



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

**6-07**

**3 October 2007**

## **FINAL ASSESSMENT REPORT**

### **PROPOSAL P291**

### **REVIEW OF NOVEL FOOD STANDARD**

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

## **Executive Summary**

FSANZ received policy guidance on novel foods from the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) in December 2003. The policy guidance recommends that FSANZ review Standard 1.5.1 – Novel Foods, of the *Australia New Zealand Food Standards Code* (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. In response, FSANZ prepared this Proposal to review the regulation for novel foods.

Standard 1.5.1 requires a risk-based assessment process to ensure the safety of novel foods before they can be sold in Australia and New Zealand. There is general support for the purpose of the Standard, namely that novel foods undergo a risk assessment to ensure their safety prior to sale, and it is seen as fulfilling a valid role in the protection of public health and safety. The determination as to whether a food or food ingredient is novel is made in accordance with the definitions for ‘non-traditional food’ and ‘novel food’ in the Standard.

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

Consideration has also been given to the process of determining whether a food is novel or not. FSANZ has proposed replacing the existing informal Novel Foods Reference Group (NRFGR) with a new committee, the Advisory Committee on Novel Foods (ACNF). The ACNF will be set up under section 118 (1)<sup>1</sup> of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) and will provide recommendations to the General Manager – Food Standards (Canberra) on whether a food should be considered a ‘non-traditional food’ in accordance with the definition in Standard 1.5.1 and whether an assessment of public health and safety considerations should be required. The outcomes of the ACNF recommendations will be published on the FSANZ website. In addition, a guidance tool has been developed to assist the ACNF in making its recommendations to the General Manager – Food Standards (Canberra).

The revised definitions for ‘non-traditional food’ and ‘novel food’ in Standard 1.5.1 will assist in improving consistency in the application of the Standard. The appointment of the ACNF, together with the introduction of the guidance tool, will provide additional transparency to the process of determining whether a food is novel or not.

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

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<sup>1</sup> The Board may establish such committees as it thinks fit to assist in carrying out its functions, and may abolish any such committee.

## Purpose

This Proposal was prepared in response to Ministerial Policy Guidelines to review Standard 1.5.1, including the process for determining whether a food is novel or not.

## Decision

Retain an amended Standard 1.5.1 – Novel Foods, to provide regulation for novel foods. The main amendments to Standard 1.5.1 are revised definitions for ‘non-traditional food’ and ‘novel food’. The process for determining whether a food is novel or not will be formalised by replacing the Novel Foods Reference Group with an Advisory Committee on Novel Foods. A guidance tool for determining whether a food is novel or not has been developed to assist the ACNF in making its recommendations.

## Reasons for Decision

An amended Standard 1.5.1 will be retained to provide regulation for novel foods for the following reasons:

- There is general support from stakeholders for the purpose of the Standard, that novel foods undergo a risk-based assessment to ensure their safety prior to sale.
- To ensure consistency with the specific objectives of this Proposal, particularly, to ensure: (i) the safety for human consumption of novel foods; (ii) that regulations are complementary with inter-related standards in the Code; and (iii) that the Ministerial Policy Guidelines have been thoroughly considered within FSANZ’s objectives under section 18 of the FSANZ Act.
- To have regard to the higher order and specific policy principles of the Ministerial Policy Guideline, specifically: (i) to ensure priority is given to the protection and improvement of public health and safety in relation to food matters; (ii) to draw on the best elements of international regulatory systems and be responsive to future trends and developments; and (iii) to ensure that public and industry confidence in the food system is maintained and to ensure consumers are not misled by novel foods or food ingredients which appear similar to existing foods but may differ in terms of nutrition or function.
- The purpose of the regulation for novel foods in Australia and New Zealand is consistent with the purpose of similar regulatory frameworks for novel foods in Canada and the EU.

Standard 1.5.1 will continue to contain definitions for both ‘non-traditional food’ and ‘novel food’ (albeit, revised definitions) for the following reasons:

- The concept of *absence of history of use in Australia and New Zealand* is important for inclusion in the regulation for novel foods as it assists in the process of determining whether a food is novel or not. A revised definition for ‘non-traditional food’ has been retained to include this element. The concept of *absence of history of safe use* is addressed in the definition for ‘novel food’. Retaining two separate definitions for ‘non-traditional food’ and ‘novel food’ ensures simplicity and clarity in the definitions.

- It is accepted that there will be some subjectivity associated with the definitions for ‘non-traditional food’ and ‘novel food’, however, the revised definitions omit the terms that were seen as most ambiguous. The guidance tool for determining whether a food is novel or not provides assistance in interpreting the definitions.
- These revisions to the definitions take into regard the Ministerial Policy Guidelines, specifically, that the subjectivity and scope of the current definitions be considered and addressed as far as possible. The revisions to the definitions also take into regard the specific objectives of this Proposal, particularly to ensure: the safety for human consumption of novel foods; and that the regulations are readily enforceable.

The process for determining whether a food is novel or not will be more formalised by replacing the NFRG with an Advisory Committee on Novel Foods set up under section 118 (1)<sup>2</sup> of the FSANZ Act. A guidance tool for determining whether a food is novel or not has been developed to assist the ACNF in making recommendations on whether a food should be considered a ‘non-traditional food’ in accordance with the definition in Standard 1.5.1 and whether an assessment of public health and safety considerations should be required. These measures have been agreed for the following reasons:

- The introduction of the proposed guidance tool will increase the level of rigour applied to the process of determining whether a food is novel or not.
- These proposed changes take into regard the Ministerial Policy Guidelines, specifically, that the user guide be reviewed to include any amendments to the novel food definition and to provide greater clarity about the process for determining if a food is novel or not.
- The measure addresses comments made by submitters to the Draft Assessment Report that: the NFRG function is supported; wider representation, particularly from jurisdictions, should be considered; and difficulties in enforcing the views of the NFRG remain.

## **Consultation**

Having regard to the Ministerial Policy Guidelines, FSANZ established a Standard Development Advisory Committee (SDAC) to assist FSANZ during the review of the Standard. The role of the SDAC was to provide advice to FSANZ on matters related to the review, rather than to endorse any regulatory option. The SDAC met on four separate occasions.

The Initial Assessment Report (IAR) was advertised for public comment from 15 December 2004 to 2 March 2005. Fifteen submissions were received during this period, 13 from Australia and two from New Zealand.

The Draft Assessment Report (DAR) was advertised for public comment from 5 October 2005 to 25 January 2006. Eighteen submissions were received during this period, 14 from Australia and four from New Zealand. Submitters’ comments have been taken into consideration in the development of this report. A summary of submissions and list of submitters to the IAR and DAR is at Attachment 9 of this Report.

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<sup>2</sup> The Board may establish such committees as it thinks fit to assist in carrying out its functions, and may abolish any such committee.

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## **INTRODUCTION**

### **1. Background**

FSANZ 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 recommended that FSANZ review Standard 1.5.1 while giving consideration to the higher order principles and specific principles of that policy guidance and to a number of issues raised during consultation on policy options. The policy guidance also recommended that FSANZ use a reference group comprising representatives of enforcement agencies to provide advice during the review.

The focus of the review has been to examine the regulatory framework for novel foods and the decision-making mechanisms that determine whether a food is subject to the regulations for novel foods. Existing permissions for novel foods were not revisited during the review and applications for the approval of novel foods in accordance with the current Standard were not affected.

The following issues have been considered within the scope of this review:

- 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 have been made as to whether a food is novel or not in accordance with the definitions;
- general history and operation of the Standard including enforcement by jurisdictions;
- mechanisms for forming a view on whether a food is novel or not, including the establishment of an Advisory Committee on Novel Foods (ACNF);
- the development of a guidance tool for determining whether a food is novel or not;
- the scope of the existing Standard 1.5.1, including the potential to capture food derived from new technologies and novel sources;
- the information provided to the public with respect to views formed on whether particular foods are novel or not;
- the costs and benefits associated with the current Standard and alternative regulatory and non-regulatory options;
- examination of inter-relationships with other projects, other existing Standards and the foods-therapeutic goods interface;
- comparison with the regulation of novel foods in other countries; and
- including categories of novel foods.

The categories of novel foods that were presented in the Draft Assessment Report have been revised and included as part of the recent development of the FSANZ *Application Handbook*.

## 1.1 Current Standard

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

### 1.1.1 *Determining whether a food is novel or not*

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

In Standard 1.5.1:

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

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

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

The current approach for determining whether a food is novel or not is discussed in Section 5.1. Some stakeholders have expressed dissatisfaction with both the outcome views formed by the internal FSANZ Novel Foods Reference Group (NFRG) and the process by which these views are formed. Some stakeholders are of the view that what they see as flawed determinations with respect to whether a food is novel or not has contributed to applications to amend the Table to clause 2 of Standard 1.5.1 being unnecessarily made and assessed.

## 1.2 Historical Background

### 1.2.1 *Development of Standard 1.5.1*

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

Proposal P168 – Novel Foods, was prepared 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. The proposed Standard with a pre-market assessment requirement 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* were gazetted in December 1999 and Standard 1.5.1 gazetted as part of the new Joint Code in December 2000. 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.

To coincide with the gazettal of Standard A19, 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 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; 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, data requirements for the assessment of novel foods and a record of views formed in response to inquiries with respect to whether a food is novel or not.

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 on whether a food is considered novel or not formed in response to enquiries. The table presents the outcome view with respect to whether a particular food or food ingredient is: (a) non-traditional or not; 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 enquiry to be made directly to FSANZ and the information would be made available on a case-by-case basis.

### *1.2.2 Ministerial Policy Guideline on Novel Foods*

The Food Regulation Standing Committee (FRSC) established a working group to develop policy options in relation to novel foods. The novel foods working group produced a policy options paper on novel foods, which was released for public consultation in February 2003. The final draft policy guideline was considered by FRSC in September 2003 and it was agreed that this draft policy guideline would be provided to the Ministerial Council in December 2003.

The Ministerial Council endorsed the 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 2. 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 misled by novel foods which appear similar to existing foods but may differ in terms of nutrition or function.

The Policy Guidelines requested that FSANZ raise a proposal to review Standard 1.5.1, having regard to the higher order and specific policy principles of the Policy Guidelines.

## **2. The Issue / Problem**

During the time between which the Novel Foods Standard was established (December 1999) and when clause 2 of the Standard, which prohibits the sale of novel foods unless included in the Table to that clause, came into full effect (June 2001), some determinations were made with respect to whether a food is novel or not.

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

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

## **3. Objectives**

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

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

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

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

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

- safety for human consumption of novel foods;
- regulations are readily enforceable;
- regulations are complementary with inter-related standards in the Code;
- regulations do not unnecessarily place a burden on industry innovation and are able to be consistently applied;
- regulations are developed having regard to the Ministerial Policy Guideline; and
- other issues raised by stakeholders are considered and covered as far as possible.

## **KEY ISSUES**

In order to assist in the review of novel foods, the FSANZ Board established a Standard Development Advisory Committee (SDAC) to provide advice to FSANZ. The SDAC has convened on four occasions (refer Section 13.1). At its fourth meeting, which was held on 15 June 2007 by teleconference, SDAC members offered their support in relation to the following key issues.

### **4. Definitions in Standard 1.5.1**

The definitions contained in the Novel Foods Standard, and the ambiguity associated with some of the terms used in these definitions, were indicated as the main reason for the development of Ministerial Policy Guidelines on Novel Foods and the subsequent review of the Novel Foods Standard.

In developing these new definitions, FSANZ has taken into account comments made:

- as part of the FRSC consultation in the development of the Ministerial Policy Guideline;
- at previous SDAC meetings; and

- in submissions in response to the Initial and Draft Assessment Reports.

