods interface.
- The uptake of existing permissions for novel foods.

A number of regulatory options are put forward for comment. The regulatory options also incorporate non-regulatory initiatives that primarily relate to the operating procedures for determining whether a food or food ingredient is novel. FSANZ has identified affected parties and discussed some possible costs and benefits for each of the regulatory options for each of the affected parties. In summary, these options are:

- Option 1 – retain the current Standard and operating procedures for determining novelty (status quo);

- Option 2 – retain the current Standard but amend the operating procedures for determining novelty (i.e., guidelines, development of a decision-tree);
- Option 3 – amend the current Standard and the operating procedures for determining novelty (considering the purpose clause, the definitions, the assessment process, the scope of the regulations to include foods produced using new technologies and the need for categories of novel foods); and
- Option 4 – remove the current Standard – no specific regulation for novel foods.

FSANZ is seeking comments from submitters on the options put forward and the potential costs and benefits for each of the options for the affected parties.

While there are number of complex issues that require further consideration, at the first SDAC meeting members supported retaining some regulation for novel foods in the Code. The SDAC members also supported including revised classes of novel foods in the guidelines.

It is likely that the SDAC will meet again in mid-2005 following receipt of submissions in response to this Report to discuss the issues raised and have input into the Draft Assessment Report. The Draft Assessment Report is likely to be released for public comment in the 3rd quarter of 2005. The SDAC will likely meet again following the release of the Draft Assessment Report and prior to the completion of the Final 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 a number of issues and to use a reference group to assist in the review. The policy guidance was developed by a Food Regulation Standing Committee (FRSC) working group including the public release of a policy options paper.

This review will cover those issues raised by submitters to the FRSC policy options paper and others issues as appropriate including, but not limited to:

- 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 and importation issues.
- The scope of the existing Standard 1.5.1 and the appropriateness of this, 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 (e.g. nutrition, health and related claims), other existing Standards and the foods-therapeutic goods interface.
- Comparison with the regulation of novel foods in other countries.

There are a variety of different foods that can potentially be captured by the Novel Foods Standard currently, ranging from whole foods to dietary macro-components and extracts of plants. The scope of the Standard and whether it reflects the purpose of the Standard will be considered during this review.

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 met for the first time on 23 September 2004 for a one-day meeting with members participating in both Canberra and Wellington. 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. Advice provided by SDAC members 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 in place (December 1999) and when clause 2 of the Standard 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 by 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. Standard 1.5.1 is at Attachment 1. The Standard prohibits the sale of novel foods unless they are listed in the Table to clause 2 of the Standard and comply with any special conditions of use in the Table. This means that for any food or food ingredient 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 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 non-traditional 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, 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 2); 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 (Attachment 3).

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.

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 (refer to Attachment 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 (refer to Attachment 1):

- Docosahexaenoic acid (DHA) – rich dried marine micro-algae (*Schizochytrium* sp.);
- Docosahexaenoic acid (DHA) – rich oil derived from marine micro-algae (*Schizochytrium* sp.);
- 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 recently completed the assessments for the applications listed below and recommended that they be approved for use as novel foods. The Final Assessment Reports, including their recommendation have been notified to the Ministerial Council.

- Application A433 – Phytosterol esters as ingredients in breakfast cereal;
- Application A434 – Phytosterol esters in low fat milk and low fat yoghurt;
- Application A494 – Alpha-cyclodextrin as a novel food; and
- Application A508 – Tall oil phytosterols in low fat milk.

In addition, FSANZ is currently assessing Application A522 – DHA-rich micro-algal oil (*Ulkenia* sp.).

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 is equivalent 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 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.

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 had 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 4). The final draft policy guidance was considered by FRSC in September 2003 and it was agreed that this draft policy guidance would be provided to the Ministerial Council in December 2003. The final draft policy guidance did not directly reflect any of the policy options or decision-making mechanisms put forward in the options paper due 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 5. 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 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 is 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).

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

    3. the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,
    4. the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or

5. 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 and 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 substances); 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 General History and Operation of Standard 1.5.1

FSANZ has worked in close collaboration with Senior Food Officers in Australian States and Territories, the Australian Quarantine and Inspection Service and New Zealand through the Technical Advisory Group (TAG) forum regarding the operation of the novel foods standard.

5.1.1 Determinations with respect to novelty

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) through the TAG forum.

The internal FSANZ Novel Foods Reference Group (NFRG) makes an initial consideration and this is reported to TAG or discussed with members at the forum with varying levels of involvement depending on the complexity. Some 70-80 potential novel foods or novel food ingredients have been examined by the NFRG, sometimes in conjunction with TAG. 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. This experience provides an extensive experience base for revision of the Novel Foods Standard, and in particular, the definitions provided within that Standard.

Making these considerations 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 that is not included on the FSANZ Standards Work Plan.

During the time between which the Novel Foods Standard was in place and when clause 2 of the Standard came into full effect, 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 by the Ministerial Policy Guidelines work program.

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. Issues related to the definitions are discussed in more detail in section 5.3.

Despite these inherent difficulties, a considerable effort has been made towards ensuring consistency in the determinations with respect to novelty and the subsequent communication of these determinations. The membership of the internal FSANZ NFRG has changed and the procedures have also changed to assist in ensuring consistency. FSANZ has also worked to build on the existing working relationship with AQIS, a main source of inquiries with respect to the Standard. It is only since January 2004 that 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') without an inquirer needing to make a specific request. FSANZ now reports to TAG quarterly on considerations by the NFRG. These changes have assisted industry and enforcement agencies and some positive feedback has been received. Continued improvements in consistency will flow from other improvements that may be made to the regulation of novel foods, particularly the definitions, as a result of this review.

An SDAC member representing industry indicated at the meeting that the inclusion of considerations with respect to novelty on the FSANZ website has assisted as a guide.

Questions:

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

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

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

5.1.2 Decision-making mechanisms

Two decision-making mechanisms were proposed in the FRSC policy options paper: a decision-tree; and an expert panel. SDAC members questioned whether there is a more efficient way of determining novelty without impacting on resources and/or timelines. The NFRG is often required to meet on an ad-hoc basis and frequently, a great deal of research is undertaken in order to provide these considerations. Given the ad-hoc nature and current resources, there are sometimes difficulties in responding quickly to inquiries.

There was support from SDAC members for the development of a decision-tree to assist in making determinations with respect from novelty. Having considered more than 70 inquiries with respect to novelty, FSANZ and some TAG members have extensive experience from which to examine emerging patterns to use in the development of a decision-tree.

To some extent, the NFRG asks certain questions when considering novelty, however, these are not well articulated. Some suggestions were made by SDAC members on factors to consider in developing a decision-tree, for example, the quantity of the food or food ingredient to be used should be considered.

With respect to establishing an expert panel to assist in determinations regarding novelty, the experience of the UK ACNFP could be examined.

There was also support from SDAC members for introducing targeted education for industry on understanding and interpreting the novel foods regulations and how to meet the data requirements. It was suggested that this could assist in reducing the number of inquiries in relation to the Standard. This suggestion is incorporated into section 6 of this Report, which discusses some of the regulatory and non-regulatory options. FSANZ would need to give careful consideration to how education may be best approached and who would be best placed to conduct this (e.g. FSANZ in conjunction with enforcement agency representation, or FSANZ in conjunction with industry representation).

Questions:

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?**

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

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?**

5.2 Purpose of the Standard

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 similar regulations for novel foods.

A number of SDAC members indicated general support for having a Standard for novel foods. There were valid reasons for introducing regulation for novel foods when the Standard was put in place and these still apply. The primary reason is the protection of public health and safety.

There was general support for retaining some regulation for novel foods. However, the wording of the stated purpose in the purpose clause of the Standard should be carefully considered. A suggestion was put forward that purpose clause should refer only to 'novel foods' rather than non-traditional foods, for example:

> *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 suggestion for the wording of the purpose clause addresses the potential ambiguity with the current definition, i.e., interpreting which non-traditional foods may have features or characteristics that raise safety concerns. A clear and workable definition for 'novel foods' would be necessary for underpinning this stated purpose.

Questions:

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?

8. Does the current Standard support this purpose?

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?

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

If it is determined as a result of this review that the scope of regulations for novel foods should be expanded or narrowed, then this could be acknowledged in the purpose clause. The scope of the novel foods review and subsequently novel foods regulation is discussed in section 5.5 of this Report.

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

Although some suggestions for alternate definitions have been made, FSANZ is not currently proposing these at Initial Assessment, but rather, will put alternative(s) forward at Draft Assessment to support the more preferred option(s) and taking into account comments received by submitters on the issues discussed below.

5.3.1 General issues related to the definitions

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. The definitions for both 'non-traditional food' and 'novel food' determine what foods or food ingredients are captured by the Standard and subject to pre-market assessment requirements. It is critical to the proper operation of the Standard to have good working definitions and as such, the definitions will require substantial evaluation during the course of this review. Currently the definitions in the Novel Foods Standard are as follows:

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.

Because of the broad nature of the definitions, there is the potential for a wide range of imported ethnic foods to be captured, at least as 'non-traditional', which increases the workload for the novel foods reference group. It may not be practical for any revised definition relating to novel foods to be entirely unambiguous and as such, criteria for assessing novelty against any definition will be important for supporting that definition.

There was considerable discussion at the SDAC meeting on the definitions for 'non-traditional food' and 'novel food'. FSANZ needs to consider whether it is necessary to define 'non-traditional food'. The following points and questions were raised:

- Neither the EU nor Canada define non-traditional food, though similar elements are incorporated in their respective definitions for 'novel food'. The full definitions for novel food used in the EU and Canada are described in sections 4.7.1 and 4.7.3 respectively of this Report. The EU definition makes reference to 'novel foods or novel food ingredients which have not been used for human consumption to a significant degree within the Community and which fall under the following categories …'. In Canada, a novel food includes 'a substance, including a microorganism that does not have a history of safe use as a food'. If 'non-traditional food' is not defined in Australia and New Zealand, the definition for 'novel food' should incorporate the element of an absence of history of safe use. The EU and Canada both refer to categories of novel foods in their definition, which can also be problematic in that not all novel foods will neatly fall within specific categories.

- There are some difficulties with the definitions in Standard 1.5.1 that may be attributed to the current definition for 'non-traditional food'. 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.

- What is meant by significant human consumption? The quantities of a food ingredient to be added may be important in determining significant human consumption and the considerations of micro and macrocomponents may be different.

- Is the use of a specified number of generations (e.g. 1-3) helpful in ascertaining a tradition of use? How would such a generation be defined (i.e. number of years)?

The Therapeutic Goods Administration (TGA) refer to 3 generations of history of use in relation to complementary medicines as a guide but the information is used in a different context – the purpose of considering this history of use is to establish efficacy.

- What is meant by the term 'broad community' and how is use by other communities (e.g. indigenous use or extensive use by populous nations such as China) considered? There have been instances of food that is apparently consumed widely in another community being considered novel and captured by the Standard, for example, Ackee fruit, which is consumed in Jamaica. If a food has been consumed in a community but not offered for sale, there would be limited evidence of use other than anecdotal evidence.

- The development of a decision tree to support the definition will assist.

- With respect to any processing required to ensure safe use (e.g. adequate cooking to remove a natural toxin) it may be possible to cover such an issue using Standard 1.2.6 – Directions for Use and Storage – of the Code. If this were the case, mention of the relevant Standard could be made in the Novel Food Standard as appropriate (e.g. editorial note or condition of use).

Questions:

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?

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?

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?

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.

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)?

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?

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

5.3.2 Enforcement and importation issues related to the definitions

Once a food is available on the market in Australia or New Zealand, particularly in mainstream supermarkets, it is difficult for enforcement officers to argue that the particular food is 'non-traditional' in accordance with the current definition, even though the view may be that little is known about the food, the community has had little exposure to it and there may be safety issues. If the food is deemed to be traditional because of such presence on the market and not captured by the Novel Foods Standard there is no scope to readily undertake a scientific risk assessment in accordance with the Code unless a specific safety issues is clearly identified.

This situation presents a problem for both FSANZ and enforcement officers and is closely related to the definitions. Enforcement officers may be reluctant to argue that the food is 'non-traditional' because this is a difficult point to prove. However, FSANZ and enforcement officers may not be convinced of the safety of the food for human consumption. Any regulation for novel foods needs to allow FSANZ to meet one of its primary objectives under the FSANZ Act, namely, the protection of public health and safety and this may not be possible in all cases with the current Standard.

Officers enforcing the Code with respect to imported food need to quickly interpret any regulations for novel foods to allow them to make effective enforcement decisions. Because the Novel Foods Standard may capture some whole foods including fresh produce such as fruit, these may deteriorate while being held by AQIS until a determination with respect to novelty is made. It should be noted however, that compliance with the Code is the responsibility of the importer in this case and if there is any question as to the novelty of the food this should be investigated prior to arrival in Australia. Notwithstanding this, FSANZ has a close working relationship with AQIS and most issues have been resolved in a timely fashion. A large number of inquiries referred to FSANZ regarding novel foods are related to imported foods, and as such this review needs to ensure that any regulations for novel foods are workable for enforcement officers working with imported food.

Question primarily for enforcement agencies:

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

5.4 Scope of novel foods regulation

5.4.1 Food derived from new technologies

A number of new technologies are being employed in food processing. It may be necessary to consider the regulation of the foods produced using these new technologies.

Foods produced from some new technologies are already regulated by separate Standards in the Code and require individual pre-market assessment, such as foods that have been irradiated and foods produced using gene technology. Some recently reported processing developments relate to:

- 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; and
- combinations of the above.

FSANZ has limited information about many of these new technologies, with ultra-high pressure processing having the most information available. A more detailed discussion of ultra-high pressure processing is at Attachment 7.

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 'Guidelines to assist in applying to amend the *Australia New Zealand Food Standards Code* – Novel Foods' (refer to Attachment 3) 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 new technology.

As part of the review, FSANZ is considering the need to regulate foods produced using new technologies and, if so, whether the scope of any new regulations for novel foods should capture these new technologies.

SDAC members acknowledged that mechanisms to consider foods produced using new technologies might be required and there may be some consumer wariness about foods produced using new technologies. There was a clear view amongst SDAC members that it is the resultant food that would potentially require assessment and not the process itself. It was suggested by an SDAC member that a specific standard(s) could be introduced for foods produced using specific processes if there is a need based on safety concerns.