#### **4.1 Definition for non-traditional food**

FSANZ has proposed the following definition for non-traditional food at Final Assessment:

*non-traditional food means -*

- (a) *a food that does not have a history of human consumption in Australia or New Zealand; or*
- (b) *a substance derived from a food, where that substance does not have a history of human consumption in Australia or New Zealand other than as a component of that food; or*
- (c) *any other substance, where that substance, or the source from which it is derived, does not have a history of human consumption as a food in Australia or New Zealand.*

Some examples of non-traditional foods that have already been considered which relate to (a), (b), and (c) are:

- (a) ackee fruit; yoghurt produced using high pressure processing (a food produced by a process not previously applied to food);
- (b) phytosterol esters; conjugated linoleic acid; and
- (c) docosahexaenoic acid (DHA) derived from marine micro-algae; pine bark extract.

##### *4.1.1 Rationale*

There was general concern that the definition presented at Draft Assessment would be difficult to interpret, particularly in terms of what constituted ‘generally available’, ‘broad cross section of consumers’ (both in part (a) of the definition presented at Draft Assessment) and ‘a history of human consumption’ (in parts (b) and (c) of the definition presented at Draft Assessment). At Final Assessment, FSANZ has removed the phrases ‘generally available’ and ‘broad cross section of consumers’ from part (a) of the definition. Instead, the term ‘history of human consumption’, will be used consistently across parts (a), (b) and (c) of the revised definition. Under the new definition, this is the only term that may require some interpretative guidance, however, the guidance tool for determining whether a food is novel or not (Section 6) will provide guidance around the interpretation of this term.

The implications of the change to part (a) of the definition is that whole native foods may be less likely to be captured by the definition. However, there are mechanisms within the Code that may be appropriately used to address potential safety issues with native foods, though these do not require pre-market safety assessments e.g. Standard 1.2.6 – Directions for Use and Storage; Standard 1.4.1 – Contaminants and Natural Toxicants; and Standard 1.4.4 – Prohibited and Restricted Plants and Fungi. It will still be possible for part (a) of the proposed definition to capture whole foods that do not have a history of human consumption in Australia and New Zealand (e.g. Ackee fruit).

#### **4.2 Definition for novel food**

FSANZ has proposed the following definition for novel food at Final Assessment:

*novel food means a non-traditional food and the food requires an assessment of the public health and safety considerations having regard to -*

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

#### *4.2.1 Rationale*

The key change in this new definition compared with the definition proposed at Draft Assessment is the removal of the phrase ‘may be unsafe having regard to’, as there is uncertainty associated with the use of the word ‘may’.

FSANZ has also given further consideration to the logical order of the considerations (a) to (e). The potential for adverse effects in humans is critical in determining whether an assessment of public health considerations is necessary and so has been listed as consideration (a). The next three considerations relate to the final food itself. The patterns and levels of consumption relates to consumption rather than the food and so has been moved from (c) to (e) to allow grouping of like considerations. The order in which matters are listed does not reflect an order of importance.

In relation to part (f), it is a general rule of interpretation that ‘any other relevant matters’ are guided by, but not limited to, the considerations in (a) to (e). This enables a recommendation to be based on specific issues that although not listed would be relevant to public health and safety considerations related to the food. Any matters outside the scope of what is addressed in (a) to (e) would not be considered relevant. If a recommendation is made in respect of item (f), the process of coming to that decision would be disclosed.

At Draft Assessment, a number of submitters commented that the proposed definition did not reflect the intent to require pre-market assessment of foods produced using new processes or from novel sources only where the final food has altered characteristics and any such altered characteristics raise safety concerns.

Foods or food ingredients may only be considered novel, if they are first considered non-traditional. The definition of ‘non-traditional food’ would not encompass foods produced using new processes or foods derived from novel sources unless there were some altered characteristics. The definition of ‘novel food’ would not encompass foods produced using new technologies or foods derived from novel sources unless there was a need to undertake an assessment of public health and safety considerations. That is, if there are no identified public health and safety considerations from any altered characteristics in the final food, the final food would not be consistent with the definition of novel food and would not be subject to the pre-market safety assessment requirements of the Novel Food Standard. Therefore, the definition for novel food achieves the intended outcome.

## **5. Process for determining whether a food is novel or not**

### **5.1 Current approach**

Prior to an application to amend the Code being assessed by FSANZ, a determination as to whether the potential novel food is ‘non-traditional’ and ‘novel’ is made in accordance with the definitions in the current Standard 1.5.1. The internal FSANZ NFRG forms a view in response to enquiries received and based on the information available. These views are made publicly available on the FSANZ website (in the document, ‘Record of views formed in response to enquiries’) and any updates to this information are reported to Australian State and Territory jurisdictions, the New Zealand Food Safety Authority (NZFSA) and the Australian Quarantine and Inspection Service (AQIS).

FSANZ notes that there are difficulties with this approach. For example, there is a degree of subjectivity to many considerations by the NFRG and enforcement of the views of the NFRG may be problematic.

### **5.2 Advisory Committee on Novel Foods**

FSANZ has proposed to replace the NFRG with a new committee, to be referred to as the Advisory Committee on Novel Foods (ACNF). This recommendation takes into consideration comments made by submitters to the Draft Assessment that:

- the NFRG function is supported;
- wider representation, particularly from jurisdictions, should be considered; and
- difficulties in enforcing the views of the NFRG remain.

The ACNF will be set up under section 118 (1)<sup>3</sup> of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act), to assist the FSANZ Board in carrying out its functions. The main function of the ACNF is to provide recommendations to the General Manager – Food Standards (Canberra) as follows:

1. Whether the food that is the subject of the enquiry should be considered a ‘non-traditional food’ in accordance with the definition in Standard 1.5.1.
2. Whether an assessment of public health and safety considerations should be required for the food that is the subject of the enquiry in order to confirm that there is a reasonable certainty that no harm will result from the intended use of the food and recommend whether any risk management strategies are warranted to ensure the safe use of the food.
3. Whether the enquirer and/or company needs to make an application to Food Standards Australia New Zealand (FSANZ) to amend the Code in order for an assessment of public health and safety considerations to be undertaken.

The establishment of the ACNF as a committee under the FSANZ Act formalises an arrangement that is inclusive of input from the jurisdictions and assists to make the final view formed by FSANZ to be more transparent and accountable.

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<sup>3</sup> The Board may establish such committees as it thinks fit to assist in carrying out its functions, and may abolish any such committee.

Having a view expressed in a letter from the General Manager – Food Standards (Canberra), based on the recommendation of a committee set up under the FSANZ Act and with representation from jurisdictions with enforcement responsibility, should greatly assist in any prosecution where novel food has been placed on the market without the requisite permission in Standard 1.5.1.

The outcome of the ACNF recommendations to the General Manager – Food Standards (Canberra), will be published on the FSANZ website, as is currently the case for views formed by the NFRG. The Terms of Reference, Membership and Mode of Operation for the ACNF will also be published on the FSANZ website and are provided at Attachment 3.

There is no obligation on an enquirer to seek the view of the ACNF. A potential applicant may proceed directly to submit an application seeking to amend Standard 1.5.1 of the Code to permit a novel food.

## **6. Guidance tool for determining whether a food is novel or not**

The SDAC supported the development of a guidance tool (Attachment 4) to assist the ACNF in making recommendations to the General Manager – Food Standards (Canberra) on:

1. whether a food should be considered a ‘non-traditional food’ in accordance with the definition in Standard 1.5.1; and
2. whether an assessment of public health and safety considerations should be required for the non-traditional food to confirm there is reasonable certainty that no harm will result from the intended use of the food and to determine whether any risk management strategies are warranted to ensure the safe use of the food.

The guidance tool was developed initially at a workshop with a sub-group of SDAC members and was subsequently refined following consultation with the broader SDAC group.

The guidance tool has four elements:

1. **Introduction.** The introduction provides general information on the Novel Foods Standard, the Advisory Committee on Novel Foods and the use of the guidance tool.
2. **Information to be provided by enquirer.** This part refers the reader to the information that needs to be provided by the enquirer and how this information is to be considered by the ACNF when using the guidance tool.
3. **Guidance tool Part 1.** Part 1 of the guidance tool provides assistance in determining whether a food is non-traditional or not. It is to be used by the ACNF when making a recommendation as to whether a food is non-traditional or not. This part highlights the information to be provided by the enquirer that should be taken into consideration when making this recommendation as to whether a food is non-traditional or not.
4. **Guidance tool Part 2.** Part 2 of the guidance tool is only used if a recommendation is firstly made that the food is non-traditional. This part provides assistance for the ACNF in making a recommendation as to whether a non-traditional food should also be subject to an assessment of public health and safety considerations.

This part also highlights the information to be provided by the enquirer that should be taken into consideration when making a recommendation as to whether an assessment of public health and safety considerations is required.

## **7. Monitoring of novel food permissions**

FSANZ considers that it is not feasible or necessary to initiate a review of existing novel food permissions unless new public health and safety considerations arise. Applications may be made, accompanied by the necessary data, to remove existing novel food permissions and FSANZ would need to consider any such application.

### **7.1 Background**

The issue of monitoring of novel food permissions has been raised with FSANZ on a number of occasions, on the basis that post-market monitoring data can provide additional assurance regarding the long-term safety of products and their impact on the food supply. FSANZ has also received requests to put in a place a system whereby an approved novel food is removed from Standard 1.5.1 once it has been used extensively or after a certain period of time e.g. 10 years. FSANZ sought comment on these issues at Draft Assessment.

There was general support for a review of novel food permissions, however ten years was considered too long a period of time after permission was granted; and five years was suggested as more appropriate. Some submitters suggested that a novel food should be declared no longer novel after review if there were no concerns associated with that food. A small number of submitters did not support a review process and considered it unnecessary, given that the food had already gone through a full assessment process.

### **7.2 Evaluation**

In order for any novel food permission to be removed, there would need to be sufficient data to demonstrate that the food is no longer 'novel' and this would require data on the extent of use and data to establish that it has been used safely. It is not possible to determine how long it would take for this data to be generated because it depends on the business decisions of relevant industry as to when and how they place a permitted novel food on the market. FSANZ is aware that some of the novel foods that have been approved for some time have still not been marketed because of the decision made by the company. In these cases, five years and probably even 10 years would be insufficient time to demonstrate that a food is no longer novel.

FSANZ could consider, on a case-by-case basis, conducting a review of any existing novel food permission in accordance with section 113 of the FSANZ Act. After a review is completed, FSANZ would need to consider whether a Proposal should be raised in order to amend the Standard. This is a highly resource intensive approach and would generally only be undertaken if new public health and safety considerations arose in relation to a particular novel food. This is not something FSANZ would undertake in order to remove a novel food permission, particularly one with general applicability (i.e. no conditions of use specified) as we would not be in a position to collect the required data.

## 8. The Ministerial Policy Guidelines

In developing and varying standards, FSANZ must have regard to any written guidelines formulated by the Ministerial Council. The way in which FSANZ has had regard to the guidelines is described in Attachment 5, and some of the main elements are summarised here:

In response to the higher order principles:

- Retaining regulation for novel foods with a risk-based approach for pre-market assessment ensures the protection of public health and safety.
- Consumers would have access to sufficient information to enable informed choice through any labelling information specified in the conditions of use for novel food permissions and through general labelling requirements.
- FSANZ has considered other relevant regulations for novel foods, namely in the European Union and Canada and has discussed these regulations with members of the SDAC, in revising the definitions in Standard 1.5.1. Relevant international regulations for novel foods are at Attachment 6.
- Increased transparency will be achieved by the establishment of the ACNF with a clear structure and role and detailed information on its operation on the FSANZ website. The development of a guidance tool for determining whether a food is novel or not to be used by the proposed ACNF and provided on the website will further increase transparency. Transparency will also be increased by the inclusion of justifications of views formed in relation to whether a food is novel or not on the FSANZ website.

In response to the specific principles:

- The maintenance of public and industry confidence in the food system was considered in the impact analysis of the regulatory options and in increasing transparency with respect to determining whether a food is novel or not through the establishment of the proposed ACNF.
- Commercially sensitive information is protected to the extent possible under the FSANZ Act. Options for addressing the issue of data protection have been considered by the FRSC steering committee addressing the FSANZ assessment and approval process. In accordance with the recommendations to this process, changes to the FSANZ Act will result in most novel food applications being assessed in 9 months with one round of public comment only. Another recommendation of this work was to allow applicants to seek exclusive permissions for novel foods for a 15 month period. Proposal P305 has been raised to consider exclusivity of novel foods.
- Conditions of use for novel foods can be specified to provide consumers with appropriate information on novel foods or novel food ingredients that may assist them in understanding the functionality of the ingredients. This provision coupled with the general labelling requirements including full disclosure of the name of the novel food ingredient should ensure that consumers are not misled by novel foods or novel food ingredients which appear similar to existing foods but may differ in terms of nutrition or function.



## 9. Categories of novel foods

At Draft Assessment, FSANZ presented a revised list of categories of novel foods. It had been agreed through the previous SDAC meetings, and supported in comments to the Initial Assessment Report, that providing categories of novel foods was helpful since there was a diverse range of potential novel foods but that these categories are appropriately provided in guidelines rather than in the Standard.

The purpose of such categories is to provide information to potential applicants on the nature of the data that would be required to accompany an application for a particular novel food. It was recognised that the categories of novel foods provided would not necessarily cover all potential novel foods. In submissions made in response to the Draft Assessment Report, there was general support for the inclusion of categories in the guideline document.

Amendments to the FSANZ Act will result in a requirement that all applications are required to contain certain minimum information. For this purpose FSANZ has developed an *Application Handbook*, approved by the FSANZ Board in March 2007. The *Application Handbook* contains general requirements as well as specific requirements for certain types of applications.

In the section of the *Application Handbook* that states the requirements for novel food applications, the categories listed are as follows:

- I. Plants or animals and their components
- II. Plant or animal extracts
- III. Herbs (both non-culinary and culinary) including extracts
- IV. Single chemical entities
- V. Dietary macro-components
- VI. Micro-organisms (including probiotics)
- VII. Food ingredients derived from new sources
- VIII. Foods produced by a process not previously applied to food

## 10. Foods-therapeutic goods interface

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 follows: foods in accordance with the Code; dietary supplements in accordance with the New Zealand *Dietary Supplements Regulations 1985* (NZDSR); or 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.

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.

If a question arises as to whether a product may be more appropriately regulated as a therapeutic good rather than a food, the issue will be referred to the Foods-Therapeutic Goods Interface Group. The consideration as to whether a product is in fact a food (as opposed to a therapeutic good), should always occur prior to the Advisory Committee on Novel Foods using the guidance tool for determining whether a food is novel or not. This is specified in the Terms of Reference for the Committee and in the guidance tool.

## **RISK MANAGEMENT**

### **11. Options**

#### **11.1 Option 1: Retain the *status quo***

- Retain the current Standard 1.5.1 – Novel Foods.
- Retain the current assessment process for novel foods.
- Retain the current supporting documents on the website but continue to update the considerations by the NFRG in the guidelines as is the case currently.
- Retain the current operation for determining whether a food is novel or not i.e. NFRG working in conjunction with jurisdictions.

#### **11.2 Option 2: Retain the current standard but amend operating procedures**

- Retain the current Standard 1.5.1 – Novel Foods.
- Retain the current assessment process for novel foods.
- Amend the supporting documents as required. Review the categories of novel foods referred to in the guidelines.
- Review and amend operating procedures for determining whether a food is novel or not.
- Develop a guidance tool to assist in the interpretation of the definitions.
- Undertake targeted education for stakeholders in response to demand. This may assist in reducing the load with respect to determining whether a food is novel or not.

#### **11.3 Option 3: Amend Standard 1.5.1 and operating procedures**

- Maintain the intent of the current Standard but review the wording of the purpose clause and the definitions for ‘non-traditional food’ and ‘novel food’.
- Amend the definition for novel foods to capture foods produced using new technologies with altered characteristics that raise safety concerns.
- Amend the supporting documents as required. Review the categories of novel foods referred to in the guidelines.
- Review and amend operating procedures for determining whether a food is novel or not.
- Develop a guidance tool to assist in the interpretation of the definitions.
- Undertake targeted education for stakeholders in response to demand. This may assist in reducing the load with respect to determining whether a food is novel or not.

## **12. Impact Analysis**

### **12.1 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 therefore are subject to the pre-market assessment requirements of Standard 1.5.1, including small business and importers of novel foods.

### **12.2 Benefit cost analysis and comparison of options**

FSANZ currently has limited quantitative data in relation to the impacts on the various affected parties of each of the regulatory options put forward, though some qualitative information has been made available. FSANZ has sought advice from the SDAC on the possible costs and benefits associated with each option, however, it was widely acknowledged that quantitative data is difficult to obtain due to the limited number of novel foods on the market in Australia and New Zealand.

This section presents a summary of the analysis of the costs and benefits for each of the affected parties for each of the Options. The detailed impact analysis is at Attachment 7.

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

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

Option 3 affords a clear benefit to consumers, public health professionals and government in comparison with Option 2 due to the opportunity to provide increased clarity around the definitions in addition to the process for determining whether a food is novel or not.

Increased clarity around definitions would increase industry confidence in determining which foods are captured by the Standard and improve the efficiency of government enforcement agencies. Regulation of foods produced using new technologies would benefit consumers and public health professionals, and any cost to industry is likely to be minimal since only those foods with altered characteristics that raise safety concerns would be considered to be novel. Option 3 is the only option that allows FSANZ to adequately address and implement the Ministerial Council Policy Guideline on novel foods.

Overall, Option 3 is the preferred regulatory Option.

## **COMMUNICATION AND CONSULTATION STRATEGY**

### **13. Communication**

FSANZ identified a targeted group of stakeholders with which consultation occurred via the SDAC. It was also beneficial to communicate the nature of the review and timelines with a broader group identified as ‘interested parties’. The group is made up of submitters to all applications that have been assessed in accordance with the novel foods standard. This interested parties group has been provided with updates in relation to the review on three occasions.

FSANZ has included information on the review of novel foods in *Food Standards News* during the course of the review.

### **14. Consultation**

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

#### **14.1 Standard Development Advisory Committee**

The policy guidance issued by the Ministerial Council on novel foods requested that FSANZ use a reference group that includes representatives from relevant Australian Government, New Zealand and State and Territory enforcement agencies to provide advice in reviewing the Standard. Nominations were sought for representatives from industry, public health and consumer groups to participate on the SDAC in addition to government representatives. The FSANZ Board established the SDAC and agreed to the Terms of Reference. The membership of the SDAC and its terms of reference are at Attachment 8.

The first meeting was held on 23 September 2004. The meeting focussed on the background and discussion of issues relating to the review of the novel foods standard. The issues raised were incorporated in the IAR. The second meeting was held on 21 June 2005. Submissions received in response to the IAR were discussed and the issues raised were incorporated in the DAR and informed the direction taken at Draft Assessment.

The third meeting of the SDAC was held on 19 October 2006, by teleconference. The key issues addressed at this meeting related to the proposed changes to the FSANZ Act and the impact on the review of novel foods, in particular, the proposed implementation of exclusivity for novel foods (Proposal P305).

The fourth SDAC meeting was held on 15 June 2007, also by teleconference. SDAC members discussed and supported the following:

- the revised definitions for non-traditional food and novel food;
- the proposed ACNF to replace the NFRG, including the terms of reference, membership and mode of operation for the ACNF;
- the formation of a working group to progress the development of the guidance tool;
- the decision to not pursue the monitoring of novel food permissions unless a public health and safety issue arises; and
- that the Ministerial Policy Guideline had been adequately addressed in the novel foods review.

The SDAC will remain active until such times as amendments to Standard 1.5.1 are gazetted and the Committee will then be disbanded.

## **14.2 Comments raised in submissions to the Initial and Draft Assessment Reports**

The Initial Assessment Report was advertised for public comment from 15 December 2004 to 2 March 2005. Fifteen submissions were received, 13 from Australia and two from New Zealand. The majority of submissions received were from the industry sector (8), followed by government (5), public health/nutrition (1), and individual (1). Six of the submissions received were from agencies/industry bodies or associations represented on the SDAC. The remaining 11 SDAC representatives did not submit.

The Draft Assessment Report was advertised for public comment from 5 October 2005 to 25 January 2006. Eighteen submissions were received, 14 from Australia and four from New Zealand. Twelve submissions were from the industry sector, with five submissions from government and one from a consumer organisation. Six of the submissions received were from agencies/industry bodies or associations represented on the SDAC.

A summary of submissions and list of submitters to both Reports is at Attachment 9. Key issues raised in response to the Draft Assessment Report are summarised below. The FSANZ response to these key issues can be found in sections 4 through to 9 of this Report. A detailed individual response to additional issues raised is included in Attachment 9.

### *14.2.1 Summary of submissions raised in response to the Draft Assessment Report*

The majority of submitters supported Option 3 (13). One submitter favoured removing the standard and requiring new foods to be treated under the remaining provisions of the Code, but considered Option 3 to be the best of the options put forward. Another submitter supported Option 3 but re-iterated their suggestion made in response to the Initial Assessment Report, of adopting a GRAS system. Two submitters favoured Option 2 but because they did not support the definitions as proposed at Draft Assessment.

The majority of submitters focussed their comments around the proposed definitions for non-traditional food and novel food. In relation to the proposed definition for non-traditional food, comments centred on the perceived ambiguity associated with terms used in the definition of non-traditional food such as ‘generally available’, ‘broad cross-section’ and ‘history of human consumption’. There was general support for (a), (b) and (c) of the proposed definition for novel food, however there were a number of comments on parts (d), (e) and (f) which relate to the process by which the food has been prepared, the source from which the food has been derived and any other relevant matters.

Submitters generally supported the provision of a guidance tool, suggesting that it would be a valuable tool for industry and consumers. A number of submitters provided specific comments for improving the proposed tool. There was general support for the inclusion of categories of novel foods in the novel foods guidelines, but that they should be non-exclusive since it is possible that some foods may fall outside the listed categories. Those submitters who commented on the operation of the NFRG were supportive of its function and some submitters made useful comments to assist in improving the visibility of its operation and outcomes. Two jurisdictions commented on the difficulties in enforcing views of the NFRG on the novel status of foods or food ingredients. Other comments related to data protection, review of novel food permissions and education.

### **14.3 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. Although the Standard currently covers a broad range of foods and captures a number of imported foods, amending the Code in relation to the regulation of novel foods is unlikely to have a significant effect on international trade.

The proposed amendments to Standard 1.5.1 are intended to clarify the definition for novel foods and it is not anticipated that the range of foods that are subject to the Standard will vary significantly from what is captured currently. Therefore, the proposed amendments to Standard 1.5.1 were not notified to the WTO under either the Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) agreements as the amendments are unlikely to significantly affect trade.

## **CONCLUSION**

### **15. Conclusion and Decision**

#### **Decision**

Retain an amended Standard 1.5.1 – Novel Foods, to provide regulation for novel foods. The main amendments to Standard 1.5.1 are revised definitions for ‘non-traditional food’ and ‘novel food’.

The process for determining whether a food is novel or not will be formalised by replacing the Novel Foods Reference Group with an Advisory Committee on Novel Foods. A guidance tool for determining whether a food is novel or not has been developed to assist the ACNF in making its recommendations.