FSANZ would need to carefully consider whether the resulting food from a new process is in fact a novel food or whether it may simply be a food where contaminants need to be evaluated, however, this may mean that it is not subject to pre-market assessment (unless captured by another, yet to be developed, Standard). Related to this are the comments made by SDAC members as to whether a food from a novel source is in fact a novel food and whether the approach of substantial equivalence could be applied in this case. Employing the approach of substantial equivalence is discussed further in section 5.5. Similarly, a food containing higher amounts of a particular nutritive substance (e.g. a vitamin or mineral), that is produced using a novel process, could potentially be viewed as a novel food.

Questions:

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

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

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

5.4.2 Categories of novel foods

The 'Guidelines to assist in applying to amend the *Australia New Zealand Food Standards Code* – Novel Foods' (refer to Attachment 3) contains information on the likely categories of novel foods, though novel foods are not limited to these categories. The categories are as follows:

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

These categories are included in the document and described in relation to the definition for novel foods to assist potential applicants. The categories are not mentioned in the Novel Foods Standard itself.

One of the policy options presented in the FRSC policy options paper discussed the inclusion of defined categories of novel foods into the Novel Foods Standard. This would result in a more prescriptive standard.

Categories are used in the definitions for novel foods in Canada and the EU and there have been some difficulties with this approach. Some submitters believed that this would assist industry and protect consumers most effectively. Other submitters believed that not all novel foods would sit within one of the categories and the inclusion of such categories is against the principle of minimum effective regulation. Overall this option was not supported.

SDAC members commented that including specific categories in regulation may not be particularly helpful and there would need to be a clear reason for including categories. One reason for identifying classes of novel foods is that examples of the data requirements for each identified category can assist applicants. Data requirements are discussed in section 5.5 of this Report.

If categories were to be derived, how these are determined would need to be carefully considered. Members indicated that categories are useful as a guide and for this reason categories would probably be more appropriate in the guidelines document rather than the actual regulation as is currently the case. However, SDAC members indicated that the current classes as identified in the guidelines could be improved upon and the consideration by the NFRG could be used as a guide for their revision.

Questions:

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?

23. Are the current classes in the guidelines 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?

5.5 Data requirements

The 'Guidelines to assist in applying to amend the *Australia New Zealand Food Standards Code* – Novel Foods' (refer to Attachment 3) contains information on the data requirements that need to be submitted to FSANZ as part of an application for a novel food to be assessed. The evaluation of the safety of novel foods involves consideration of a variety of toxicological and nutritional issues together with information on chemistry and dietary intake of the product. Further detail on how the assessments for novel foods are conducted was presented in section 4.4 of this Report.

It may be difficult for applicants to determine what type of data needs to be submitted for the assessment of a novel food due to the differing nature of novel foods and hence the difference in data requirements. In addition, some of the data may be more difficult to obtain, for example, relevant and detailed human studies. Improving on the categories in the guidelines for novel foods and providing examples of the type of data required to be submitted with an application for each of these categories may provide further assistance to potential applicants.

5.6 Data protection for industry

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 commercial-in-confidence (CIC) 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 CIC is often sought and granted in relation to novel foods. 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. 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 guidelines 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. SDAC members noted that patents are expensive, although a one-year provisional patent is cheaper than a full patent and generally 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.

SDAC members discussed these related issues of CIC for industry and commercial advantage. It was acknowledged that the issues were raised previously through consideration of Health Claims. A couple of alternate approaches were suggested by SDAC members such as: shortening the assessment process to one round of public comment to reduce the time a competitor has available to undertake product development; or allowing a quarantine of use to the applicant following gazettal. Neither of these options are currently viable in accordance with the FSANZ Act. Novel food assessments would rarely, if ever, be sufficiently simple to consider under section 36 of the FSANZ Act and thus allow for only one round of public comment and the FSANZ Act does not allow for exclusivity.

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

Question:

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

5.7 Assessment process for novel foods

For each novel food assessed, FSANZ undertakes a comprehensive and thorough risk assessment. The risk assessment and risk management of novel foods was described in section 4.4 of this Report and a detailed description of the risk assessment process for novel foods is at Attachment 4. SDAC members questioned whether a novel food derived from a novel source could be assessed by using the approach of substantial equivalence and potentially, whether the approval process could be simplified.

The EU regulations for novel foods allows for a simplified notification procedure for those novel foods that are purported to be substantially equivalent to existing foods. This simplified procedure was designed for GM foods. A relevant example of how the approach of substantial equivalence has been used for a novel food in the EU is DHA-rich oil derived from micro-algal species. FSANZ previously assessed and approved DHA-rich oil derived from a micro-algal source (*Schizochytrium* sp.) and is currently in the process of assessing another DHA-rich oil from a micro-algal source (*Ulkenia* sp.) by undertaking a thorough risk assessment. In seeking approval in the EU, the applicant argued that DHA-rich oil (*Ulkenia* sp.) is substantially equivalent to the previously assessed DHA-rich oil (*Schizochytrium* sp.).

If the approach of substantial equivalence were to be used in assessing certain novel foods, the assessment process may be simplified for novel food ingredients. However, it would not be possible to apply this approach to all novel foods, particularly whole 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.

Question:

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

5.8 Inter-relationships with other 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 other related Standards will need to be considered during the course of the review.

5.9 Inter-relationship with other projects

The review of novel foods is closely related to some other projects for which FSANZ has raised Proposals to address, but which are currently subject to policy development, being undertaken by FRSC. These projects are:

- review of food-type dietary supplements;
- review of sports foods; and
- use of non-culinary herbs in foods.

Another project is plant-derived native foods, which FSANZ has given some consideration to. Some food-type dietary supplements and sports foods contain 'non-traditional' ingredients, for example, alpha lipoic acid in food-type dietary supplements or alpha-ketoglutarate in sports foods. Some non-culinary herbs and plant-derived native foods would be considered novel and captured by Standard 1.5.1 but others may not. As a result they are being addressed separately as distinct categories.

5.10 Inter-relationship with foods-therapeutic goods interface

5.10.1 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 1 July 2005, the joint agency will replace the Australian TGA and New Zealand's Medsafe. The current legislation in Australia and New Zealand governing regulation of therapeutic goods will be repealed and replaced by new legislation that will cover regulation of therapeutic products in both countries. The Joint Scheme will introduce risk-based regulation of complementary medicines as therapeutic products for the first time in New Zealand.

5.10.2 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.

5.11 Uptake of existing permissions for novel foods

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.

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. Based on limited information from industry stakeholders, FSANZ understands that: there are two edible oil spreads containing phytosterol esters on the Australian market – ProActive and Logicol; and that there are currently no products on the Australian or New Zealand markets which contain any of the other approved novel foods although a great deal of product development has been undertaken.

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.

QUESTIONS:

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?

6. Regulatory Options

The review of novel foods is a broad review with a number of issues to consider and there are a large number of potential regulatory and non-regulatory options. In this Report, FSANZ is presenting the most feasible options. FSANZ is seeking preliminary views of submitters on preferred options but is also seeking input as to whether there are other points that should be covered in addition to or in combination with those covered in the options presented. SDAC members were provided with some of the main points to be covered in the regulatory options presented in this Report at the SDAC meeting. The following options incorporate suggestions made by SDAC members and cover both regulatory and non-regulatory initiatives.

6.1 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 and/or TAG in the guidelines as is the case currently.
- Retain the current operation for determining novelty i.e. NFRG working in conjunction with TAG.

6.2 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.
- Consider engaging an expert panel to assist in determining novelty either in place of or in addition to developing a decision-tree.
- Consider introducing an education program for industry that would assist in reducing the load on the NFRG. This can be considered in combination with all of the regulatory options described.

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'. Consider whether it is necessary to define 'non-traditional food' or whether it is sufficient to define only 'novel'.
- Amend the operating procedures by reviewing the supporting documents and developing a decision-tree or engaging an expert panel to assist in determining novelty as per Option 2.
- Consider introducing an education program for industry as per Option 2.

Within this Option, a number of issues (or sub-options) would still need to be considered as follows:

- Retain the current assessment process or consider adopting a simplified assessment process for those novel foods that are claimed to be substantially equivalent to another novel food or a traditional food. This may be appropriate for novel foods that are derived from a novel source.
- Consider amending the definition for novel foods to capture foods produced using new technologies. The appropriate assessment process for foods produced using new technologies will need to be considered. It may be possible to assess the some resultant foods using the substantial equivalence approach.
- Consider introducing prescribed classes of novel foods into the Standard itself rather than only in the guidelines, as is currently the case. Consider the appropriate assessment process for each of the classes of novel foods.

6.4 Option 4: No specific regulation for novel foods

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

Questions:

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

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

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?

31. Would industry benefit from such an initiative?

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 will seek advice from the SDAC on the possible costs and benefits associated with each option.

Question:

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

7.3 Impact Analysis

This section presents a summary of the preliminary analysis of the costs and benefits for each of the affected parties for each of the Options. The preliminary impact analysis is at Attachment 8. 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 interested parties, which should be further considered and addressed if possible.

Option 2 would result in amending the operating procedures and including a decision-tree in the guidelines would provide increased clarity to all affected parties. The industry sector would particularly benefit by an education program to assist in understanding the process for determining novelty. The use of an expert panel would impact on resources for government (e.g. secretariat role) and industry (e.g. provision of papers) in comparison with the use of a decision-tree. Most submitters to the FRSC policy options paper favoured a decision-tree over an expert panel as the preferred decision-making mechanism.

Option 3 allows review of the definitions (and other parts of the Standard), clearly benefiting all affected parties, particularly industry and government. Clear and workable definitions would increase industry confidence in determining which foods are captured by the Standard and would also improve the efficiency of government enforcement agencies. Further consideration should be given to regulating foods produced using new technologies and the appropriateness of addressing this within the regulations for novel foods. Introducing more prescriptive categories of novel foods into the Standard has little support based on submissions to the FRSC policy options paper and discussions at the SDAC meeting for novel foods. SDAC members felt that categories of novel foods are more appropriately referred to in the guidelines rather than the regulation.

Option 4 would not afford adequate protection to public health and safety.

Question:

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

8. Consultation

8.1 Consultation strategy

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. In addition to the two rounds of public consultation where interested parties are invited to make written submissions, a Standard Development Advisory Committee (SDAC) has been established for the review of novel foods.

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 has established the SDAC and agreed to the Terms of Reference.

A FSANZ Board member was nominated as an observer. In addition, guidelines for SDAC 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 8. The Kahui (Maori Reference Group) were represented and FSANZ also approached OATSI seeking an indigenous representative however, no nomination was put forward.

The first meeting of the SDAC for novel foods was a one-day meeting 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. The agenda for the meeting and the issues paper prepared and circulated prior to the meeting are at Attachment 9. Outcome notes were circulated to members the following day. The issues raised in discussions throughout the meeting and since the meeting have been incorporated into the relevant issues section of this Report. SDAC members were also provided with a draft version of this Report to provide comment on but not endorsement. Careful consideration was given to the format of the meeting to enable all members to feel confident in understanding the content and contributing to discussions. The discussions on allocated topics were extremely helpful and covered the issues in depth.

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 was written to in May 2004 informing them that FSANZ has commenced work on the review of novel foods and providing an anticipated timeframe for the review. FSANZ will keep this group informed of progress through the course of the review.

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. Amending the Code in relation to the regulation of novel foods may have a significant effect on international trade as the Standard currently covers a broad range of foods and captures a number of imported foods. This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

9. Conclusion

This Report highlights many complex issues that will need to be examined during the course of the review. FSANZ has given detailed consideration to some of these issues and, with the assistance of the SDAC, now has a better understanding of the scope of the review and the issues that are likely to be debated during the course of the review.

The report provides a description of each issue in order to elicit comments from submitters and enable further consideration. Submissions to this Initial Assessment Report will be used to develop a Draft Assessment Report for Proposal P291, which will be circulated for a second round of public comment. It is likely that the Draft Assessment Report will be available for comment in the third quarter of 2005 following consideration of submissions received in response to this Report by the SDAC.

10. Implementation and review

It is anticipated that the review of novel foods will not be completed until early 2006 at the earliest. The review of novel foods will cover a number of complex issues and will involve regular consultation with SDAC members and also stakeholders more generally. The public comment period for this Initial Assessment Report is longer than usual to give sufficient time for submitters to address the large number of issues FSANZ is seeking input on.

It is likely that the SDAC will meet again around mid 2005 following receipt of submissions in response to this Report to discuss the issues raised and have input into the Draft Assessment Report. The Draft Assessment Report is likely to be released for public comment in the 3rd quarter of 2005. The SDAC will likely meet again following the release of the Draft Assessment 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 will consider implementing some mechanism to track the uptake of permissions for novel foods by industry including 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. Standard 1.5.1 – Novel Foods, of the *Australia New Zealand Food Standards Code*
2. Format for applying to amend the Code – Novel Foods
3. Guidelines to assist in 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. Policy guidelines for novel Foods
7. Ultra-high pressure processing
8. Preliminary impact analysis

9. SDAC membership, terms of reference and guidelines
10. SDAC meeting agenda, issues paper and PowerPoint slides

ATTACHMENT 1

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**
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.)	May only be added to food according to Standard 1.3.4.
Docosahexaenoic acid (DHA) – rich oil derived from marine micro-algae (*Schizochytrium* sp.)	May only be added to food according to Standard 1.3.4.
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	
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:

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 2

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

updated August 2003

This document provides information to people wishing to apply to FSANZ to permit the use of a novel food, as provided for in the *Australia New Zealand Food Standards Code* (the Code). Before you apply you are encouraged to discuss your application with FSANZ staff or with Senior Food Officers (SFOs) in one of the States, Territories or New Zealand in order to determine whether the matter warrants an application to vary Standard 1.5.1. For further information contact the Standards Management Officer at email slo@foodstandards.gov.au or in Australia phone (02) 6271 2222 or fax (02) 6271 2278 or in New Zealand contact the FSANZ Office - phone (04) 473 9942 or fax (04) 473 9855

Following is a suggested format which you may use for an application to amend the Code. Applications can be lodged electronically (with the exception of confidential commercial information) via http://www.foodstandards.gov.au/forms/index.cfm?fuseaction=Application.

Other application formats to vary or develop Standards may be more suited to your needs—they are available from the Authority and are listed below:

- Format for applying to amend the Code – General
- Format for applying to amend the Code - GM Foods
- Format for applying to amend the Code - Food Additives

Your responsibilities

All criteria outlined in the following pages should be addressed to the best of your ability. If you leave information out because it is unavailable, or you consider it irrelevant or inappropriate, please indicate this at the appropriate section and provide an explanation for the omission.

Please send the completed checklist (which you will find at the end of this document) with four copies of your application to FSANZ.

Your application should be presented clearly in a format which is easy to read and evaluate. It should also be of a sensible size for ease of handling.

Please sequentially number each page and paragraph. It is not necessary to delete original page numbers on documents included in your application, provided they do not interfere with the application page numbers.

OPERATION OF THE STANDARD

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 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 1.5.1.

The purpose of the Standard is to ensure that a safety assessment will be undertaken of those non-traditional foods for which, in the words of the Standard, there is 'insufficient knowledge in the broad community to enable safe use in the form or context in which [they] are presented'. Because the Standard has a definition of a novel food that is based on the level of knowledge in the community about the safe use of a non-traditional food, an assessment of this level of knowledge is needed in order to assess whether a variation to the Standard is necessary. The Standard provides some assistance in this regard by indicating the factors to be taken into account in this decision-making process.

Use of the Standard

For non-traditional foods, two steps may be necessary to meet the requirement of this Standard: an initial step to decide whether a particular food falls within the scope of the Standard, and, if this is the case, a subsequent step via an application to FSANZ to establish the safety of the novel food. The first step, is to assess the novelty of the food, while the second step is to assess the safety of the novel food.

Role of the Senior Food Officers

Enforcement of the Code is the responsibility of the Commonwealth, State, Territory and New Zealand Governments. Decisions regarding the novelty of food, therefore, need to be made in close consultation with the SFOs of the Commonwealth, States, Territories and New Zealand. For those foods that are clearly novel according to the definition in the Standard, the industry will be informed that an application is required and the matter will be reported to SFOs.

Where a decision on the novelty, or otherwise, of a particular food needs to be made, all relevant information should be submitted and be supported by arguments for or against the novelty of the food, in accordance with the definition in the Standard. In these cases, a consensus decision will be sought from SFOs.

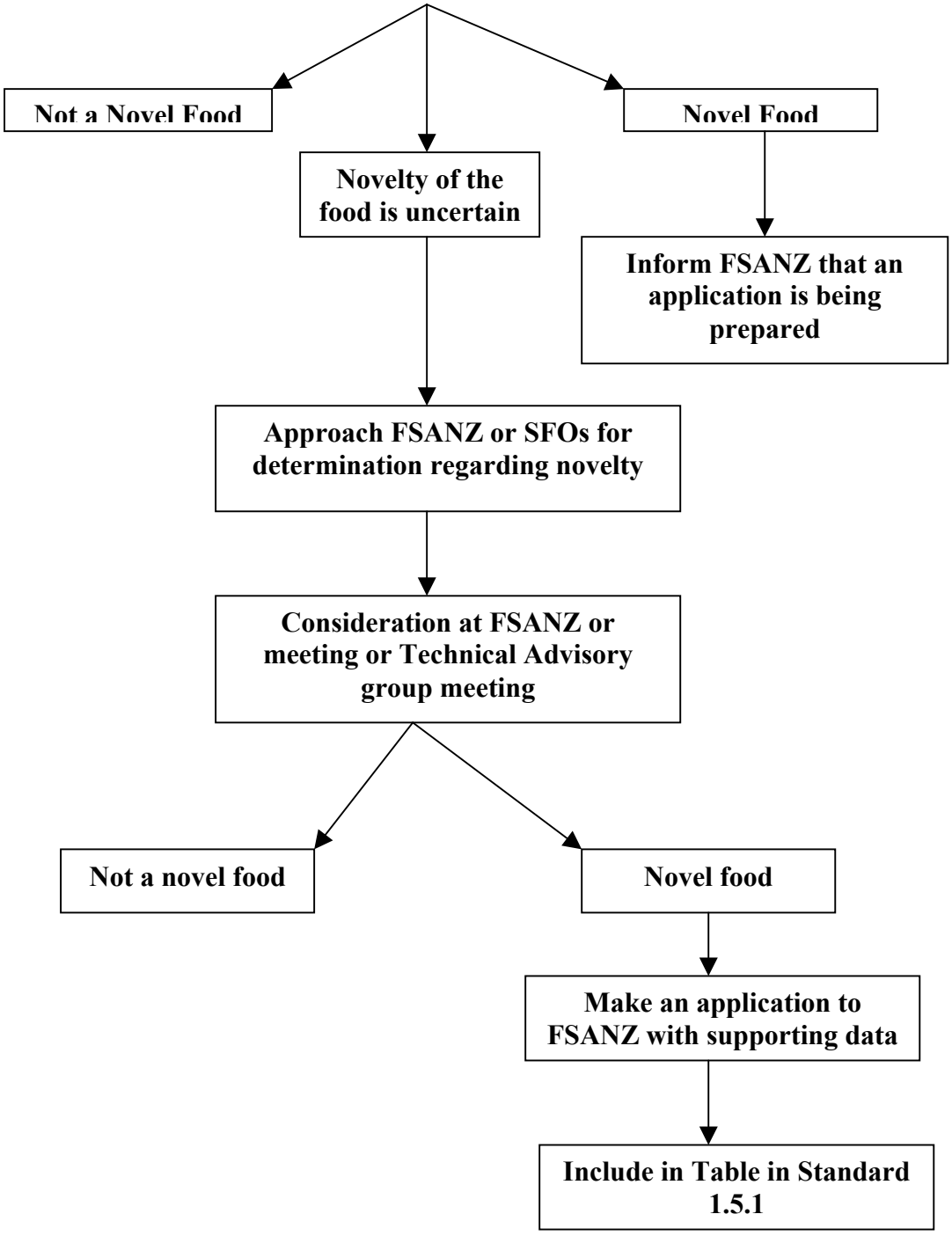
Consultation with FSANZ and SFOs

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:

PROCESS FOR CONSIDERING POTENTIAL NOVEL FOODS

Potential novel food

(consideration by industry according to the decision tree)



In order to assist industry and enforcement officers, the requirements of the Standard have been re-formulated as a decision-tree (see the end of the next Section).

Novel foods approved under Standard 1.5.1

The table to clause 2 in Standard 1.5.1 includes all novel foods approved under the Standard and includes, where relevant, conditions of use such as:

(i) the need to meet the specifications identified in Standard A11;
(ii) the need to restrict the level of certain natural toxicants as per Standard A12;
(iii) the need to carry particular warning statements;
(iv) the need to carry particular preparation instructions; or
(v) the need to restrict the use of a novel foods to certain foods.

Over time, as a particular novel food gains acceptance in the market place, sufficient knowledge may be gained in the broad community to enable safe use. At this point, it may be possible to remove the food from the Table. The availability of post-market monitoring data will be essential for some categories of novel foods for this to occur. When considered necessary, removal of a food from the Table could be achieved through a Proposal initiated by FSANZ.

IDENTIFYING NOVEL FOODS

Factors Influencing the Novelty of a Food

The Standard defines a novel food as '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;
(b) levels of undesirable substances in the product;
(c) known potential for adverse effects in humans;
(d) traditional preparation and cooking methods; or
(e) patterns and levels of consumption of the product'.

Each of these factors is discussed in further detail below:

<u>The composition or structure of the product</u>

Food ingredients that have a new or changed molecular structure are likely to fall within the Standard since there is unlikely to be tradition of use of such foods in Australia or New Zealand and no knowledge in the community in relation to the safety of such products. 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.

Levels of undesirable substances in the product

Foods which are new to the broad community in Australia or New Zealand and which are known to contain toxic substances or anti-nutrients could be considered under this Standard. In some cases, these are foods that may be consumed by particular sub-population groups (who may or may not be located overseas) who are familiar with the risks involved and can manage this risk either by limiting intake or by treating the food to reduce the level of the hazardous substance. The safety assessment conducted on such foods may result in:

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

In some cases, it may be appropriate to specify such an outcome in another standard in addition to Standard 1.5.1.

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. On the other hand, a traditional food in which the only change has been to the level of a naturally occurring toxin is still a traditional food and, therefore, would not be regarded as novel. A maximum level for the toxin could still be required, if necessary.

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. In some cases, a specification for the novel food may be necessary to ensure its safety.

Known 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.

Traditional preparation and cooking methods

Traditional methods of preparation of foods are in some cases designed to make food fit for human consumption by reducing the levels of toxic substances in the food. Examples include the soaking and/or boiling of cassava, and the need to extensively boil red kidney beans. Some of the traditional foods of the Aboriginal, Torres Strait Islander and Maori people would be in this category. The safe use of these foods is based on a detailed understanding of techniques of preparation and safe levels of consumption that have developed over many generations. In the broader Australian or New Zealand population, such foods may be considered non-traditional and may require consideration under Standard 1.5.1 so that appropriate information or preparation instructions can be provided to consumers.

Patterns and levels of consumption of the product

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.

Categories of Novel Foods

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

(i) Dietary macro-components
(ii) Extracts of plants, animals or micro-organisms
(iii) Single ingredient foods
(iv) Viable micro-organisms

Each of these is discussed below in terms of the definition of a novel food.

Dietary macro-components

There are now a number of substances used to fully or partially replace fats or carbohydrates in foods, in order, in some cases, to produce a low fat and/or low energy product. These include olestra, Salatrim, D-tagatose, polyols, inulin, sorbestrin, trehalose, caprenin, isomalt and polydextrose. Such products are generally used in significant amounts and are considered an integral part of the food rather than food additives. Some have been on the market for some time and are now considered traditional foods.

Dietary macro-components may need to be considered under Standard 1.5.1 because of the composition and structure of the product; and/or their pattern or level of consumption.

Extracts of plants, animals or micro-organisms

Increasingly, extracts of plants, animals or micro-organisms are being added to other foods for either a functional or nutritional purpose. Such extracts have the potential to concentrate hazardous substances and therefore need to be assessed to ensure their safety.

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 required specifications. While the distinction between a food, an extract and a food additive is not always clear in all cases, the purpose of adding the substance to food must be a consideration.

Extracts may need to be considered under Standard 1.5.1 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.

Single ingredient foods

This category includes foods that have not traditionally formed part of the diet of the broad community in Australia and New Zealand, such as foods from other parts of the world, traditional native foods, or new foods produced from traditional breeding techniques. 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.

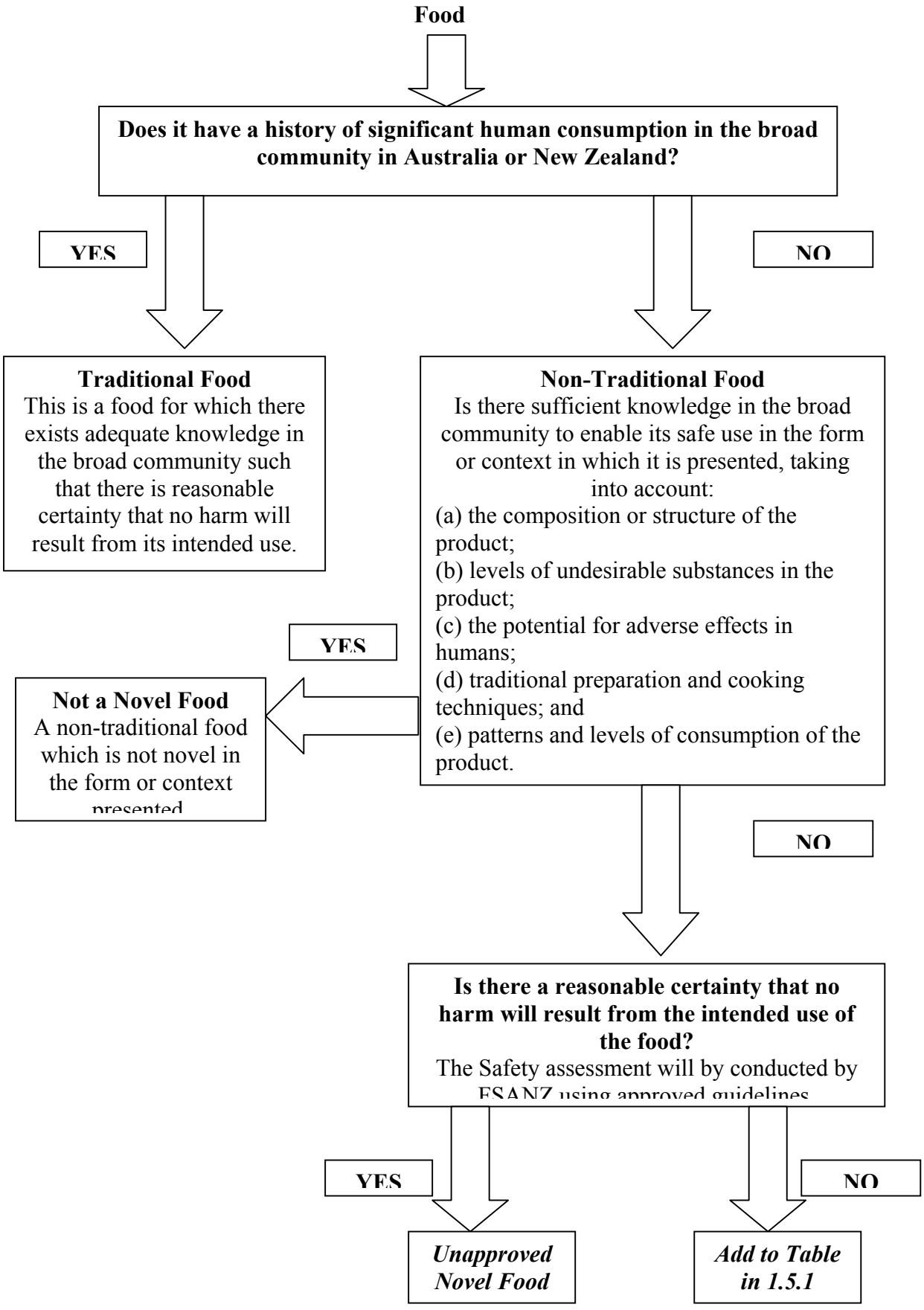
Single ingredient foods may need to be considered under Standard 1.5.1 because of the level of undesirable substances in the product, known potential for adverse effects in humans, and/or the use of traditional preparation and cooking techniques.