## 15.1 Reasons for Decision

An amended Standard 1.5.1 will be retained to provide regulation for novel foods for the following reasons:

- There is general support from stakeholders for the purpose of the Standard, that novel foods undergo a risk-based assessment to ensure their safety prior to sale.
- To ensure consistency with the specific objectives of this Proposal, particularly, to ensure: (i) the safety for human consumption of novel foods; (ii) that regulations are complementary with inter-related standards in the Code; and (iii) that the Ministerial Policy Guidelines have been thoroughly considered within FSANZ's objectives under section 18 of the FSANZ Act.
- To have regard to the higher order and specific policy principles of the Ministerial Policy Guideline, specifically: (i) to ensure priority is given to the protection and improvement of public health and safety in relation to food matters; (ii) to draw on the best elements of international regulatory systems and be responsive to future trends and developments; and (iii) to ensure that public and industry confidence in the food system is maintained and to ensure consumers are not misled by novel foods or food ingredients which appear similar to existing foods but may differ in terms of nutrition or function.
- The purpose of the regulation for novel foods in Australia and New Zealand is consistent with the purpose of similar regulatory frameworks for novel foods in Canada and the EU.

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

- The concept of *absence of history of use in Australia and New Zealand* is important for inclusion in the regulation for novel foods as it assists in the process of determining whether a food is novel or not. A revised definition for 'non-traditional food' has been retained to include this element. The concept of *absence of history of safe use* is addressed in the definition for 'novel food'. Retaining two separate definitions for 'non-traditional food' and 'novel food' ensures simplicity and clarity in the definitions.
- It is accepted that there will be some subjectivity associated with the definitions for 'non-traditional food' and 'novel food', however, the revised definitions omit the terms that were seen as most ambiguous. The guidance tool for determining whether a food is novel or not provides assistance in interpreting the definitions.
- These revisions to the definitions take into regard the Ministerial Policy Guidelines, specifically, that the subjectivity and scope of the current definitions be considered and addressed as far as possible.

The revisions to the definitions also take into regard the specific objectives of this Proposal, particularly to ensure: the safety for human consumption of novel foods; and that the regulations are readily enforceable.

The process for determining whether a food is novel or not will be more formalised by replacing the NFRG with an Advisory Committee on Novel Foods set up under section 118 (1)<sup>4</sup> of the FSANZ Act. A guidance tool for determining whether a food is novel or not has been developed to assist the ACNF in making recommendations on whether a food should be considered a ‘non-traditional food’ in accordance with the definition in Standard 1.5.1 and whether an assessment of public health and safety considerations should be required. These measures have been agreed for the following reasons:

- The introduction of the proposed guidance tool will increase the level of rigour applied to the process of determining whether a food is novel or not.
- These proposed changes take into regard the Ministerial Policy Guidelines, specifically, that the user guide be reviewed to include any amendments to the novel food definition and to provide greater clarity about the process for determining if a food is novel or not.
- The measure addresses comments made by submitters to the Draft Assessment Report that: the NFRG function is supported; wider representation, particularly from jurisdictions, should be considered; and difficulties in enforcing the views of the NFRG remain.

## **16. Implementation and Review**

It is proposed that the draft variation to Standard 1.5.1 will have effect on the date of gazettal. FSANZ has reviewed the guidelines for novel foods. In addition, a number of supporting documents will be made available on the FSANZ website at the time of gazettal, including the guidance tool to be used by the ACNF for making recommendations in relation to potential novel foods and details about the ACNF. FSANZ will call for membership to the ACNF and commence operation of the Committee.

## **ATTACHMENTS**

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Ministerial Council Policy Guidelines
3. Advisory Committee on Novel Foods Terms of Reference, Membership and Mode of Operation
4. Guidance Tool for Determining Whether a Food Is Novel or Not
5. Addressing the Ministerial Policy Guidelines
6. International Regulations for Novel Foods
7. Impact Analysis
8. Standard Development Advisory Committee Membership and Terms of Reference
9. Summary of Submissions to the Initial and Draft Assessment Reports

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<sup>4</sup> The Board may establish such committees as it thinks fit to assist in carrying out its functions, and may abolish any such committee.



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

*Standards or variations to standards are considered to be legislative instruments for the purposes of the Legislative Instruments Act (2003) and are not subject to disallowance or sunseting.*

**To commence: on gazettal**

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

[1.1] *omitting the second paragraph of the Purpose*

[1.2] *omitting clause 1, substituting –*

**1. Definitions**

In this Standard –

**non-traditional food** means –

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

**novel food** means a non-traditional food and the food requires an assessment of the public health and safety considerations having regard to -

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

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

**Editorial Note:**

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

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

### 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:

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.

- a) 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.
  - b) 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.
  - c) 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.

**Advisory Committee on Novel Foods Terms of Reference, Membership and Mode of Operation**

**Terms of Reference**

1. Consider enquiries in relation to potential novel foods (in conjunction with the required data), including previously considered enquiries in relation to potential novel foods where new data has been submitted.
2. Make recommendations to the General Manager – Food Standards (Canberra) in response to enquiries in relation to potential novel foods. The recommendations should contain the following advice:
  - (a) Whether the food that is the subject of the enquiry should be considered a ‘non-traditional food’ in accordance with the definition in Standard 1.5.1.
  - (b) Whether an assessment of public health and safety considerations should be required for the food that is the subject of the enquiry to confirm that there is a reasonable certainty that no harm will result from the intended use of the food and to decide whether any risk management strategies are warranted to ensure the safe use of the food. In preparing this recommendation, the ACNF would in effect, be performing a preliminary hazard identification step in the context of the risk analysis framework. If the recommendation is made that an assessment of public health and safety considerations is required, this equates to a view that the food meets the definition of ‘novel food’ in Standard 1.5.1 and therefore an application would be required to amend the Code, before the food could be sold in Australia or New Zealand.
  - (c) Whether the enquirer should make an application to Food Standards Australia New Zealand (FSANZ) to amend the Code in order for an assessment of public health and safety considerations to be undertaken.

Where consensus is not reached, the majority view will be put forward in the recommendation to the General Manager – Food Standards (Canberra) and alternative views will be noted.

3. Use the guidance tool for determining whether a food is novel or not in forming recommendations.
4. Agree to provide a draft letter in response to the enquiry, to the General Manager – Food Standards (Canberra) to accompany the recommendations.
5. Agree to minutes of previous meetings.
6. Agree to the placement of views in relation to whether a food is ‘non-traditional’ and whether an assessment of public health and safety considerations is required, and the justification for this view, on the FSANZ website.

For the first meeting the ACNF will:

1. Consider and agree to the draft Terms of Reference and the proposed Mode of Operation, with any required amendments.
2. Consider and agree to the proposed format of the meetings, with any required changes.
3. Consider and agree to the proposed questionnaire to be provided to enquirers seeking specific information.
4. Consider and agree to the proposed information to be required of enquirers, with any proposed amendments.

If a question arises as to whether a product may be more appropriately regulated as a therapeutic good rather than a food, the issue is to be referred to the Foods-Therapeutic Goods Interface Group. The consideration as to whether a substance is a food within the meaning of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) (as opposed to a therapeutic good), is a threshold question that will be considered prior to the ACNF using the guidance tool to form a view whether a food is novel or not.

## Membership

The membership of the Committee and the role of each member on the Committee are as follows:

### FSANZ membership

<b>Member</b>	<b>Role</b>
Chief Scientist (or their delegate)	Chair Risk Management Advice (ToR 1, 2(i), (iii), 3-7)
Senior Risk Manager	Secretariat Risk Management Advice (ToR 1, 2(i), (iii), 3-7)
Principal Toxicologist (or their delegate)	Scientific advice on safety (ToR 1, 2(ii), 3-7)
Senior Toxicologist/Senior Food Scientist	Scientific advice on safety (ToR 1, 2(ii), 3-7)
Social scientist	To assist with the interpretation of 'non-traditional food' in accordance with the definition and the guidance tool (ToR 1, 2 (i), 3-7)

Advice will be sought from Office of Legal Counsel, Principal Food Technologist, Principal Nutritionist, Principal Microbiologist, Standards Management Officer or other relevant expertise on an as-needs basis, but they will not be appointed to the Committee. These FSANZ staff members may be requested to attend particular meetings of the ACNF and provide specific input when requested, which will then form part of the recommendation to the General Manager (Food Standards) Canberra.

### Representation from other areas of government

A representative is to be sought from three Australian State or Territory jurisdictions. More jurisdictions can nominate if they wish to. Representation from jurisdictions will be called for every two years as a starting point.

In addition, one representative will be sought from each of the following:

1. The Australian Quarantine and Inspection Service; and

## 2. The New Zealand Food Safety Authority

The role of each of these representatives is to:

1. Assist with the recommendation on whether the food, the subject of the inquiry should be considered a 'non-traditional food' in accordance with the definition in Standard 1.5.1 (ToR 2(i)), as well as addressing ToR 1, 3-7).
2. Raise issues related to enforcement for discussion.
3. To bring issues to the Committee related to potential novel foods.

### **Mode of Operation**

#### Meetings

Meetings will be held by teleconference and will last approximately one and a half hours. Frequency of meetings will be once per month (or two months) on the same day at a regular time, or as needed.

Meetings will follow an agreed standard format, to be agreed at the first meeting of the proposed ACNF. The format is likely to include adoption of minutes from the previous meeting, progress of matters already considered (e.g. at the previous meeting), new enquiries for discussion (typically limited to 4 new enquiries). Only new enquiries for which information has been collated and circulated will be considered at meetings to allow members to read the information beforehand.

It is expected that the majority of enquiries would be addressed within 2 months of receipt.

Meetings will be chaired by FSANZ.

#### Secretariat

FSANZ will provide the administrative support for the proposed ACNF. A mailbox will be set up for new novel food enquiries and a template will be devised for enquirers to complete when submitting a novel food enquiry. The FSANZ secretariat for the proposed ACNF will collate information submitted on new novel foods enquiries, liaise with the enquirer to obtain any further information required and prepare agenda papers for circulation ahead of the meetings. FSANZ will be responsible for outputs from the proposed ACNF. Novel food enquiries that have already been considered and a view formed will be addressed by the Advice Line.

#### Agenda Papers

The agenda and agenda papers will be prepared by FSANZ based on the information provided in conjunction with a new novel food enquiry. Any member may suggest agenda items, but the item must be accompanied by the required information as specified in the questionnaire that has been developed for potential novel food enquirers to complete. A standard format for the agenda papers will be developed and this will be discussed at the first meeting of the ACNF. Agenda papers will be circulated to members one week ahead of the regular meeting time.

### Outputs from the proposed ACNF

The ACNF will make a recommendation to the General Manager – Food Standards (Canberra) Branch in response to each enquiry in accordance with the Terms of Reference. The ACNF should strive for consensus, however when consensus is not reached, the recommendation will be based on the majority view. Alternative views will be noted in the recommendation of the ACNF. The guidance tool for determining whether a food is novel or not will be used as the basis for forming recommendations.

A draft letter of response to the enquirer will be developed by FSANZ in accordance with the recommendation and will accompany the recommendation provided to the General Manager – Food Standards (Canberra) for signature.

Minutes will be prepared by FSANZ based on the recommendations on new novel food enquiries, and circulated in sufficient time ahead of the next meeting. The outcome of the ACNF recommendations to the General Manager – Food Standards (Canberra) will be published on the FSANZ website. The enquirer will be notified of an outcome before the view is published on the FSANZ website.



## Guidance Tool for Determining Whether a Food is Novel or Not

This guidance tool has four elements:

1. **Introduction.** The introduction provided general information on the Novel Foods Standard, the Advisory Committee on Novel Foods and the use of the guidance tool.
2. **Information to be provided by enquirer.** This part refers the reader to the information that needs to be provided by the enquirer and how this information is to be considered by the Advisory Committee on Novel Foods when using the guidance tool.
3. **Guidance tool Part 1.** Part 1 of the guidance tool provides assistance in determining whether a food is non-traditional or not. It is to be used by the Advisory Committee on Novel Foods when making a recommendation as to whether a food is non-traditional or not. This part highlights the information to be provided by the enquirer that should be taken into consideration when making this recommendation as to whether a food is non-traditional or not.
4. **Guidance tool Part 2.** Part 2 of the guidance tool is only used if a recommendation is firstly made that the food is non-traditional. This part provides assistance for the Advisory Committee on Novel Foods in making a recommendation as to whether a non-traditional food should also be subject to an assessment of public health and safety considerations. This part highlights the information to be provided by the enquirer that should be taken into consideration when making a recommendation as to whether an assessment of public health and safety considerations is required.

### INTRODUCTION

The purpose of regulating novel foods is to apply a risk-based approach to ensuring the safety of new foods coming onto the market. Standard 1.5.1 – Novel Foods of the *Australia New Zealand Food Standards Code* (the Code) provides definitions for ‘non-traditional food’ and ‘novel food’ and prohibits the sale of novel foods in Australia and New Zealand unless an express permission is given in the Table to clause 2 of that Standard.

The definitions for ‘non-traditional food’ and ‘novel food’ have been revised since the introduction of the Novel Foods Standard. This guidance tool is intended to assist with the interpretation of the revised definitions and their application to determining whether a food is novel or not. Separate definitions for ‘non-traditional food’ and ‘novel food’ within Standard 1.5.1 have been retained to keep the operation of the two-step process for determining whether a food is novel or not. This two-step process makes it clear that not all non-traditional foods raise safety concerns and therefore, not all non-traditional foods should be subject to the pre-market assessment requirements of the Novel Foods Standard.

This guidance tool is used by the Advisory Committee on Novel Foods to assist in forming recommendations, as specified in the Terms of Reference, to the General Manager – Food Standards (Canberra) on:

1. whether a food should be considered a ‘non-traditional food’ in accordance with the definition in Standard 1.5.1; and

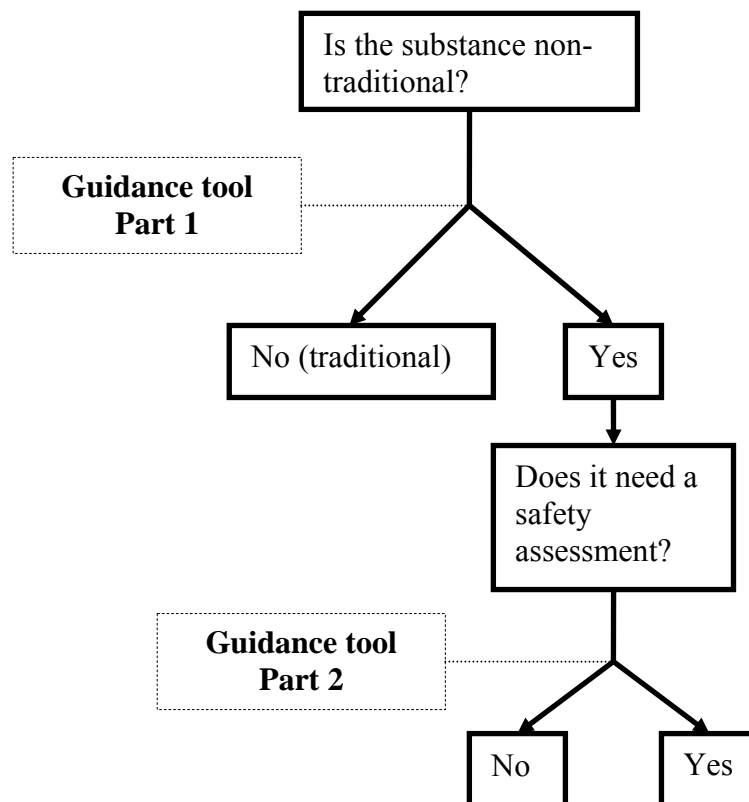
- whether an assessment of public health and safety considerations should be required for the non-traditional food to confirm there is reasonable certainty that no harm will result from the intended use of the food and to determine whether any risk management strategies are warranted to ensure the safe use of the food.

It is not mandatory for potential applicants to seek the view of the Advisory Committee on Novel Foods. A potential applicant may proceed directly to submitting an application seeking to amend Standard 1.5.1 of the Code to permit a particular food that they believe meets the definition of novel food in Standard 1.5.1. This guidance tool should be read in conjunction with the Terms of Reference [insert hyperlink] for the Advisory Committee on Novel Foods.

A number of factors are considered in determining whether a food is novel or not, including consistency with previous determinations for similar foods or food ingredients. However, this tool may not be exhaustive of all factors that could be taken into account in determining whether a food is non-traditional or not and whether an assessment of public health and safety considerations should be required for a non-traditional food. Accordingly, judgement will be needed in the application of the guidance tool.

The guidance tool is divided into:

**Guidance tool Part 1** – Determining whether a food is non-traditional or not; and  
**Guidance tool Part 2** – Determining whether an assessment of public health and safety considerations is required for a non-traditional food.



The recommendation made by the Advisory Committee on Novel Foods in relation to whether an assessment of the public health and safety considerations is required does not constitute a safety assessment in itself. If an assessment of public health and safety considerations is required, this information will be provided by the General Manager – Food Standards (Canberra) to the enquirer, who will then determine whether to progress to make an application to FSANZ to amend Standard 1.5.1. The actual assessment of public health and safety considerations will be conducted as part of the assessment of the application to amend the Novel Foods Standard.

If a question arises as to whether a product may be more appropriately regulated as a therapeutic good rather than a food, the issue will be referred to the Foods-Therapeutic Goods Interface Group. The consideration as to whether a substance is a food within the meaning of the FSANZ Act (as opposed to a therapeutic good), is a threshold question that will be considered prior to the Advisory Committee on Novel Foods using the guidance tool to form a view whether a food is novel or not. This is specified in the Terms of Reference for the Committee.

In the purpose clause of Standard 1.5.1 – Novel Foods, reference is made to the FSANZ’s safety assessment guidelines. FSANZ’s safety assessment guideline is available on the FSANZ website and is referred to as *Guidelines to assist in applying to amend the Australia New Zealand Food Standards Code – Novel Foods*<sup>5</sup>.

## **INFORMATION TO BE PROVIDED BY THE ENQUIRER**

A questionnaire has been devised for enquirers seeking advice on whether a food is considered novel or not (Attachment 1). The questionnaire will need to be completed by the enquirer before the Advisory Committee on Novel Foods considers the enquiry. This includes questions about the identity of the food and the proposed use of the food, questions relevant to the consideration of whether a food is non-traditional or not and questions relevant to public health and safety considerations. The relevant questions from the questionnaire are listed in parts 1 and 2 respectively of this guidance tool.

If the data supplied by the enquirer is inadequate or insufficient, the Advisory Committee on Novel Foods would not be in a position to use the guidance tool to consider the matter further until such information is obtained. The Committee could either request that the enquirer provide further clarification, or elect to supplement the data supplied by the enquirer in order to address outstanding questions.

Other relevant documents include:

- The *Application Handbook*, that sets out the required information to be provided in an application to amend the Novel Foods Standard [hyperlink to be inserted]. The required information is set out in relation to the potential categories of novel foods.
- Guidelines for the safety assessment of novel foods  
[<http://www.foodstandards.gov.au/standardsdevelopment/informationforapplic559.cfm>  
- to be revised in 2007].

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<sup>5</sup> <http://www.foodstandards.gov.au/standardsdevelopment/informationforapplic559.cfm> sourced on 13 August 2007.

## PART 1 – DETERMINING WHETHER A FOOD IS NON-TRADITIONAL OR NOT

The definition of non-traditional food in Standard 1.5.1 is as follows:

**non-traditional food** means –

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

Some examples of non-traditional foods that have already been considered which relate to (a), (b), and (c) are:

- (a) ackee fruit; yoghurt produced using high pressure processing (a food produced by a process not previously applied to food).
- (b) phytosterol esters; conjugated linoleic acid.
- (c) docosahexaenoic acid (DHA) derived from marine micro-algae; pine bark extract.

Key areas influencing the interpretation of the term ‘history of human consumption’ are: length of use; extent of use; quantity (level of intake) of use; and purpose or context of use.

There are a number of questions from the questionnaire that will be used to make a recommendation on whether a food is non-traditional or not. This includes all questions in **section 4** of the questionnaire.

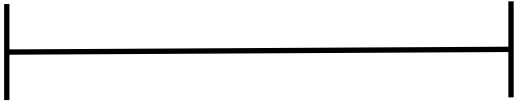
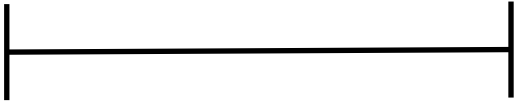
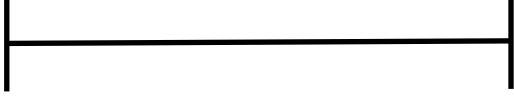
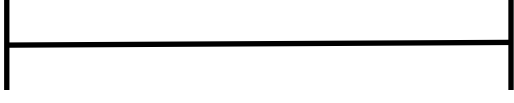
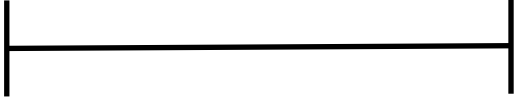
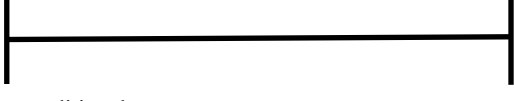
1. **Length of use.** This information could be in the form of number of years of use, a reference to previous times when it has been used or a number of generations of use (**questions 4.1 and 4.2** of the questionnaire). As a general guide, 2-3 generations would be considered to be a long period of use, whereas 5 years or less would be considered a short period of use, while 10-20 years of use may be sufficient to establish history of use, depending on the three other components taken into account.
2. **Extent of use.** Relevant information includes whether the food is recognised worldwide, regionally or in isolated populations (**question 4.3** of the questionnaire) and whether the food has been used by the general population or by a specific sub-population (**question 4.4** of the questionnaire). As a general guide, use by the general population in either Australia or New Zealand would be considered extensive use, whereas use by one sub-population group would be considered limited use. Use by a number of sub-populations in different regional areas, or use by a number of sub-populations in combination with some use by the general population may be sufficient to establish history of use, depending on the three other components taken into account.

3. **Quantity (level of intake) of use.** Relevant information includes the amount of the food consumed, the frequency of consumption in both the general population and sub-population groups and in the case of a food ingredient, the amount of the ingredient used in the range of final foods in which it is typically used compared with the enquirers intended use (**questions 4.5, 4.6, 4.10 and 4.11** of the questionnaire). As a general guide, use of a food ingredient in a range of different foods at levels consistent with food macro-components would constitute a high level of intake, as would a whole food consumed on a regular basis. The use of food ingredients at low levels in a relatively small range of foods would be considered a low level of intake.
4. **Purpose or context of use.** Relevant information includes whether the food has been used as a regular part of the diet or only at certain times (e.g. for ceremonial purposes or during famine) and whether the substance has been used for medicinal purposes (**questions 4.7 – 4.9** of the questionnaire). As a general guide, food that has been consumed as a regular part of the diet would be considered to be of high relevance to food use, whereas an herb used for medicinal purposes would be considered of low relevance to food use. A food ingredient that is extracted from a common food, but added at higher levels to a range of foods that may or may not naturally contain the component would not normally be sufficient to establish a relevant history of use as food (because the context of use is different).

**Questions 4.12, 4.13 and 4.14** of the questionnaire relate to the process by which the food is produced and the source from which the food is derived. If the answer to either question 4.13 or 4.14 is yes, then length of use would generally be considered to be short, extent of use would generally be considered to be low and quantity of use (level of intake) would generally be considered to be low. Purpose or context of use would need to be considered based on the other information available for any particular enquiry.