Viable micro-organisms

This category refers to those micro-organisms that are now being developed as ingredients of food products which may contribute to the intestinal microbial balance. These include micro-organisms know as probiotics. The safety of new strains of micro-organisms needs to be established before use in widely consumed foods.

Viable micro-organisms may need to be considered under Standard 1.5.1 because of levels of undesirable substances in the product and/or known potential for adverse effects in humans.

NOVEL FOOD DECISION TREE



Your responsibilities

All criteria outlined in the following pages should be addressed to the best of your ability. If you leave information out because it is unavailable, or you consider it irrelevant or inappropriate, please indicate this at the appropriate section and provide an explanation for the omission.

Please send the completed checklist (which you will find at the end of this document) with four copies of your application to FSANZ.

Your application should be presented clearly in a format which is easy to read and evaluate. It should also be of a sensible size for ease of handling.

Please sequentially number each page and paragraph. It is not necessary to delete original page numbers on documents included in your application, provided they do not interfere with the application page numbers.

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*. 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 you provided in Parts 1 to 5 must be attested to by a statutory declaration in a suitable form along the following lines:

I, ..., do solemnly and sincerely declare that the information provided in this application fully sets out the matters required and that this information is true to the best of my knowledge and belief and that no information has been withheld which might prejudice this application.

And I make this solemn declaration by virtue of the *Statutory Declarations Act 1959* and subject to the penalties provided by that Act for the making of false statements in statutory declarations, conscientiously believing the statements contained in this declaration to be true in every particular.

Declared at …….

the …… day of ……20…….

Signature ……

before me*.....

Title: …….

*a list of persons who may witness statutory declarations under the *Statutory Declaration Act 1959* is contained in the *Statutory Declarations Regulations 1993*, available online at http://scaleplus.law.gov.au/

PART 6 STATUTORY DECLARATION - NEW ZEALAND

The information you provided in Parts 1 to 5 must be attested to be a statutory declaration in a suitable form along the following lines:

I, ... of .....

..... solemnly and sincerely declare that the information provided in this application fully sets out the matters required and that the information is true to the best of my knowledge and belief and that no information has been withheld which might prejudice this application.

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 …….

the …… day of ……20…….

Signature ……

before me*.....

Title: …….

*a list of persons who may witness statutory declarations under the *Oaths and Declarations Act 1957* is contained in that Act, available online at http://www.legislation.govt.nz/

GUIDELINES FOR THE SAFETY ASSESSMENT OF NOVEL FOODS

Regulatory framework

The safety of food is addressed in the broad provisions of State, Territory and New Zealand Food and Health Acts.

The Food and Health Acts require that:

- food must be safe and suitable;
- food must not be adulterated, damaged, deteriorated or perished; and
- food must not be falsely described, or represented in a way that is misleading or deceptive.

Under the Food and Health Acts, the responsibility for the safety of food lies with the food industry. Consideration of the safety of the food under Standard 1.5.1 will provide assistance to industry in identifying those parameters that will establish that the food is fit for human consumption. Assessment of the safety of the food in an open and consultative manner will give confidence to consumers in relation of the safety of the food supply and assist government enforcement agencies to ensure compliance with the Food and Health Acts.

Historically, foods have been regarded as natural, beneficial and necessary, and presumed safe unless a significant hazard has been identified. Thus, 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 is considered safe i.e. there is a reasonable certainty that no harm will result from their intended use.

Many non-traditional foods, i.e. those without a history of significant human consumption in the broad community in Australia and New Zealand, are also considered safe because they represent a relatively minor variation from traditional foods.

For those non-traditional foods that are regarded as 'novel' under the definition in the Standard, there is a need for a safety assessment to be conducted. The following broad guidelines may assist in this process. When making an application for the approval of a novel food, it is the responsibility of the applicant to establish a case for the safety of the particular food. The following guidelines indicate the types of data that can assist in this process.

General safety issues

The purpose of a risk assessment of a novel food is to confirm that there is a reasonable certainty that no harm will result from the intended use of the food, despite the lack of traditional use of this food in the broad community. In this regard, the safety assessment confirms the novel food to be equivalent to the traditional food, with all the benefits and risks normally associated with such food. It also confirms that the novel food offers the same basic level of safety that is expected for all foods.

In some cases, particularly where a new production process is involved, a food may be assessed for novelty by a comparison to the benchmark of a commonly consumed traditional food. This concept is referred to internationally as 'substantial equivalence' and means that the biochemical or compositional identity is within the limits of natural diversity of the traditional counterpart, including comparability with the nutritional value, metabolism, intended use and the level of undesirable substances contained in the new food. This concept will have limited application to the safety assessment of novel foods since, under the definition in the Standard, most will not have a traditional counterpart. In some cases where a traditional food has been altered, it may be useful in focusing the risk assessment on those particular changes.

The evaluation of the safety of foods involves consideration of a variety of toxicological and nutritional issues together with information on 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. 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 more likely to cause physiological, morphological or biochemical changes which reflect an altered nutritional status rather than an indication of a toxic response. The usefulness of animal studies is thus more limited for the safety assessment of foods, and human studies are more likely to offer relevant data.

Matters to consider when identifying suitable studies for assessing the safety of novel foods are presented in **Table 1**. This represent a general guide only to the types of information that might be useful and each food needs to be considered on an individual basis. The exact data requirements will depend on the type of novel food being considered. It is ultimately the responsibility of the food manufacturer or retailer to present a case to establish the safety of the novel food.

As experience in the risk assessment of novel foods grows, it may be possible to more clearly identify data requirements for particular groups of products or to preclude certain products from further detailed evaluation. Data will be required in a broad range of areas, a number of which have overlapping requirements.

Toxicology data

The nature and extent of the toxicology data used to assess the potential risk associated with a novel food depends largely on the nature of the novel food. Other than direct toxicity studies in animals, factors which might influence decisions regarding the safety of novel foods include source and composition of the novel food, evidence of previous human exposure, the level of consumption or extent of use, the specifications of the ingredient, metabolic and toxicokinetic data, toxicity of any related substances or foods, and any known cases of adverse effects on humans.

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. On the other hand, for foods traditional to only a small community which are now being presented to the broad community, it may be more important to identity any inherent hazards that might require attention. For novel micro-organisms, there is a potential for adverse effects associated with colonisation of the gastrointestinal tract.

Rodent 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. Pathogenicity of a novel micro-organism is also a consideration. For a new plant extract, genotoxicity and short-term feeding studies can provide a basic level of information to ensure safety. The nature and variety of toxicity studies required will need to be commensurate with the level and extent of human exposure.

Studies in humans are likely to have a much greater role in assessment of the safety of novel foods than in other areas of toxicology. Provided the in vivo animal studies demonstrated no adverse effects, human studies should be considered in order to confirm the absence of metabolic and physiological disturbances. A greater emphasis would be placed on available toxicokinetics to complement animal data. Additional mechanistic studies may be appropriate to investigate unexpected adverse effects.

Nutritional data

Novel foods 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 of foods, 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 nutritional evaluation of novel foods is expected to be important for those novel foods which are likely to have a significant nutritional impact, for example, macronutrient substitutes. The nutritional consequences of consumption of a novel food need to be assessed at predicted normal and maximum levels of consumption.

Foods are a mixture of nutrients, non-nutritive biologically active substances, and biologically inactive substances. While it might be possible to estimate the effects of novel foods on the absorption of other nutrients, it is not yet possible to assess their impact on the non-nutritive biologically active components of foods. Scientific studies have begun to demonstrate the importance of some non-nutritive biologically active component of foods, for example antioxidants, in the prevention of diseases such as cancer and heart disease. Thus, the use of novel foods could change the composition of foods, which in turn could alter levels of active substances in foods and thus pose health risks to consumers.

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 was likely to be compromised by the substitution of less nutritious food varieties or by the presence of constituents which would 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 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.

Post-market monitoring

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.

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).

Where the applicant is the manufacturer of the novel food, but not involved in food production, the applicant would still be expected to assist in obtaining post-marketing monitoring data. Major distributors would be expected to provide information on the volume of novel food sold and the foods that contain novel foods.

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

Dietary macro-components	
Product information	identity of the novel macro-component method of preparation specifications for identity and purity purpose and use in food use overseas and by population sub-groups stability in cooking and processing post-market monitoring of market share
Dietary exposure data	proposed pattern of usage dietary exposure for average and extreme consumer dietary exposure for special groups post-market monitoring of dietary intake

Toxicological & nutritional data	bioavailability
	fate on unabsorbed material
	effects on fermentation in the gut
	effect on bioavailability of other nutrients
	anti-nutritional effects
	metabolism/toxicokinetics
	mutagenicity studies
	3-month rodent studies
	long-term rodent studies, if required
	human toleration studies
	post-market monitoring of adverse effects
Extracts of plants, animals or micro-organisms	
Product information	identity of the novel food
	source and purpose of use in food
	method of preparation
	compositional information
	use overseas and by population sub-groups
	stability in cooking and processing
Dietary exposure data	proposed pattern of usage
	dietary exposure for average and extreme consumer
	dietary exposure for special groups
	post-market monitoring of dietary intake
Toxicological & nutritional data	nutrient content
	effect on bioavailability of other nutrients
	levels of anti-nutrients
	levels of natural toxins
	potential for allergenicity
	metabolism/toxicokinetics
	3-month rodent studies
	long-term rodent studies, if required
	mutagenicity studies
	human toleration studies
	post-market monitoring of adverse effects
Single ingredient foods	
Product information	identity of the novel food
	source and purpose of use in food
	compositional information
	use overseas and by population sub-groups
	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
	anti-nutritional factors
	levels of natural toxins
	potential for allergenicity
	3-month rodent studies
	mutagenicity studies
	human toleration studies
	post-market monitoring of adverse effects
Viable micro-organisms	
Product information	identity of the micro-organism
	source and purpose of use in food
	use overseas and by population sub-groups
	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 interaction with other nutrients related organisms and potential pathogenicity rodent studies examining the potential for gut colonisation potential for toxins production human toleration studies post-market monitoring of adverse effects

GUIDELINES FOR DETERMINING THE ENERGY VALUE OF A NOVEL FOOD

These are available at Energy Factors.

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 3

General information to assist in applying to amend the *Australia New Zealand Food Standards Code* – Novel Foods

updated September 2004

Operation of the Standard

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 purpose of the Standard is to ensure that a safety assessment will be undertaken of those non-traditional foods for which, in the words of the Standard, there is 'insufficient knowledge in the broad community to enable safe use in the form or context in which [they] are presented'. Because the Standard has a definition of a novel food that is based on the level of knowledge in the community about the safe use of a non-traditional food, an assessment of this level of knowledge is needed in order to assess whether a variation to the Standard is necessary. The Standard provides some assistance in this regard by indicating the factors to be taken into account in this decision-making process.

Use of the Standard

For non-traditional foods, two steps may be necessary to meet the requirement of this Standard: an initial step to decide whether a particular food falls within the scope of the Standard, and, if this is the case, a subsequent step via an application to FSANZ to establish the safety of the novel food. The first step is to assess the novelty of the food while the second step is to assess the safety of the novel food.

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 NFRG examines the available information on the food in relation to the definitions provided in Standard 1.5.1 and considers:

1. whether or not the food or food ingredient appears to be traditional or non-traditional; and
2. 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.

Role of the Senior Food Officers

Enforcement of the Code is the responsibility of the Commonwealth, 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 Commonwealth, 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, this information is reported to SFOs in the State, Territory and New Zealand Governments and AQIS. In these circumstances, an application to FSANZ to amend Standard 1.5.1 needs to be made and approved for the food to be lawfully sold in Australia and New Zealand. Where the novelty of a food is less clear, a consensus view may be reached following consultation with the SFOs at their regular meetings.

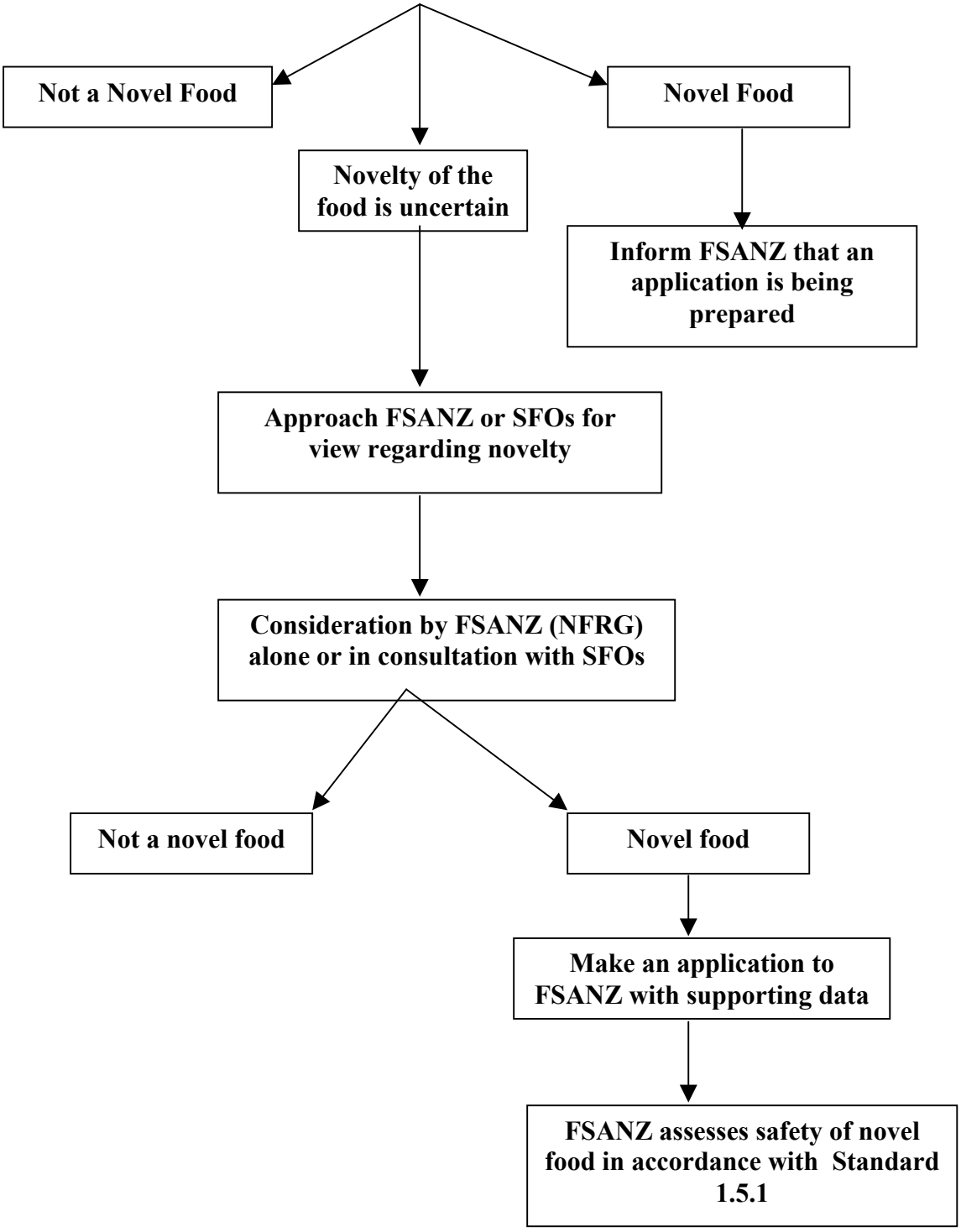
Consultation with FSANZ and SFOs

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:

PROCESS FOR CONSIDERING POTENTIAL NOVEL FOODS

Potential novel food

(consideration by industry according to the decision tree)



In order to assist industry and enforcement officers, the requirements of the Standard have been re-formulated as a decision-tree (see the end of the next Section).