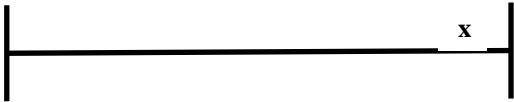
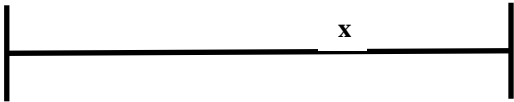
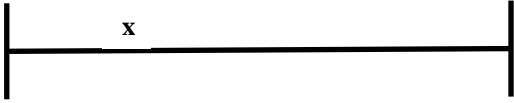
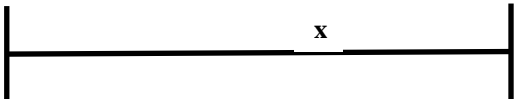
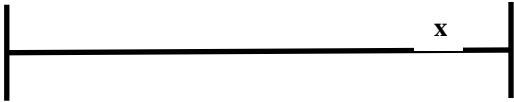

5. **Confidence in the information provided.** A fifth consideration is our confidence in the information available to establish history of human consumption and, subsequently to make recommendations on whether a food should be considered non-traditional or not. A record of use could take various forms such as verbal accounts or interviews with traditional consumers, though written reference with information drawn from reliable sources would be the most convincing means of demonstrating use. If the Advisory Committee on Novel Foods has low confidence in the data supplied from the enquirer, the Committee can elect to supplement the data.
6. **Overall consideration.** These first four components of ‘history of human consumption’ are considered to be of equal importance. However, it is possible that a deficiency of a particular food in one of these components could be balanced by another component. For example, a particular food may have been consumed for a relatively short period of time (e.g. 6 years) but has been consumed extensively (e.g. by the general population) and at relatively high levels of intake (e.g. in a range of different foods). In this case, a reasonable argument could be made that this food has a history of human consumption. This is merely an example of how an overall consideration may be made by the Committee. The Committee makes recommendations as to whether a food is non-traditional or not on a case by case basis, using the best available information to inform a particular recommendation. Questions in relation to these four components should be addressed based on the information available on their use in Australia and New Zealand. So while a particular fruit may have been consumed extensively in another part of the world, the extent of use in Australia and New Zealand may be very limited, if any.

**TEMPLATE for Part 1 of Guidance Tool: To be used for making a recommendation as to whether a food should be considered non-traditional or not**

History of human consumption	Notes	Rating
1. Length of use		 <p data-bbox="778 600 858 651">5 yrs or less</p> <p data-bbox="1246 600 1362 674">2-3 generations or more</p>
2. Extent of use		 <p data-bbox="778 880 975 931">One sub-population group</p> <p data-bbox="1246 880 1362 931">General population</p>
3. Quantity of use (level of intake)		 <p data-bbox="778 1126 959 1178">Low levels / small range of foods</p> <p data-bbox="1214 1126 1394 1178">High levels / wide range of foods</p>
4. Purpose or context of use		 <p data-bbox="778 1395 975 1469">Medicinal use / extracted from food at high levels</p> <p data-bbox="1241 1395 1362 1447">Regular part of diet</p>
5. Confidence in information provided		 <p data-bbox="778 1664 906 1715">Low level of confidence</p> <p data-bbox="1241 1664 1369 1715">High level of confidence</p>
6. Overall consideration		 <p data-bbox="778 1921 927 1951">Non-traditional</p> <p data-bbox="1246 1944 1362 1973">Traditional</p>

**Recommendation**

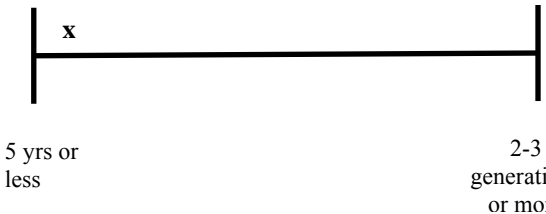
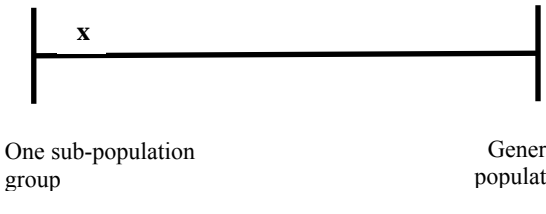
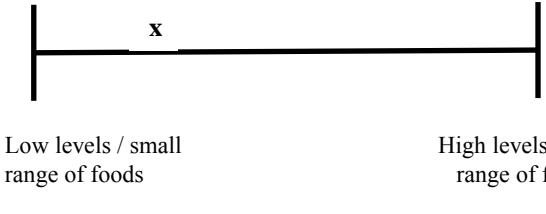
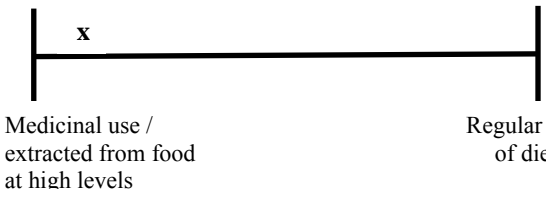
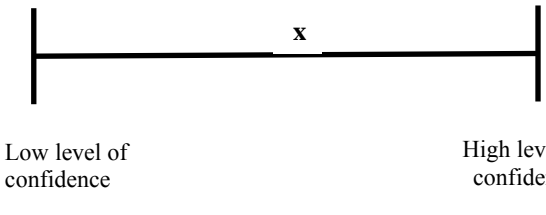
**Example: Plant ingredient – *Hibiscus sabdariffa* (flower)**

History of human consumption	Notes	Rating
1. Length of use	Appears to be a long history of use in Australia.	 <p data-bbox="778 562 858 613">5 yrs or less</p> <p data-bbox="1246 562 1362 636">2-3 generations or more</p>
2. Extent of use	Appears to have been available to the general population, but particularly in local market type situation. More recent availability in mainstream supermarkets.	 <p data-bbox="778 842 975 896">One sub-population group</p> <p data-bbox="1246 842 1362 896">General population</p>
3. Quantity of use (level of intake)	Used as an ingredient in jams and jellies and in champagne for decoration and flavour.	 <p data-bbox="778 1115 959 1169">Low levels / small range of foods</p> <p data-bbox="1214 1115 1394 1169">High levels / wide range of foods</p>
4. Purpose or context of use	Used as an ingredient in jams and jellies and in champagne for decoration or flavour. Use appears to be predominately as a food.	 <p data-bbox="778 1346 975 1422">Medicinal use / extracted from food at high levels</p> <p data-bbox="1241 1346 1362 1400">Regular part of diet</p>
5. Confidence in information provided	Information provided was supplemented by knowledge of committee considering this food.	 <p data-bbox="778 1704 906 1758">Low level of confidence</p> <p data-bbox="1241 1704 1369 1758">High level of confidence</p>
6. Overall consideration	There is a history of consumption in Australia.	 <p data-bbox="778 1989 932 2016">Non-traditional</p> <p data-bbox="1246 1989 1362 2016">Traditional</p>

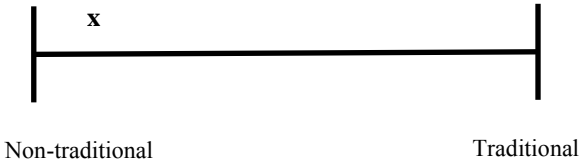
## Recommendation

There is a long history of use of *Hibiscus sabdariffa* in Australia as a food. While it has been used in a narrow range of foods, it has been used by the general population and has more recently become available in mainstream supermarkets. On balance, there is sufficient evidence to demonstrate a history of use as a food in Australia and it is therefore not considered to fall within the scope of the definition for 'non-traditional food'. Further consideration under Part 2 of this guidance tool is not necessary.

### Example: Plant ingredient – *Hoodia gordonii*

History of human consumption	Notes	Rating
1. Length of use	Appears to be no history of use as a food in Australia or New Zealand.	
2. Extent of use	Not used as a food in Australia and New Zealand.	
3. Quantity of use (level of intake)	Use in Africa is apparently to chew the raw plant (cactus) when required (see purpose below).	
4. Purpose or context of use	Appears to have traditional use in African tribe as an appetite and thirst suppressant while on long treks. Also used in supplement type products overseas for weight management.	
5. Confidence in information provided	Information provided included interviews of African tribe members and use of hoodia in supplement type products overseas.	

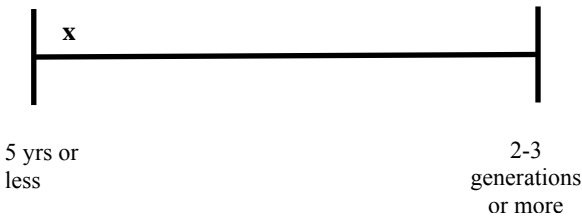
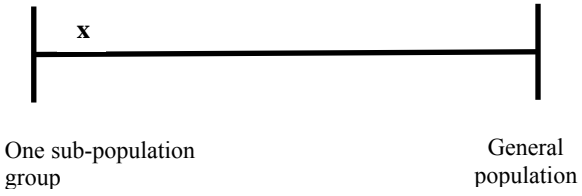
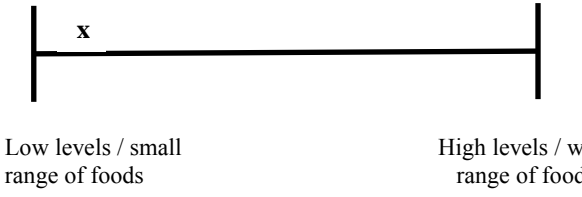
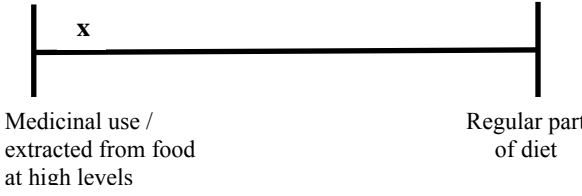


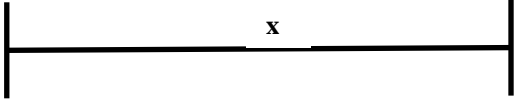
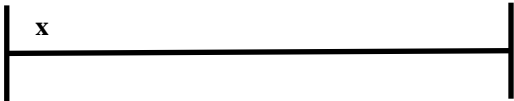
<b>6. Overall consideration</b>	Not a history of consumption in Australia and New Zealand.	
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**Recommendation**

There is no evidence of a history of use of *Hoodia gordonii* in Australia or New Zealand. While there is a long history of use in Africa, the purpose of use is appetite and thirst suppression. On balance, there is sufficient evidence to consider that *Hoodia gordonii* falls within the scope of the definition for ‘non-traditional food’ (part (a)). Further consideration as to whether an assessment of public health and safety considerations is required under part 2 of this guidance tool.

**Example: Source of food ingredient –DHA sourced from *Schizochytrium sp.* (micro-algae)**

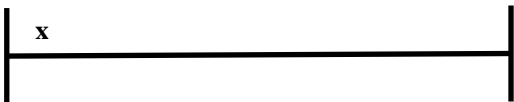
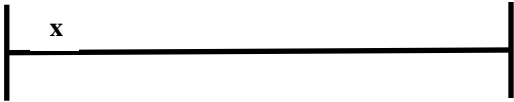
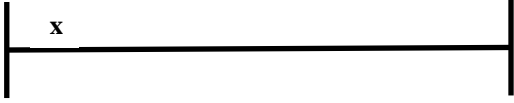
History of human consumption	Notes	Rating
<b>1. Length of use</b>	There does not appear to be a history of consumption of <i>Schizochytrium sp.</i> or products derived from it in Australia or New Zealand.	
<b>2. Extent of use</b>	Does not appear to be use by any population group in Australia or New Zealand.	
<b>3. Quantity of use (level of intake)</b>	While there is a reasonably high level of intake of DHA in the diet from other sources, this is not from <i>Schizochytrium sp.</i>	
<b>4. Purpose or context of use</b>	While DHA is to be used in the food context, the marine micro-algae is not used as food.	