Novel foods approved under Standard 1.5.1

The Table to clause 2 in Standard 1.5.1 includes all novel foods approved under the Standard and includes, where relevant, conditions of use such as:

(i) the need to meet the specifications identified in Standard 1.3.4;
(ii) the need to restrict the level of certain natural toxicants as per Standard 1.4.1;
(iii) the need to carry particular advisory statements;
(iv) the need to carry particular preparation instructions; or
(v) the need to restrict the use of a novel food to certain foods.

Identifying novel foods

Factors Influencing the Novelty of a Food

The Standard defines a novel food as '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;
(b) levels of undesirable substances in the product;
(c) known potential for adverse effects in humans;
(d) traditional preparation and cooking methods; or
(e) patterns and levels of consumption of the product'.

Each of these factors is discussed in further detail below:

<u>The composition or structure of the product</u>

Food ingredients that have a new or changed molecular structure are likely to fall within the Standard since there is unlikely to be tradition of use of such foods in Australia or New Zealand and no knowledge in the community in relation to the safety of such products. 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.

<u>Levels of undesirable substances in the product</u>

Foods which are new to the broad community in Australia or New Zealand and which are known to contain toxic substances or anti-nutrients could be considered under this Standard. In some cases, these are foods that may be consumed by particular sub-population groups (who may or may not be located overseas) who are familiar with the risks involved and can manage this risk either by limiting intake or by treating the food to reduce the level of the hazardous substance. The safety assessment conducted on such foods may result in:

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

(iii) a labelling instruction on appropriate preparation methods.

In some cases, it may be appropriate to specify such an outcome in another standard in addition to Standard 1.5.1.

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. On the other hand, a traditional food in which the only change has been to the level of a naturally occurring toxin is still a traditional food and, therefore, would not be regarded as novel. A maximum level for the toxin could still be required under Standard 1.4.1, if necessary.

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. In some cases, a specification for the novel food may be necessary to ensure its safety.

Known 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.

Traditional preparation and cooking methods

Traditional methods of preparation of foods are in some cases designed to make food fit for human consumption by reducing the levels of toxic substances in the food. Examples include the need to extensively boil red kidney beans. Some of the traditional foods of the Aboriginal, Torres Strait Islander and Maori people would be in this category. The safe use of these foods is based on a detailed understanding of techniques of preparation and safe levels of consumption that have developed over many generations. In the broader Australian or New Zealand population, such foods may be considered non-traditional and may require consideration under Standard 1.5.1.

Patterns and levels of consumption of the product

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.

Categories of Novel Foods

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

(i) Dietary macro-components
(ii) Extracts of plants, animals or micro-organisms
(iii) Single ingredient foods/whole foods
(iv) Viable micro-organisms

Each of these is discussed below in terms of the definition of a novel food.

Dietary macro-components

There are now a number of substances used to fully or partially replace fats or carbohydrates in foods, in order, in some cases, to produce a low fat and/or low energy product. These include olestra, Salatrim, D-tagatose, polyols, inulin, sorbestrin, trehalose, caprenin, isomalt and polydextrose. Such products are generally used in significant amounts and are considered an integral part of the food rather than food additives. Some have been on the market for some time and are now considered traditional foods.

Dietary macro-components may need to be considered under Standard 1.5.1 because of the composition and structure of the product; and/or their pattern or level of consumption.

Extracts of plants, animals or micro-organisms

Increasingly, extracts of plants, animals or micro-organisms are being added to other foods for either a functional or nutritional purpose. Such extracts have the potential to concentrate hazardous substances and therefore need to be assessed to ensure their safety.

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 required specifications. 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.

Extracts may need to be considered under Standard 1.5.1 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.

Single ingredient foods/whole foods

This category includes foods that have not traditionally formed part of the diet of the broad community in Australia and New Zealand, such as foods from other parts of the world, traditional indigenous foods, or new foods produced from traditional breeding techniques. 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.

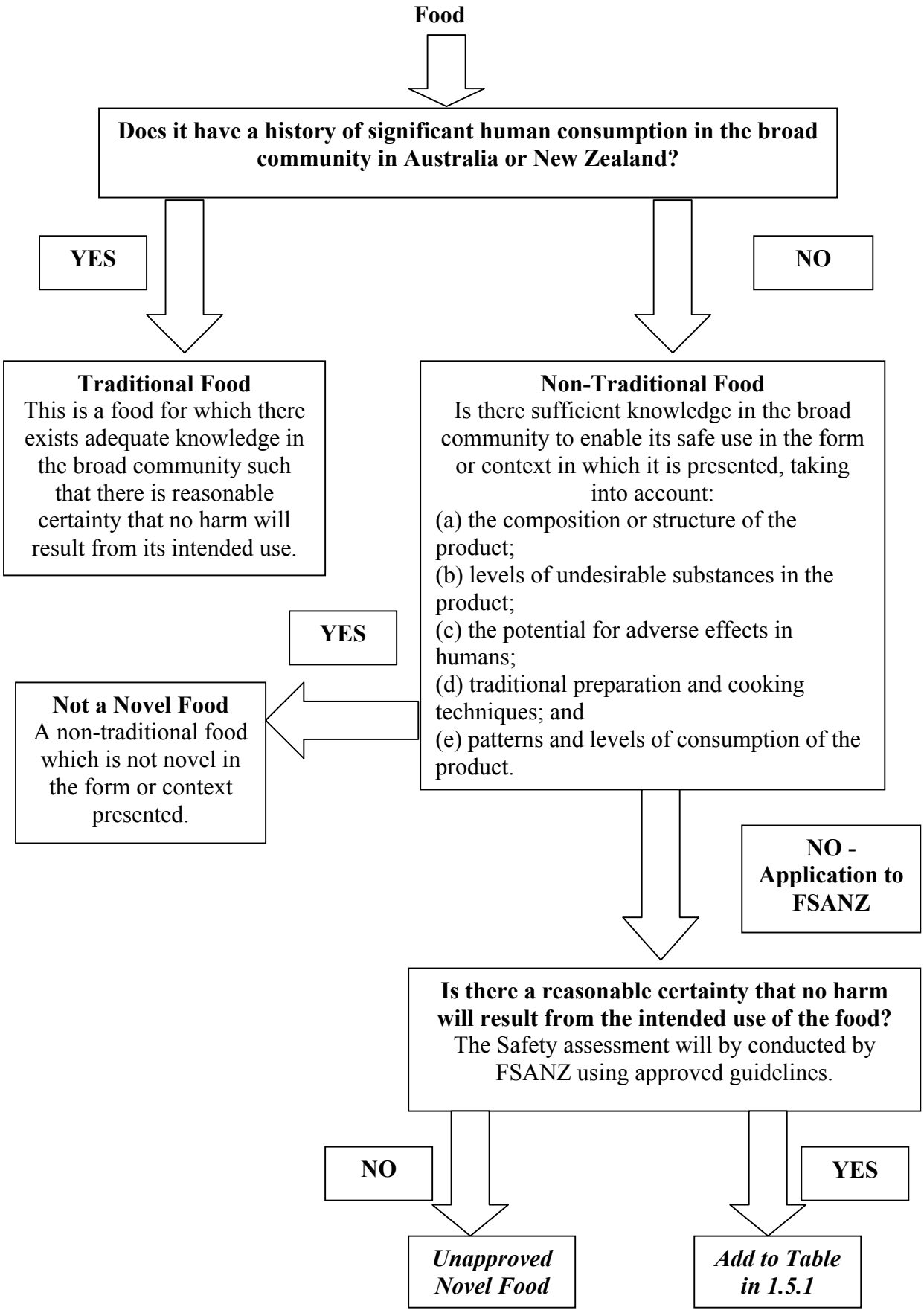
Single ingredient foods may need to be considered under Standard 1.5.1 because of the level of undesirable substances in the product, known potential for adverse effects in humans, and/or the use of traditional preparation and cooking techniques.

Viable micro-organisms

This category refers to those micro-organisms that are now being developed as ingredients of food products which may contribute to the intestinal microbial balance. These include micro-organisms know as probiotics. The safety of new strains of micro-organisms needs to be established before use in widely consumed foods.

Viable micro-organisms may need to be considered under Standard 1.5.1 because of levels of undesirable substances in the product and/or known potential for adverse effects in humans.

NOVEL FOOD DECISION TREE



GUIDELINES FOR THE SAFETY ASSESSMENT OF NOVEL FOODS

Regulatory framework

The safety of food is addressed in the broad provisions of State, Territory and New Zealand Food and Health Acts.

The Food and Health Acts require that:

- food must be safe and suitable;
- food must not be adulterated, damaged, deteriorated or perished; and
- food must not be falsely described, or represented in a way that is misleading or deceptive.

Under the Food and Health Acts, the responsibility for the safety of food lies with the food industry. Consideration of the safety of the food under Standard 1.5.1 will provide assistance to industry in identifying those parameters that will establish that the food is fit for human consumption. Assessment of the safety of the food in an open and consultative manner will give confidence to consumers in relation of the safety of the food supply and assist government enforcement agencies to ensure compliance with the Food and Health Acts.

Historically, foods have been regarded as natural, beneficial and necessary, and presumed safe unless a significant hazard has been identified. Thus, 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 i.e. those without a history of significant human consumption in the broad community in Australia and New Zealand, are also considered safe because they represent a relatively minor variation from traditional foods.

For those non-traditional foods that are regarded as 'novel' under the definition in the Standard, there is a need for a safety assessment to be conducted. The following broad guidelines may assist in this process. When making an application for the approval of a novel food, it is the responsibility of the applicant to establish a case for the safety of the particular food. The following guidelines indicate the types of data that can assist in this process. Further information for potential applicants is included in the document: 'Format for applying to amend the Code – Novel Foods' available in either Word or PDF format.

General safety issues

The purpose of a risk assessment of a novel food is to confirm whether or not there is a reasonable certainty that no harm will result from the intended use of the food, despite the lack of traditional use of this food in the broad community. The risk assessment also determines whether or not the novel food offers the same basic level of safety that is expected for all foods.

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 'substantial equivalence' and means that the biochemical or compositional identity is within the limits of natural diversity of the traditional counterpart, including comparability with the nutritional value, metabolism, intended use and the level of undesirable substances contained in the new food. This concept will have limited application to the safety assessment of novel foods since, under the definition in the Standard, most will not have a traditional counterpart. In some cases where a traditional food has been altered, it may be useful in focusing the risk assessment on those particular changes.

The evaluation of the safety of foods involves consideration of a variety of toxicological and nutritional issues together with information on 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. 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 more likely to cause physiological, morphological or biochemical changes which reflect an altered nutritional status rather than an indication of a toxic response. The usefulness of animal studies is thus more limited for the safety assessment of foods, and human studies are more likely to offer relevant data.

Matters to consider when identifying suitable studies for assessing the safety of novel foods are presented in **Table 1**. This represents a general guide only to the types of information that might be useful and each food needs to be considered on an individual basis. The exact data requirements will depend on the type of novel food being considered. It is ultimately the responsibility of the applicant to present a case to establish the safety of the novel food.

As experience in the risk assessment of novel foods grows, it may be possible to more clearly identify data requirements for particular groups of products or to preclude certain products from further detailed evaluation. Data will be required in a broad range of areas, a number of which have overlapping requirements.

Toxicology data

The nature and extent of the toxicology data used to assess the potential risk associated with a novel food depends largely on the nature of the novel food. Other than direct toxicity studies in animals, factors which might influence decisions regarding the safety of novel foods include source and composition of the novel food, evidence of previous human exposure, the level of consumption or extent of use, the specifications of the ingredient, metabolic and toxicokinetic data, toxicity of any related substances or foods, and any known cases of adverse effects on humans.

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. On the other hand, for foods traditional to only a small community which are now being presented to the broad community, it may be more important to identity any inherent hazards that might require attention.

For novel micro-organisms, there is a potential for adverse effects associated with colonisation of the gastrointestinal tract. Rodent 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. Pathogenicity of a novel micro-organism is also a consideration.

For a new plant extract, genotoxicity and short-term feeding studies can provide a basic level of information to ensure safety. The nature and variety of toxicity studies required will need to be commensurate with the level and extent of human exposure.

Studies in humans are likely to have a much greater role in assessment of the safety of novel foods than in other areas of toxicology. Provided the *in vivo* animal studies demonstrated no adverse effects, human studies should be considered in order to confirm the absence of metabolic and physiological disturbances. A greater emphasis would be placed on available toxicokinetics to complement animal data. Additional mechanistic studies may be appropriate to investigate unexpected adverse effects.

Nutritional data

Novel foods 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 of foods, 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 nutritional evaluation of novel foods is expected to be important for those novel foods which are likely to have a significant nutritional impact, for example, macronutrient substitutes. The nutritional consequences of consumption of a novel food need to be assessed at predicted, normal and maximum levels of consumption.

Foods are a mixture of nutrients, non-nutritive biologically active substances, and biologically inactive substances. While it might be possible to estimate the effects of novel foods on the absorption of other nutrients, it is not yet possible to assess their impact on the non-nutritive biologically active components of foods. Scientific studies have begun to demonstrate the importance of some non-nutritive biologically active component of foods, for example antioxidants, in the prevention of diseases such as cancer and heart disease. Thus, the use of novel foods could change the composition of foods, which in turn could alter levels of active substances in foods and thus pose health risks to consumers.

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 which 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 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.

Post-market monitoring

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.

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).

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

Dietary macro-components	
Product information	identity of the novel macro-component
	method of preparation
	specifications for identity and purity
	purpose and use in food
	use overseas and by population sub-groups
	stability in cooking and processing
	post-market monitoring of market share
Dietary exposure data	proposed pattern of usage
	dietary exposure for average and extreme consumer
	dietary exposure for special groups
	post-market monitoring of dietary intake
Toxicological & nutritional data	bioavailability
	fate on unabsorbed material
	effects on fermentation in the gut
	effect on bioavailability of other nutrients
	anti-nutritional effects
	metabolism/toxicokinetics
	mutagenicity studies
	3-month rodent studies
	long-term rodent studies, if required
	human toleration studies
	post-market monitoring of adverse effects

Extracts of plants, animals or micro-organisms

Product information	identity of the novel food
	source and purpose of use in food
	method of preparation
	compositional information
	use overseas and by population sub-groups
	stability in cooking and processing
Dietary exposure data	proposed pattern of usage
	dietary exposure for average and extreme consumer
	dietary exposure for special groups
	post-market monitoring of dietary intake
Toxicological & nutritional data	nutrient content
	effect on bioavailability of other nutrients
	levels of anti-nutrients
	levels of natural toxins
	potential for allergenicity
	metabolism/toxicokinetics
	3-month rodent studies
	long-term rodent studies, if required
	mutagenicity studies
	human toleration studies
	post-market monitoring of adverse effects

Single ingredient foods

Product information	identity of the novel food
	source and purpose of use in food
	compositional information
	use overseas and by population sub-groups
	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
	anti-nutritional factors
	levels of natural toxins
	potential for allergenicity
	3-month rodent studies
	mutagenicity studies
	human toleration studies
	post-market monitoring of adverse effects

Viable micro-organisms

Product information	identity of the micro-organism
	source and purpose of use in food
	use overseas and by population sub-groups
	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
	interaction with other nutrients
	related organisms and potential pathogenicity
	rodent studies examining the potential for gut colonisation
	potential for toxins production
	human toleration studies
	post-market monitoring of adverse effects

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.

Record of views formed in response to inquiries

Table 2 provides a record of views formed and actions taken in relation to Standard 1.5.1 – Novel Foods of the Code. The table lists foods and food ingredients with views as to their status as non-traditional/novel foods reached either by the NFRG alone or in consultation with SFOs. 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. The following views were formed primarily by FSANZ, with some consultation with SFOs, on the basis of information provided by inquirers in relation to particular products, as well as some independent research.

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 table 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.

Table 2: Record of views formed in response to inquiries as of September 2004

Food or food ingredient	Outcome View[1]	Action
Acerola (*Malpighia glabra L*) – frozen fruit pulp	• Non-traditional food • Not novel	Regulate as a food
Ackee fruit (*Blighia sapida*) – sourced from Jamaica	• Non-traditional food • Novel food	No application received
Agaricus blazei murill mushroom	• Non-traditional food • Novel food	No application received
Aloe vera (juice and juice concentrate)	• Non-traditional food • Not novel	Regulate as a food
Alpha Lipoic acid (also known as thiotic acid)	• Non-traditional food ingredient • Novel food ingredient	No application received
Arachidonic acid (ARA) sourced from Fungus *Mortierella alpina*	• Traditional food for infants • Not novel	Regulate as a food in infant formula

[1] Where the view is that a food or food ingredient is non-traditional but not novel, the basis for this view is that the available data suggests that there is no safety concerns.

Argan oil (derived from the fruit kernels of *Argania spinosa*)	• Non-traditional food • Not novel	Regulate as a food
L-Arginine alpha-ketoglutarate	• Non-traditional food • Novel food	No Application received
Berries from palm fruit Acai (*Euterpe oleracea*) sourced from Brazil	• Non-traditional food • Not novel	Regulate as a food
Birds' nests (as produced by swiftlets in south-east Asia from saliva)	• Non-traditional food • Not novel food	Regulate as a food. Relevant quarantine requirements exist.
Boab fruit (otherwise known as boab nuts, from the Boab tree, *Adansonia*)	• Non-traditional food • History of safe use in WA • Not novel food	Regulate as food
Cashew (*Anacardium occidentale L*) – frozen fruit pulp	• Non-traditional food • Not novel food	Regulate as a food
Cassava (*Manihot esculenta* Crantz)	• Traditional food (tapioca and cassava chips) • Not novel food	Proposal P257 raised to consider labelling of raw cassava.
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	Regulate as a food
Conjugated linoleic acid (CLA)	• Non-traditional food • Novel food	No Application received
γ-Cyclodextrin	• Non-traditional food • Novel food	Application to FSANZ (A438). Permission in Standard 1.5.1.
α-Cyclodextrin	• Non-traditional food • Novel food	Application to FSANZ (A494).
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	Regulate as food when used in beverages at less than 100 mg/kg. Current relevant Proposal being assessed, Proposal P260 – Non-culinary herbs.
Docosahexanoic acid (DHA) sourced from *Schizochytrium* sp. marine algae	• Non-traditional food • Novel food	Application to FSANZ (A428). Permission in Standard 1.5.1.
DHA sourced from algae *Crypthecodinium cohnii*	• Traditional food for infants • Not novel	Regulate as a food in infant formula.
Diacyl glycerol (DAG) oil	• Non-traditional food • Novel food	Application to FSANZ (A505).
D-Tagatose	• Non-traditional food • Novel food	Application to FSANZ (A472).
Fresh bamboo shoots	• Traditional food (canned bamboo shoots) • Not novel food	Being considered as part of Proposal P257, which is assessing the need for labelling requirements being provided in conjunction with raw cassava.
β-Glucan enriched cereals	• Non-traditional food ingredient • Not novel food ingredient	Regulate as a food
Glucosamine sulphate	• Non-traditional food • Novel food ingredient	No application received
Grape pomace extract	• Non-traditional food • Not novel food	Regulate as a food
Grapeseed extract	• Non-traditional food • Not novel food	Regulate as a food
Graviola (*Annona muricata L*) – frozen	• Non-traditional food	Regulate as a food

fruit pulp	• Not novel food	
Hawthorn-berry (*Cratagegus oxyacantha*) based jam	• Non-traditional food • Novel food	No application received
Hemp (*Cannabis* spp.)	• Non-traditional food • Novel food	Application (A360) assessed. Rejected by ministers.
Hu-hu grub (*Prionoplus reticularis*)	• Traditional food • Not novel food	Regulate as a food
Isoflavones from red clover (*Trifolium pratense L.*)	• Non-traditional food • Novel food	No application received
Konjac (100% konjac in elastic, thermo-irreversible gel rather than as an additive)	• Non-traditional food in Australia and New Zealand. • Not novel food	Regulate as a food
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 ingredients when used in small quantities	Regulate as a food
Korean supplement drink (2) including *Angelica Keiskei*, *Artemisia princes*, *Ganoderma lucidum*, and *Cordyceps*	• Non-traditional food ingredients • Novel food ingredients	No Application received
Lavender (*Lavendula angustifolia*)	• Traditional food • Not novel food	Regulate as a food
Longjack (*Eurycoma longifolia*)	• Not considered a food	More appropriately regulated as a therapeutic good.
Long neck turtle (*Chelodina longicollis*)	• Non-traditional food in the broader community • Traditional food in some areas of Australia • Not novel food	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.)	• Non-traditional food • Not novel food but extract is intense sweetener, mogroside	No Application for approval of extract as an intense sweetener received.
Lycopene-enriched tomato extracts	• Non-traditional food • Not novel food	Regulate as food
Manuka plant (*Leptospermum scoparium*) – extract of New Zealand Manuka plant for use in alcoholic beverages	• Non-traditional food • Novel food	No application received
Maca powder (*Lepidium meyenii*)	• Non-traditional food in Australia and New Zealand • Not novel food	Regulate as food
Melaleuca (*Melaleuca quinquenervia*) isolates	• Non-traditional food • Food additive	No application received
Nata de Coco (a fermented coconut-gel dessert)	• Traditional food • Not novel food	Regulate as a food
Phytostanols derived from tall oils	• Non-traditional food • Novel food	No application received
Phytosterol esters derived from vegetable oils	• Non-traditional food • Novel food	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	• Non-traditional food • Novel food	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	• Non-traditional food • Novel food	Application to FSANZ – subsequently withdrawn by applicant.
Pigeon pea (*Cajanus cajan* (L.) Millsp.)	• Traditional food • Not novel food	Regulate as a food
Pine bark extract	• Non-traditional food • Not novel when used as a surface treatment for cut fruit.	Regulate as a food when used as a surface treatment agent for cut fruit.
Plant ingredients (3) in fruit drink – *Garcinia mangostena*, *Rhodiola crenulated* and *Momordica grosvenori*	• *Garcinia mangostena* – not novel • *Rhodiola crenulate* – novel • *Momordica grosvenori* – sweetener	No applications received for either *Momordica grosvenori* as a sweetener or *Rhodiola crenulated* as a novel food.
Quinoa (grain sourced from South America)	• Possibly non-traditional in the broader Australian and New Zealand communities • Not novel food	Regulate as a food
Quorn	• Non-traditional food • Novel food	No application received
Salvia columariae	• Traditional food • Not novel food	Regulate as a food
Scaevola spinescens	• Non-traditional food • Novel food	No application received
Schizandra (*Schizandra chinensis*) – non-culinary herb	• Non-traditional food • Not novel food when used in beverages at less than 100 mg/100 ml	Regulate as food when used in beverages at less than 100 mg/kg. Current relevant Proposal being assessed, Proposal P260 – Non-culinary herbs.
Sheep's placenta	• Non-traditional food • Not novel food	Regulate as a food
Stevia (crushed leaf)	• Non-traditional food • Novel food • 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.
Tempeh (fermented food made from soybeans) and Kefir (cultured milk beverage)	• Traditional foods • Not novel food	Regulate as a food
Tequila worm in lollipops	• Traditional food • Not novel food	Regulate as a food
Trehalose	• Non-traditional food • Novel food	Application to FSANZ (A453). Permission in Standard 1.5.1.
Yacon (*Smallanthus sonchifolius*)	• Non-traditional food • Not novel food	Regulate as a food

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.*

4. 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

Consumers and Dietitians

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

Ultra-high pressure processing

Ultra-high pressure (UHP) processing is an emerging non-thermal food treatment that destroys pathogens and spoilage microorganisms, thereby making food products safer and extending their shelf life. UHP processing is undertaken at pressures greater than 50,000 psi (345 MPa) and causes little or no change in the sensory and nutritional attributes of the product being processed. Overall, UHP processing is still in the research stage, although guacamole processed using this technology is commercially available in the United States of America.

UHP processing applies uniform[2] hydrostatic pressure to food products. The equal distribution of pressure ensures that all areas of the product are equally treated. The uniformity in pressure also maintains the original integrity, consistency, and structure of the food product as no opposing forces that could interfere with the integrity of the food, are produced. As the hydrostatic pressure does not affect covalent bonds, the food does not undergo significant chemical transformations, allowing the food to retain many of its original qualities. However, the greater the pressure used for UHP processing the more likely the original quality of the food could be altered.

Effect of UHP on microorganisms

Although UHP does not alter the original integrity of food products, it does destroy bacteria by interfering with their metabolism, through the inactivation of vital enzymes, and their structure, through altering the permeability of cell membranes. Scientific studies have shown that different bacterial strains have different sensitivities to pressure treatment[3] (Styles, Hoover, & Farkas 1991; Patterson et al. 1995a; Alpas et al. 1999; Alpas et al. 2000). In addition, UHP processing at different temperatures can also alter the sensitivity of bacteria to destruction by pressure treatment.

Table 1 lists the D-values[4] for different microorganisms at different temperatures and pressure.

[2] A recent report has challenged the hypothesis that pressure is uniformly transmitted through products (Minerich & Labuza 2003). In this report, a pressure indicator was placed in the geometric centre of a large food product (a ham). The indicator showed that the internal section of the ham received 9 MPa less than the 400-600MPa that the pressure vessel was delivering.

[3] Those bacterial strains that are sensitive to pressure are generally also sensitive to thermal treatments.

[4] D-value is defined as time required to cause a 10-fold reduction in a microbial population at a constant pressure and temperature.

Table 1.[5] D-values for different microorganisms at different temperatures and pressure

Microorganism	Pressure (MPa)	Temperature (°C)	D-value (min)	Reference
Clostridium pasteurianum	700	60	2.4	Maggi et al. (1995)
	800	60	3.4	Maggi et al. (1995)
Listeria inocula	400	2	3.12	Gervilla et al. (1997a)
			7.35	Ponce et al. (1998)
		20	8.23	Ponce et al. (1998)
		25	4	Gervilla et al. (1997a)
Listeria monocytogenes	414	25	2.17	Ananth et al. (1998)
Salmonella typhimurium	414	2	1.48	Ananth et al. (1998)
Staphylococcus aureus	350	20	2.6	Erkmen and Karatas (1997)

There are a number of factors other than temperature and pressure that can alter the extent of bacteria destruction and therefore D-values. In general, bacteria destruction not only increases with increasing pressure and temperature, but also with increasing pressurisation time, bacteria concentration, presence of antimicrobial agents, acidity (decreasing pH) and cell growth phase (Metrick, Hoover, & Farkas 1989; Shigehisa et al. 1991; Styles, Hoover, & Farkas 1991; Patterson et al. 1995a; Patterson et al. 1995b; Kalchayanand et al. 1998a; Kalchayanand et al. 1998b; Alpas et al. 1999; Benito et al. 1999; Alpas et al. 2000; Furukawa et al. 2002).