<b>5. Confidence in information provided</b>		 <p data-bbox="778 353 1369 409">Low level of confidence <span style="float: right;">High level of confidence</span></p>
<b>6. Overall consideration</b>	Not a history of human consumption in Australia and New Zealand.	 <p data-bbox="778 633 1369 667">Non-traditional <span style="float: right;">Traditional</span></p>

### Recommendation

While there is a history of consumption of DHA from various food sources, there is no evidence to support a history of human consumption of marine micro-algae (*Schizochytrium* sp.), or DHA derived thereof. Therefore, DHA derived from *Schizochytrium* sp. is considered to fall within the scope of the definition for ‘non-traditional food’ because of the source of the substance (part (c)). Further consideration as to whether an assessment of public health and safety considerations is required under part 2 of this guidance tool.

### Example: Substance derived from food – Betaine (extracted from sugar beet)

History of human consumption	Notes	Rating
<b>1. Length of use</b>	Some consumption of natural levels in sugar beet. However, no indication of use when extracted and added back to other foods at higher levels than naturally present.	 <p data-bbox="778 1395 1369 1473">5 yrs or less <span style="float: right;">2-3 generations or more</span></p>
<b>2. Extent of use</b>	Does not appear to have been consumed by any population group in Australia or New Zealand in the context presented.	 <p data-bbox="778 1648 1369 1704">One sub-population group <span style="float: right;">General population</span></p>
<b>3. Quantity of use (level of intake)</b>	Natural levels are quite low in foods - less than proposed levels of addition to foods. Proposed to be extracted from sugar beet.	 <p data-bbox="778 1901 1369 1957">Low levels / small range of foods <span style="float: right;">High levels / wide range of foods</span></p>

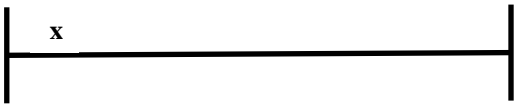
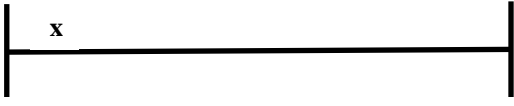
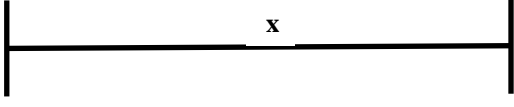

History of human consumption	Notes	Rating
<b>4. Purpose or context of use</b>	Extracted from sugar beet and added to other foods at higher levels.	
<b>5. Confidence in information provided</b>	Information provided was satisfactory and was supplemented by investigation into European Union consideration of same substance.	
<b>6. Overall consideration</b>	Not a history of human consumption in Australia and New Zealand in the context presented.	

## Recommendation

There is some very limited consumption of betaine from food via natural levels present in sugar beet. However, there is no history of consumption when the substance is extracted from sugar beet and added to other foods at levels significantly higher than that naturally present. Therefore, betaine is considered to fall within the scope of the definition of ‘non-traditional food’ (part (b)). Further consideration as to whether an assessment of public health and safety considerations is required under part 2 of this guidance tool.

### Example: Whole food – Ackee fruit

History of human consumption	Notes	Rating
<b>1. Length of use</b>	There does not appear to be a history of consumption of ackee fruit in Australia or New Zealand. There is a history of use in Jamaica.	
<b>2. Extent of use</b>	Little or no use in Australia and New Zealand. Generally available in Jamaica.	

<b>3. Quantity of use (level of intake)</b>	Appears to be used in some traditional dishes in Jamaica. Little or no use in Australia or New Zealand.	 <p>Low levels / small range of foods</p> <p>High levels / wide range of foods</p>
<b>4. Purpose or context of use</b>	Not used in Australia or New Zealand.	 <p>Medicinal use / extracted from food at high levels</p> <p>Regular part of diet</p>
<b>5. Confidence in information provided</b>	Information provided seemed reputable, though not extensive.	 <p>Low level of confidence</p> <p>High level of confidence</p>
<b>6. Overall consideration</b>	Not a history of human consumption in Australia and New Zealand.	 <p>Non-traditional</p> <p>Traditional</p>

### Recommendation

There is documented consumption of ackee fruit being consumed in Jamaica. However, there does not appear to be any history of use in Australia or New Zealand. Therefore, ackee fruit is considered to fall within the scope of the definition for ‘non-traditional food’ (part (a)). Further consideration as to whether an assessment of public health and safety considerations is required under part 2 of this guidance tool.

## **PART 2 – DETERMINING WHETHER AN ASSESSMENT OF PUBLIC HEALTH AND SAFETY CONSIDERATIONS IS REQUIRED FOR A NON-TRADITIONAL FOOD**

This part of the guidance tool should only be used for a particular food if a recommendation is firstly made that the food is non-traditional.

The definition for novel food in Standard 1.5.1 is as follows:

**novel food** means a non-traditional food and the food requires an assessment of the public health and safety considerations having regard to -

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

For those foods that are considered non-traditional, further consideration will need to be given to whether those foods will also require an assessment of the public health and safety considerations.

There are a number of questions from the questionnaire that will be used to inform a recommendation on whether an assessment of public health and safety considerations should be required for a non-traditional food. This includes all questions in **section 5** of the questionnaire.

The template for part 2 of the guidance tool, for informing a recommendation as to whether an assessment of public health and safety considerations is required, is a simple table with explanatory notes around each of the matters to have regard to in the definition (a) – (f), and space provided for justifications to be included. The explanatory notes are intended for use as a guide and are not necessarily exhaustive of all potential relevant information.

If the data supplied by the enquirer is inadequate or insufficient, the Advisory Committee on Novel Foods would not be in a position to use the guidance tool to consider the matter further until such information is obtained. The Committee could either request that the enquirer provide further clarification, or elect to supplement the data supplied by the enquirer in order to address outstanding questions. In particular, in relation to the questions about safety concerns, the Committee may elect to supplement the data provided by the enquirer.

**TEMPLATE for Part 2 of Guidance Tool: To be used for making a recommendation as to whether an assessment of public health and safety considerations is required for a non-traditional food**

Matters to be considered	Explanatory notes	Evaluation
<b>(a) The potential for adverse effects in humans</b>	Relevant information could include: reports of adverse reactions from food use in other countries; demonstration of safe use in other countries; reports of adverse reactions from medicinal use <sup>6</sup> ; animal toxicity studies; observations in humans participating in clinical trials; or the presence of a particular component known to cause adverse reaction or illness.	
<b>(b) The composition or structure of the food</b>	Relevant information could include: the presence of a particular component known to cause adverse reaction or illness (e.g. a natural toxicant, contaminant or allergen); analyses of the amount of any such substances known to cause adverse reaction or illness; structural similarity of any of the components to substances for which there are known safety concerns; special preparation required to enable safe use; or whether the structure of the substance is completely new such that its safety for human consumption has not been established.	
<b>(c) The process by which the food has been prepared</b>	If the structure or composition of the food or food ingredient is altered because of a process by which the food has been prepared, what is the nature of any alterations? Do the alterations give rise to any safety concerns (relevant information would include that listed in the explanatory notes for (a) and (b))?	
<b>(d) The source from which it is derived</b>	If the food is considered non-traditional because of the source from which it is derived, does the source itself give rise to any particular safety concerns? Relevant information could include: whether the source is known to contain undesirable substances; whether the source is uncharacterised such that its safety for human consumption has not been established; relevant information is listed in the explanatory notes for (a) and (b).	
<b>(e) Patterns and levels of consumption of the food</b>	Does an altered pattern or level of consumption of the food give rise to safety concerns? Is the expected level of intake likely to exceed levels at which there are known adverse effects? Is the level of intake likely to exceed any medicinal use levels? Is the level of use likely to exceed use in a country that it is used traditionally?	
<b>(f) Any other relevant matters</b>	Any other relevant matters are guided by, but not limited to, considerations in (a) to (e). This enables a recommendation to be based on specific issues that although not listed would be relevant to public health and safety considerations related to the food.	

<sup>6</sup> An opinion on whether a product should be regulated as a food or a therapeutic good will have been provided (by the foods-therapeutic goods interface group) before any consideration is made by the Advisory Committee on Novel Foods. Reference to information about adverse reaction reports has been included in (a) because it is recognised that some ingredients could be used in both foods and complementary medicines (regulated as therapeutic goods). Any adverse reaction report on such an ingredient when used in a therapeutic good would raise safety concerns about its use in food and would be a trigger for requiring a public health and safety assessment for that ingredient when proposed for use in a food.

## Recommendation

### Example: Plant ingredient – *Hoodia gordonii*

Matters to be considered	Explanatory notes	Evaluation
<b>(a) The potential for adverse effects in humans</b>	Relevant information could include: reports of adverse reactions from food use in other countries; reports of adverse reactions from medicinal use; animal toxicity studies; observations in humans participating in clinical trials; or the presence of a particular component known to cause adverse reaction or illness.	The purpose of consumption in Africa is as an appetite and thirst suppressant. Reductions in food intake and bodyweight are considered an adverse effect for many of the general population and some population sub-groups (e.g. children).
<b>(b) The composition or structure of the food</b>	Relevant information could include: the presence of a particular component known to cause adverse reaction or illness (e.g. a natural toxicant, contaminant or allergen); analyses of the amount of any such substances known to cause adverse reaction or illness; structural similarity of any of the components to substances for which there are known safety concerns; special preparation required to enable safe use; or whether the structure of the substance is completely new such that its safety for human consumption has not been established.	
<b>(c) The process by which the food has been prepared</b>	If the structure or composition of the food or food ingredient is altered because of a process by which the food has been prepared, what is the nature of any alterations? Do the alterations give rise to any safety concerns (relevant information would include that listed in the explanatory notes for (a) and (b))?	
<b>(d) The source from which it is derived</b>	If the food is considered non-traditional because of the source from which it is derived, does the source itself give rise to any particular safety concerns? Relevant information could include: whether the source is known to contain undesirable substances; whether the source is uncharacterised such that its safety for human consumption has not been established; relevant information is listed in the explanatory notes for (a) and (b).	
<b>(e) Patterns and levels of consumption of the food</b>	Does an altered pattern or level of consumption of the food give rise to safety concerns? Is the expected level of intake likely to exceed levels at which there are known adverse effects? Is the level of intake likely to exceed any medicinal use levels? Is the level of use likely to exceed use in a country that it is used traditionally?	Hoodia gordonii is proposed for use as dried powder whereas any tradition of use, albeit as an appetite suppressant, is related to the consumption of the plant itself. This altered pattern and level of consumption may result in further reductions in food intake and bodyweight, considered an adverse effect.
<b>(f) Any other relevant matters</b>	Any other relevant matters are guided by, but not limited to, considerations in (a) to (e). This enables a recommendation to be based on specific issues that although not listed would be relevant to public health and safety considerations related to the food.	

**Recommendation** – an assessment of public health and safety considerations should be required in relation to (a) and (d).

**Example: Source of food ingredient – DHA from *Schizochytrium* sp. (micro-algae)**

Matters to be considered	Explanatory notes	Evaluation
<b>(a) The potential for adverse effects in humans</b>	Relevant information could include: reports of adverse reactions from food use in other countries; reports of adverse reactions from medicinal use; animal toxicity studies; observations in humans participating in clinical trials; or the presence of a particular component known to cause adverse reaction or illness.	
<b>(b) The composition or structure of the food</b>	Relevant information could include: the presence of a particular component known to cause adverse reaction or illness (e.g. a natural toxicant, contaminant or allergen); analyses of the amount of any such substances known to cause adverse reaction or illness; structural similarity of any of the components to substances for which there are known safety concerns; special preparation required to enable safe use; or whether the structure of the substance is completely new such that its safety for human consumption has not been established.	
<b>(c) The process by which the food has been prepared</b>	If the structure or composition of the food or food ingredient is altered because of a process by which the food has been prepared, what is the nature of any alterations? Do the alterations give rise to any safety concerns (relevant information would include that listed in the explanatory notes for (a) and (b))?	
<b>(d) The source from which it is derived</b>	If the food is considered non-traditional because of the source from which it is derived, does the source itself give rise to any particular safety concerns? Relevant information could include: whether the source is known to contain undesirable substances; whether the source is uncharacterised such that its safety for human consumption has not been established; relevant information is listed in the explanatory notes for (a) and (b).	The source itself, <i>Schizochytrium</i> sp. (marine micro algae) gives rise to potential safety concerns due to the potential for undesirable substances such as natural toxins and pathogens.
<b>(e) Patterns and levels of consumption of the food</b>	Does an altered pattern or level of consumption of the food give rise to safety concerns? Is the expected level of intake likely to exceed levels at which there are known adverse effects? Is the level of intake likely to exceed any medicinal use levels? Is the level of use likely to exceed use in a country that it is used traditionally?	
<b>(f) Any other relevant matters</b>	Any other relevant matters are guided by, but not limited to, considerations in (a) to (e). This enables a recommendation to be based on specific issues that although not listed would be relevant to public health and safety	



Matters to be considered	Explanatory notes	Evaluation
	considerations related to the food.	