The extent of bacteria destruction in food products by UHP processing will also depend on the food that is examined. Industry data obtained from the 'Fresher Under Pressure' [6] project run by Avure Technologies illustrate the effectiveness of UHP at destroying a variety of bacteria types in a variety of food products. Products tested range from fruit juices, ready-to-eat meats, avocado products and salsa. Bacteria tested include *E. coli* 0157:H7, *L. monocytogenes* and *Salmonella* sp. The survival of yeast and mould in fruit juice products treated using UHP have also been tested. Overall, these studies have shown that UHP can completely destroy microorganisms as no bacteria[7] was isolated from the food products either after the food products were incubated for various periods up to two months, or after the food products were incubated at various temperatures up to 27 ºC.

Application of UHP processing

UHP processing can be used to inactivate food-borne pathogens, spoilage organisms, and bacterial spores. As previously stated this helps to reduce the potential for food-borne illness and extend product shelf life. UHP processing also has potential for activating or inactivating enzymes, marinating meats, shucking oysters, pressure-shift freezing or thawing, ripening of cheeses and minimising oxidative browning.

[5] Adapted from Tewari, Jayas, & Holley 1999.
[6] Information on this project can be obtained from http://www.fresherunderpressure.com.
[7] Any bacteria growth from UHP processed foods was below the limit of detection for the experiments.

UHP processing can be performed by either a batch (non-pumpable products) or semi-continuous (pumpable liquid products) method. Non-pumpable products are usually packaged prior to UHP processing. For these products the packaging must be able to withstand a change in volume of up to 15% followed by a return to its original size without losing seal integrity or barrier properties.

Whatever the reason for UHP processing and whatever the method used, UHP processing is only suitable for food products with a high water content, although both raw and cooked products are able to be processed.

Table 2 details some of the research already undertaken into the effect of UHP processing on a variety of factors in a variety of food products. As well as the food products listed in Table 2, research has also been undertaken on peach, lettuce, asparagus, onion, green pea, broccoli, salsa, tofu, sprout seeds, eggs, yoghurt, luncheon meats, sausage, turkey, products, fish octopus, oyster shellstock, prawns and squid food products.

Table 2.[8] Application of UHP processing in retention of sensory and nutritional characteristics of food products.

Product	Pressure (MPa)	Holding-time (min)	Temperature (°C)	Microorganisms tested	Other parameters studied	Reference
FRUITS AND VEGETABLES						
Potato cubes	400	15	5-50	-	Microbial safety, softness, functionality	Eshtiaghi and Knorr (1993)
Chopped tomatoes	400, 600 or 800	3, 5 or 7	-	-	Color, sugar content, pH	Rovere et al. (1997)
Apricot nectar, Distilled water	600-900	1-20	20	-	*Byssochlamys fulva, B. nivea, Neosartorya fischeri, Talaromyces flavus*	Maggi et al. (1994)
Jams					Quality, volatile flavor components, anthocyanins, browning index, furfural, sucrose, vitamin C, microbiological stabilization	Kimura et al. (1994)
White and red grape must	Pressures up to 811	1-5	25		Microbiological stabilization	Moio et al. (1995)
Angelica keiskei juice	0.01	7	25		Sensory and shelf life	Dong et a/. (1996)
Fresh apples, pears, bananas, parsley, potatoes, celery, carrot juice, apple juice, vitaminized carrot, mixed apple and vitaminized carrot juice	370	6, 15	25		Preservation, aroma, flavour, microbial quality	Kloczko and Radomski (1996)
Citrus juice	500-700	1-1.5	0-5		Freshness	Pehrsson (1996)
Orange juice	350	1	30		Microbial activity and chemical composition	Donsi et al. (1996)

[8] Adapted from Tewari, Jayas, & Holley 1999

Product	Pressure (MPa)	Holding-time (min)	Temperature (°C)	Microorganisms tested	Other parameters studied	Reference
Vegetable juices (beats, carrots, cauliflower, spinach, tomatoes, kohlrabi, grapefruit, strawberries	400, 600	10	35		Anti-mutagenic activity	Butz et al. (1997)
'Guava purée'	400, 600	15	25		Quality and shelf life	Gow and Hsin (1996)
Extra virgin olive and seed oils (grape seed, sunflower, soyabean, peanut, and maize)	700	10	25		Lipid oxidation	Severini et al. (1997)
				MEAT INDUSTRY		
Minced beef muscle	Pressures up to 400	20	4, 25, 35, and 50	*Citrobacter freundii, Pseudomonas fluorescens, Listeria* inocula		Carlez et al. (1993)
Minced beef muscle	Pressures up to 450	20	20	Gram-negative and Gram-positive	Repair and/or Recovery mechanism following pressure stress of microorganisms	Carlez et al. (1994)
Minced beef muscle	Pressures up to 500				Colour and myoglobin content of minced beef samples	Carlez et al. (1995)
Surimi paste	Pressures up to 600			*Moraxella* spp., *Acinetobacter calcoaceticus, Streptococcus faecalis, Corynebacterium* spp.		Miyao et al. (1993)

Product	Pressure (MPa)	Holding-time (min)	Temperature (°C)	Microorganisms tested	Other parameters studied	Reference
Creamed salmon	700	3	2-8 (refrigeration temperature)	*Salmonella typhimurium, Listeria monocytogenes, Staphylococcus aureus, Saccharomyces cerevisiae, Penicillium expansum, Rhizopus oryzae, Clostridium sporogenes, Lactobacillus casei, Enterobacteriaceae*	Chemical and sensory changes	Carpi et al. (1995)
Fresh pork	414-826	<30 min	2 or 25		Sensory quality	Ananth et al. (1995)
Fresh pork loins	414-827	30	2 or 25	*L. monocytogenes* Scott A, *S typhimurium*	Colour, texture, moisture, water-holding capacity, and sensory qualities	Ananth et al. (1998)
Duck foie gras	400	10	50	Coliforms, *S. aureus*, vegetative mesophilic, psychrotrophic contaminants		El Moueffak et al. (1996)
Freshly ground raw chicken meat	408-818	10	25	*Carnobactrerium divergens, Serratia liquefaciens*		O'Brien and Marshall (1996)
Minced pork	<800	20	20		Lipid oxidation	Cheah and Ledward (1996)
Fresh beef	800-1000	20	25		Inhibition of metmyoglobin formation	Cheah and Ledward (1997)
DAIRY AND EGG INDUSTRY						
Whey	450	15	25		Unfolding and aggregation of an industrial beta-lactoglobulin ($-LG) protein isolate	Dumay et al. (1994)
Whey protein concentrate	600, or 800	10, 20, or 40	20		Emulsifying behaviour of whey protein concentrate	Galazka et al. (1995)
Raw milk	pressures up to 400	10-60	20		Whey protein denaturation and cheese-making properties of raw milk	Lopez et al. (1996)

Product	Pressure (MPa)	Holding-time (min)	Temperature (°C)	Microorganisms tested	Other parameters studied	Reference
Whipped and coffee cream	pressures up to 550		10-24		Crystallization of emulsified fats	Buchheim and Frede (1996)
Lactoglobulin	600, or 900	5, 10, 15, or 30	20		Changes in structural and surface properties of Lactoglobulin	Pittia et al. (1996)
Fresh goat milk cheese	400 or 500	5, 10, or 15	2, 10, or 25	*E. coli* (strain 405 CECT)		Capellas et al. (1996)
Ewe's milk	350, 400, 450, or 500	5, 10, or 15	2, 10, 25, or 50	*Listeria* inocula		Gervilla et al. (1997a)
Milk	345 or 586	1, 15, or two 1-min and three 1-min cycles	5	*E. coli* and *S. aureus*	Sensory quality of Cheddar cheese	Drake et al. (1997)
Skim milk	450, or 600	10	4, 20, or 40		Physicochemical characteristics of skim milk	Gaucheron et al. (1997)
Goat's milk	500		25 or 50		Whey protein in goat milk	Felipe et al. (1997)
Milk	350	12	20	*S. aureus* (ATC 27690)		Erkmen and Karatas (1997)

Advantages of UHP processing

UHP processing is attractive for consumers as it meets demand for freshness and minimal processing as it does not require chemical additives or high temperatures. There is also no consumer negativity that is commonly associated with other food processing technologies (i.e. irradiation).

UHP processing also has advantages for industry as the extended shelf life enables wider product distribution and results in fewer product returns. UHP also uses less energy then other technologies and has the highest processing efficiency for pumpable foods. For non-pumpable foods, processing is undertaken in the final consumer package, eliminating any post-processing contamination that could occur. Required processing times are also reduced and there are no by-products.

Future directions for the application of UHP processing

A recent paper has reviewed the effect on the inactivation of bacteria of combining non-thermal technologies, such as acidification, antimicrobial agents, carbon dioxide, ultra-sonication, pulsed electric fields, irradiation with pressure treatment (Ross et al. 2003). Based on this review, there may be some increased inactivation when such technologies are combined.

UHP processing in Australia

In Australia, CSIRO are conducting feasibility trials for the use of UHP processing for juices, jams and purees. These trials are being undertaken under the CSIRO Food Futures Flagship, which has been investigating non-thermal high-pressure processing for use in food industries. Funding for this area of research is continuing.

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ATTACHMENT 8

Preliminary 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 and/or TAG in the guidelines as is the case currently.
- Retain the current operation for determining novelty, i.e. NFRG working in conjunction with TAG.

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.
- Consider engaging an expert panel to assist in determining novelty either in place of or in addition to developing a decision-tree.
- Consider introducing an education program for industry that would assist in reducing the load on the NFRG. This can be considered in combination with all of the regulatory options described.

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'. Consider whether it is necessary to define 'non-traditional food' or whether it is sufficient to define only 'novel'.
- Amend the operating procedures by reviewing the supporting documents and developing a decision-tree or engaging an expert panel to assist in determining novelty as per Option 2.
- Consider introducing an education program for industry as per Option 2.

Within this Option, a number of issues (or sub-options) would still need to be considered as follows:

- Retain the current assessment process or consider adopting a simplified assessment process for those novel foods that are claimed to be substantially equivalent to another novel food or a traditional food. This may be appropriate for novel foods that are derived from a novel source.

- Consider amending the definition for novel foods to capture foods produced using new technologies. The appropriate assessment process for foods produced using new technologies will need to be considered. It may be possible to assess the some resultant foods using the substantial equivalence approach.
- Consider introducing prescribed classes of novel foods into the Standard itself rather than only in the guidelines, as is currently the case. Consider the appropriate assessment process for each of the classes of novel foods.

Option 4: No specific regulation for novel foods

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

Novel foods would be regulated through relevant generic standards in the Code.

Option 1

Consumers

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 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 (through the TAG forum).

Option 2

Option 2

Consumers

The potential costs and benefits to consumers listed for Option 1 apply to this Option. The amendment of the operating procedures 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. The introduction of an expert panel may increase the confidence of some consumers in comparison with a decision-tree, however it is unlikely that there will be any appreciable difference for consumers.

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. If public health professionals were requested to provide input to an expert panel, this could be interpreted as a cost (impact on resources) or benefit (increased confidence in that public health issues are considered in any determinations made).

Industry

In comparison with Option 1, amending the operating procedures would benefit industry by providing greater clarity for industry. 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.

The referral of determinations with respect to an expert panel, may adversely impact on industry because there may be requirements for providing information to that panel to allow them to perform their task. If public health professionals were requested to provide input to any such panel, this could be interpreted as a cost (further impact on resources) or benefit (increased confidence that industry perspectives are considered in any determinations made).

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 the TAG forum in developing the decision-tree and potentially also in the development of an education initiative, having an initial impact on resources, however, it is expected that in the long-term these mechanisms will provide a benefit to government.

The introduction of an expert panel would likely have an impact on resources for government under this Option with respect to representation and provision of secretariat role. There would have to be careful consideration given to the membership of an expert panel and there would need to be some representation from government because of the expertise. This is a cost in comparison with a decision-tree. On the other hand, increased confidence in the process for determining novelty could be associated with an expert panel and benefit government in comparison with a decision-tree. However, if a decision-tree is implemented that clearly describes the process and this information is communicated well, it could afford the same confidence as an expert panel could potentially provide.

Summary

The use of an expert panel would impact on resources for government and industry in comparison with the use of a decision-tree. Most submitters to the FRSC policy options paper favoured a decision-tree over an expert panel as the preferred decision-making mechanism.

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 increase the time taken to determine novelty in comparison with only amending the operating procedures.

Consumers may benefit from a simplified process for those novel foods purported to be substantially equivalent to an approved novel food or a traditional food, 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 approach of substantial equivalence would have limited application for novel foods and thus there will be minimal impact on consumers.

Regulating foods produced using new technologies 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.

Amending the assessment process to adopt the approach of substantial equivalence, where appropriate, would benefit industry by offering a simplified assessment process where an application supporting substantial equivalence is valid. This would benefit industry in the following ways:

- Resources required for preparing such an application may be reduced.
- The assessment of such an application may be faster than the normal 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. Currently, the only mechanism available for speeding up the assessment of such an application is to deal with it under section 36 of the FSANZ Act.

A potential cost is that it may be difficult for industry to judge when such an application for assessment of substantial equivalence is appropriate. This could be dealt with through the guidelines and education for industry.

Regulating foods produced using new technologies 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.

Adopting the approach of substantial equivalence 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 further ambiguity and result in an additional decision-making process (i.e. can this application be assessed using the substantial equivalence approach?).

Including foods produced using new technologies 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. However, the regulating foods produced from new processes if necessary would provide confidence in assuring public health and safety, benefiting government.

General comments on introducing categories of novel foods

Preliminary discussions have suggested that including specific categories in regulation may not be particularly helpful and there would need to be a clear reason for including categories. One reason for identifying classes of novel foods is that examples of the data requirements for each identified category can assist applicants. This could be viewed as a benefit to industry, however, there are other aspects of this approach that would be a cost to industry, for example, more prescriptive categories could be seen as restraining innovation.

Including categories in regulation could also be a cost to government, both to enforcement agencies with regard to making interpretations about a product but also to FSANZ in interpreting the appropriate category under which to assess a novel food. There are no real costs or benefits of this Option identified for consumers or public health professionals.

FSANZ, taking advice from SDAC members, believes that categories are useful as a guide and for this reason categories would probably be more appropriate in the guidelines document rather than the actual regulation as is currently the case.

Option 4

Preliminary discussions have indicated little support for removing the Standard altogether and not having any specific regulation for novel foods. There was general consensus amongst SDAC members that there are valid reasons for having specific regulation for novel foods to provide a mechanism for ensuring safety through a pre-market safety assessment if required.

Consumers

Although consumers may benefit from quicker access to novel foods in Australia and New Zealand because no pre-market assessment would be required, sufficient protection of public health and safety may not be offered by this option. Consumers could not be assured of being provided with appropriate preparation instructions or advice against consumption by certain population sub-groups, as this would not be required in the regulations.

Public health professionals

As for consumers, public health professionals may benefit from quicker market access to novel foods however, sufficient protection of public health and safety may not be assured. Public health professionals are unlikely to feel confident in suggesting the use of a novel food to a client if it has not undergone a risk assessment and little is known about its appropriate use.

Industry

Industry would likely benefit because product can be placed on market immediately without the need for a pre-market safety assessment enabling quicker flow of revenue. Resources would be saved since liaising with FSANZ and data collation to support an application would not be required. However, the protection afforded to industry by the pre-market assessment process for novel foods would be removed if there was no specific regulation for novel foods.

Government

Under this Option enforcement agencies may not be able to take any immediate action in relation to a novel food depending on the nature of that food. If FSANZ or other government agencies were concerned about the safety of a particular novel food, it would be more difficult to investigate the safety of that food outside a formal assessment process.

Summary

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

Option 2 would result in amending the operating procedures and including a decision-tree in the guidelines would provide increased clarity to all affected parties. The industry sector would particularly benefit by an education program to assist in understanding the process for determining novelty.

The use of an expert panel would impact on resources for government (e.g. secretariat role) and industry (e.g. provision of papers) in comparison with the use of a decision-tree. Most submitters to the FRSC policy options paper favoured a decision-tree over an expert panel as the preferred decision-making mechanism.

Option 3 allows review of the definitions (and other parts of the Standard), clearly benefiting all affected parties, particularly industry and government. Clear and workable definitions would increase industry confidence in determining which foods are captured by the Standard and would also improve the efficiency of government enforcement agencies. Further consideration should be given to regulating foods produced using new technologies and the appropriateness of addressing this within the regulations for novel foods. Introducing more prescriptive categories of novel foods into the Standard has little support based on submissions to the FRSC policy options paper and discussions at the SDAC meeting for novel foods. SDAC members felt that categories of novel foods are more appropriately referred to in the guidelines rather than the regulation.

Option 4 would not afford adequate protection to public health and safety.

ATTACHMENT 9

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 Kerry Bell	Queensland Health
Ms Kerry Close	Australian Quarantine and Inspection Service
Mr John van den Beuken	New Zealand Food Safety Authority
Dr John Hall	Office of Complementary Medicines, Therapeutic Goods Administration
Ms Sonia Nielsen	Department of Agriculture, Fisheries and Forestry
Ms Liz Pugh	Department of Health and Ageing
Mr Tony Downer	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 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 10

Standard Development Advisory Committee meeting agenda and papers

Agenda

First Meeting
23 September 2004

Chair: Melanie Fisher

9.00-9.30	Coffee/tea and registration	
Item 1 9.30-9.45	Welcome / Introduction / Outline	Melanie Fisher
Item 2 9.45-10.30	**Terms of Reference, Conflict of Interest and Confidentiality**	John Taylor
Item 3 10.30-10.45	Guidelines for members and timelines	Leanne Laajoki
Item 4 10.45-11.45	Presentation – background and issues	Leanne Laajoki
Item 5 11.45-12.00	General discussion / Questions	
Item 6 **12.00-12.30**	**Discussion – Purpose of the Novel Foods Standard**	Melanie Fisher
12.30-1.30	Lunch	
Item 7 1.30-2.00	Discussion – Definitions for 'non-traditional food' and 'novel food'	Peter Abbott
Item 8 2.00-2.30	Discussion – Determinations with respect to novelty and enforcement /importation issues	Paul Brent
Item 9 2.30-3.00	Discussion – Scope of the regulations for novel foods: foods produced using new technologies; and categories of novel foods.	Melanie Fisher
Item 10 3.00-3.30	**Discussion – Regulatory and non-regulatory options for novel foods**	Leanne Laajoki
3.30-3.45	Afternoon tea	
Item 11 3.45-4.00	**Summary of discussions and concluding remarks**	Melanie Fisher

Issues Paper distributed to SDAC members prior to first meeting

This paper sets out some issues for discussion at the first meeting of the Standard Development Advisory Committee (SDAC) for novel foods. FSANZ will seek input from members on various topics for discussion. We hope that you will be able to seek the views of your members and colleagues on the issues outlined in this paper and discuss these views at the SDAC. The discussion topics will be allocated half an hour each and will be as follows:

- Purpose of the Novel Foods Standard – Purpose clause;
- Definitions for 'non-traditional food' and 'novel food';
- Determinations with respect to novelty and enforcement/importation issues;
- Scope of the regulations for novel foods – foods produced using new technologies; and categories of novel foods; and
- Possible regulatory and non-regulatory options to be put forward.

A brief description of each of the issues for discussion is provided as follows:

1. Purpose of the Novel Foods Standard

At the time of development of the Novel Foods Standard, the number, variety and increasing use of non-traditional foods raised the question of public health and safety with respect to these foods. In 1996, the then ANZFA released a discussion and options paper entitled 'The safety assessment of novel foods and novel food ingredients'. 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. 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.

As stated in the purpose clause for Standard 1.5.1 (Attachment 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 for direct consumption in Australia and New Zealand.

What are your views on the purpose of the Standard as stated?
Does the current Standard support this purpose?

2. DEFINITIONS FOR 'NON-TRADITIONAL FOOD' AND 'NOVEL FOOD'

The evaluation of submissions received in response to the Food Regulation Standing Committee (FRSC) policy options paper, as prepared by the novel foods working group, indicated that 'based on the detailed concerns expressed by both consumer and industry groups, the main problems appear to stem from the broad definition in the current Standard and difficulties with some of the language used'. It was also suggested that problems with the definitions have resulted in inconsistency and subjectivity in the application of the Standard. The definitions for both 'non-traditional food' and 'novel food' determine what foods or food ingredients are captured by the Standard and subject to pre-market assessment requirements. It is critical to the proper operation of the Standard to have good working definitions and as such, the definitions will require consideration during the course of this review. Currently the definitions in the Novel Foods Standard as follows:

> **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.

It may not be practical for any revised definition relating to novel foods to be entirely unambiguous and as such, criteria for assessing novelty against any definition will be important for supporting that definition.

What are your views on the following specific issues that have been raised:

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 of use?
- a specified number of sub-groups within a population?

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?

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 will be practical consequences of any major change to the definitions.

Although some suggestions for alternate definitions have been made, FSANZ does not intend to put these forward at Initial Assessment. Alternative(s) will be proposed at Draft Assessment to support the more preferred option(s) and taking into account comments received by SDAC members and submitters.

3. DETERMINATIONS WITH RESPECT TO NOVELTY AND ENFORCEMENT/IMPORTATION ISSUES

3.1 Determinations with respect to novelty

Prior to an application to amend the Code being assessed by FSANZ, a determination as to whether the food or food ingredient in question 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) through the TAG forum.

The internal FSANZ Novel Foods Reference Group (NFRG) makes an initial consideration and this is reported to TAG or discussed with members at the forum with varying levels of involvement depending on the complexity. Some 70-80 potential novel foods or novel food ingredients have been examined by the NFRG, sometimes in conjunction with TAG. This experience provides a basis for revision of the Novel Foods Standard, and in particular, the definitions provided within that Standard.

Making these considerations 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 that is not included on the FSANZ Work Plan.

During the time between which the Novel Foods Standard was in place (16 December 1999) and when clause 2 of the Standard (prohibition) came into full effect (16 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 by the Ministerial Policy Guidelines work program.

Considerable effort has been made towards ensuring consistency in the determinations with respect to novelty and the subsequent communication of these determinations. The membership of the internal FSANZ NFRG has changed and the procedures have also changed to assist in ensuring consistency. FSANZ has also worked to build on the existing working relationship with AQIS, a main source of inquiries with respect to the Standard. It is only since January 2004 that 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') without an inquirer needing to make a specific request (Attachment 2). FSANZ now regularly reports to TAG quarterly on considerations by the NFRG. These changes have assisted industry and enforcement agencies and some positive feedback has been received.

Continued improvements in consistency will flow from other improvements that may be made to the regulation of novel foods, particularly the definitions, as a result of this review.

TWO DECISION-MAKING MECHANISMS WERE PROPOSED IN THE FRSC POLICY OPTIONS PAPER – THE USE OF A DECISION-TREE AND AN EXPERT COMMITTEE – BOTH WITH THEIR PROS AND CONS. ARE THERE ARE OTHER MECHANISMS THAT COULD BE EMPLOYED TO FURTHER ENABLE CONSISTENT DETERMINATIONS WITH RESPECT TO NOVELTY?

3.2 ENFORCEMENT / IMPORTATION ISSUES

Once a food is available on the market in Australia or New Zealand, particularly in mainstream supermarkets, it is difficult for enforcement officers to argue that the particular food is 'non-traditional' in accordance with the current definition, even though the view may be that little is known about the food, the community has had little exposure to it and there may be safety issues. If the food is deemed to be traditional because of such presence on the market and not captured by the Novel Foods Standard there is no scope to readily undertake a scientific risk assessment in accordance with the Code unless a specific safety issues is clearly identified.

This situation presents a problem for both FSANZ and enforcement officers. Enforcement officers may be reluctant to argue that the food is 'non-traditional' because this is a difficult point to prove. However, FSANZ and enforcement officers may not be convinced of the safety of the food for human consumption. Any regulation for novel foods needs to allow FSANZ to meet one of its primary objectives under the FSANZ Act, namely, the protection of public health and safety and this may not be possible in all cases with the current Standard.

Officers enforcing the Code with respect to imported food need to quickly interpret any regulations for novel foods to allow them to make effective enforcement decisions. Because the Novel Foods Standard may capture some whole foods including fresh produce such as fruit, these may deteriorate while being held by AQIS until a determination with respect to novelty is made. It should be noted however, that compliance with the Code is the responsibility of the importer in this case and if there is any question as to the novelty of the food this should be investigated prior to arrival in Australia. Notwithstanding this, FSANZ has a close working relationship with AQIS and most issues have been resolved in a timely fashion. A large number of inquiries referred to FSANZ regarding novel foods are related to imported foods, and as such this review needs to ensure that any regulations for novel foods are workable for enforcement officers working with imported food.

FOR GOVERNMENT AGENCIES ENGAGED IN ENFORCEMENT ACTIVITIES, HOW CAN THE REGULATIONS FOR NOVEL FOODS AND/OR THE PROCESS FOR DETERMINATION OF NOVELTY BE AMENDED TO ASSIST ENFORCEMENT ACTIVITIES?

4. Scope of the regulations for novel foods – foods produced using new technologies and categories of novel foods

4.1 Foods produced using new technologies

A number of new technologies are being employed in food processing, the potential regulation of which will need to be considered. Foods produced from some new technologies are already regulated by separate Standards in the Code and require individual pre-market assessment, such as foods that been irradiated and foods produced using gene technology. Some recently reported processing developments relate to:

- 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; and
- combinations of the above.

FSANZ has limited information about many of these new technologies, with high-pressure pasteurisation of juices having the most information available.

The '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 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 new technology. As part of the review, FSANZ is considering the need to regulate such new technologies and, if so, whether the scope of any new regulations for novel foods should capture these new technologies.

Are there other technologies being used that have not been mentioned here and that are relevant to consider as part of this review?
Do you have further information about the safety of any of these new technologies?
If there is a need to regulate for these new technologies, is it appropriate to consider with novel foods?

4.2 CATEGORIES OF NOVEL FOODS

The 'Guidelines to assist in applying to amend the *Australia New Zealand Food Standards Code* – Novel Foods' contains information on the likely categories of novel foods, though novel foods are not limited to these categories. The categories are as follows:

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

These categories are included in the document and described in relation to the definition for novel foods to assist potential applicants. The categories are not referred to in the Novel Foods Standard.

One of the policy options presented in the FRSC policy options paper discussed the inclusion of defined categories of novel foods into the Novel Foods Standard. This would result in a more prescriptive standard. Some submitters believed that this would assist industry and protect consumers most effectively. Other submitters believed that not all novel foods would sit within one of the categories and the inclusion of such categories is against the principle of minimum effective regulation. Overall this option was not supported.

5. POSSIBLE REGULATORY AND NON-REGULATORY OPTIONS TO PUT FORWARD

FSANZ is not seeking comment on which regulatory options are preferred by the organisation you are representing, but rather on what options could be put forward in the Initial Assessment Report. There will be an opportunity to provide views on your preferred regulatory/non-regulatory options at a later date, either during the formal public comment period or at a future meeting of the SDAC following receipt of submissions in response to the Initial Assessment Report.

The FRSC policy options paper on novel foods put forward five options, which were referred to as policy options. However, the options presented referred to regulatory outcomes and it is therefore appropriate to consider these options or similar during the review of novel foods. The options put forward in the FRSC paper were:

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.

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

Some parties represented by SDAC members already provided comments on these options in response to the FRSC paper.

Are there potential regulatory options that you support putting forward in the Initial Assessment Report that are not similar to those described in the FRSC policy options paper?

Members should recognise that any significant change in the regulation for novel foods will have implications for the novel foods already approved in accordance with Standard 1.5.1 and for consistency with international regulations.