**Recommendation** – an assessment of public health and safety considerations should be required due to (d).

**Example: Substance derived from food – Betaine (extracted from sugar beet)**

Matters to be considered	Explanatory notes	Evaluation
<b>(a) The potential for adverse effects in humans</b>	Relevant information could include: reports of adverse reactions from food use in other countries; reports of adverse reactions from medicinal use; animal toxicity studies; observations in humans participating in clinical trials; or the presence of a particular component known to cause adverse reaction or illness.	Animal toxicity studies showed treatment-related effects that were observed at all tested doses of betaine and the biological or toxicological significance of these results have not been satisfactorily clarified (EU consideration).
<b>(b) The composition or structure of the food</b>	Relevant information could include: the presence of a particular component known to cause adverse reaction or illness (e.g. a natural toxicant, contaminant or allergen); analyses of the amount of any such substances known to cause adverse reaction or illness; structural similarity of any of the components to substances for which there are known safety concerns; special preparation required to enable safe use; or whether the structure of the substance is completely new such that its safety for human consumption has not been established.	The structure of the substance is new, such that its safety for human consumption has not been established.
<b>(c) The process by which the food has been prepared</b>	If the structure or composition of the food or food ingredient is altered because of a process by which the food has been prepared, what is the nature of any alterations? Do the alterations give rise to any safety concerns (relevant information would include that listed in the explanatory notes for (a) and (b))?	
<b>(d) The source from which it is derived</b>	If the food is considered non-traditional because of the source from which it is derived, does the source itself give rise to any particular safety concerns? Relevant information could include: whether the source is known to contain undesirable substances; whether the source is uncharacterised such that its safety for human consumption has not been established; relevant information is listed in the explanatory notes for (a) and (b).	
<b>(e) Patterns and levels of consumption of the food</b>	Does an altered pattern or level of consumption of the food give rise to safety concerns? Is the expected level of intake likely to exceed levels at which there are known adverse effects? Is the level of intake likely to exceed any medicinal use levels? Is the level of use likely to exceed use in a country that it is used traditionally?	

<b>(f) Any other relevant matters</b>	Any other relevant matters are guided by, but not limited to, considerations in (a) to (e). This enables a recommendation to be based on specific issues that although not listed would be relevant to public health and safety considerations related to the food.	
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**Recommendation** – an assessment of public health and safety considerations should be required due to (a) and (b).

**Example: Whole food – Ackee fruit**

<b>Matters to be considered</b>	<b>Explanatory notes</b>	<b>Evaluation</b>
<b>(a) The potential for adverse effects in humans</b>	Relevant information could include: reports of adverse reactions from food use in other countries; reports of adverse reactions from medicinal use; animal toxicity studies; observations in humans participating in clinical trials; or the presence of a particular component known to cause adverse reaction or illness.	Reports of ‘vomiting sickness’ in humans in Jamaica. Onset can be sudden with periods of vomiting and quiescence followed by convulsions, coma and death.
<b>(b) The composition or structure of the food</b>	Relevant information could include: the presence of a particular component known to cause adverse reaction or illness (e.g. a natural toxicant, contaminant or allergen); analyses of the amount of any such substances known to cause adverse reaction or illness; structural similarity of any of the components to substances for which there are known safety concerns; special preparation required to enable safe use; or whether the structure of the substance is completely new such that its safety for human consumption has not been established.	Two toxic substances, hypoglycin A and hypoglycin B (nonprotein amino acids) are present when the fruit is either green or over-ripe. In the unripened fruit, hypoglycin is located throughout the fruit, seeds, membrane under the seeds, and outer rind. In ripe ackee, the edible portion of the fruit may be consumed but the seeds and outer rind still contain high levels of hypoglycins.
<b>(c) The process by which the food has been prepared</b>	If the structure or composition of the food or food ingredient is altered because of a process by which the food has been prepared, what is the nature of any alterations? Do the alterations give rise to any safety concerns (relevant information would include that listed in the explanatory notes for (a) and (b))?	
<b>(d) The source from which it is derived</b>	If the food is considered non-traditional because of the source from which it is derived, does the source itself give rise to any particular safety concerns? Relevant information could include: whether the source is known to contain undesirable substances; whether the source is uncharacterised such that its safety for human consumption has not been established; relevant information is listed in the explanatory notes for (a) and (b).	
<b>(e) Patterns and levels of consumption of the food</b>	Does an altered pattern or level of consumption of the food give rise to safety concerns? Is the expected level of intake likely to exceed levels at which there are known adverse effects? Is the level of intake likely to exceed any medicinal use levels? Is the level of use likely to exceed use in a	

<b>Matters to be considered</b>	<b>Explanatory notes</b>	<b>Evaluation</b>
	country that it is used traditionally?	
<b>(f) Any other relevant matters</b>	Any other relevant matters are guided by, but not limited to, considerations in (a) to (e). This enables a recommendation to be based on specific issues that although not listed would be relevant to public health and safety considerations related to the food.	

**Recommendation** – an assessment of public health and safety considerations should be required due to (a) and (b).

## APPENDIX 1

The following questions are to assist in determining if a substance is likely to be considered a novel food or novel food ingredient in Australia and New Zealand. FSANZ reserves the right to ask for further information. This communication is not to be taken as approval. You are advised to seek independent advice.

### QUESTIONNAIRE to be completed by Enquirer

Product Name/Identifier	
Enquirer /Company	
Postal Address/contact details	
Telephone (include area code)	
Email	
If you are not the enquirer, please state your interest in this enquiry	
Date	
Attachments – if any please list	

**Please answer all of the following questions. It is not sufficient to provide a ‘yes’ or ‘no’ response. You must provide justification for your answers and details of any reference material accessed in order to answer the questions.**  
**We are unable to consider your inquiry until all questions are satisfactorily answered.**  
**We recognise that not all questions will be relevant to all enquiries. If you believe that a particular question is not applicable to your enquiry, please provide justification.**  
**FSANZ may request additional information.**

<b>1. Identity of food or food ingredient</b>	
1.1 What is the name of the food/food ingredient?	
1.2 What are the specifications for the food or food ingredient?	

**2 If the food is a plant or plant product, please complete the following information on botanical characterisation:**

2.1 What is the common and botanical name of the plant or ingredient?	
2.2 What part of the plant is used or intended for use?	
2.3 What is the form of the final food/food ingredient? For example, does the final food product contain the plant itself, a ground up preparation such as a powder, or an extract?	

**3. Proposed use of the food or food ingredient**

3.1 How is the substance to be used in food?	
3.2 What type of products is the substance intended to be used in?	
3.3 At what level (or range of levels) is the ingredient intended to be used?	

**4. Questions relevant to the consideration of whether a food is non-traditional or not**

4.1 Does the food or food ingredient have a history of use as a food in Australia, New Zealand or any other country? Details should be provided.	
4.2 How long has it been used as a food or food ingredient?	
4.3 Is the food or food ingredient recognised worldwide, regionally, or in isolated populations?	
4.4 Is the food or food ingredient used by the general population or by a specific	

sub-population?	
4.5 What is the expected level of intake of the food or the substance from its use in food?	
4.6 How does the proposed level of intake compare with any traditional use as a food in any other country or region in which it has been used?	
4.7 Has the food or food ingredient been used as part of the regular diet or only at certain times (e.g. during famine or for ceremonial purposes)?	
4.8 Has the substance been used in the food context or has it been used for other purposes in addition to or instead of food use (e.g. traditional medicine)?	
4.9 If the substance has been used for medicinal purposes in any country, what are the <u>therapeutic claims</u> associated with its use?	
4.10 If the substance has been used for medicinal purposes in any country, what are the typical <u>use levels prescribed</u> ?	
4.11 How do these medicinal use levels relate to the proposed level of intake from foods?	
4.12 Is the food produced by a process which has not previously been applied to food? Please include a flow process chart to describe the production method.	
4.13 Is the structure or composition of the final food or food ingredient altered because of the process by which the food has been prepared?	
4.14 Is the food or food ingredient produced from a source that in itself is not normally consumed as part of	

the diet?	
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<b>5. Public health and safety considerations</b>	
5.1 Are there any known adverse effects associated with the use of the food or food ingredient in any country or region in which it has been used? <u>Please detail the nature and extent of any such adverse effects.</u>	
5.2 Does the food or food ingredient contain any substance known to cause adverse reaction or illness, including an allergenic response? <u>Please detail the nature and extent of any such adverse effects</u>	
5.3 At what levels of use have any such adverse effects been noted?	
5.4 Are any such adverse effects based on observations in humans or animal studies? <u>Please provide copies of the referenced studies.</u>	
5.5 What is the approximate amount present of any such substance known to cause adverse reaction or illness?	
5.6 Is any special preparation required before use? Is the food consumed raw or are there any cooking or processing steps required before the food is consumed?	
5.7 Is the structure of the substance similar to any other compound for which there are known safety concerns?	
5.8 Is the structure of the substance completely new, such that its safety for human consumption has not been established?	
5.9 If the food is a complex mix of ingredients, are there known safety concerns for any of the components?	

Are any of the components similar to those for which there are known safety concerns?	
5.10 If the structure or composition of the final food or food ingredient is altered because of the process by which the food has been prepared, what is the nature of any such alterations? Is the altered structure or composition likely to give rise to any safety concerns?	
5.11 If the source of the food or food ingredient is non-traditional, is the source itself known to contain undesirable substances?	
5.12 Is the source of the food or food ingredient new or uncharacterised such that its safety for human consumption has not been established?	
5.13 Does an altered pattern or level of consumption (refer to questions 4.5, 4.6, 4.10 and 4.11) give rise to any safety concerns?	
5.14 Is the expected level of intake likely to exceed levels at which there are known adverse effects?	
5.15 Is the level of intake likely to exceed any medicinal use levels?	
5.16 Is the level of use likely to exceed use in a country that it is used traditionally?	



<b>6. Additional information</b>	
6.1 Is there any other information that you possess and which would assist in determining the issue? You should submit all information which is relevant even if not requested.	

### Addressing the Ministerial Policy Guidelines

In developing and varying standards, FSANZ must also have regard to any written guidelines formulated by the Ministerial Council. The way in which FSANZ has had regard to the guidelines is described below.

In response to the higher order principles:

- Retaining regulation for novel foods with a risk-based approach for pre-market assessment ensures the protection of public health and safety.
- Consumers would have access to sufficient information to enable informed choice through any labelling information specified in the conditions of use for novel food permissions and through general labelling requirements.
- The purpose of regulation for novel foods is to provide a framework for the risk-based assessment of new foods to ensure their safety prior to sale. Since the focus of this regulation is on safety, it is not inconsistent with (though also not directly relevant to) national policies and legislation including those relating to nutrition and health promotion.
- FSANZ has considered other relevant regulations for novel foods, namely in the European Union and Canada and has discussed these regulations with members of the Standard Development Advisory Committee (SDAC), in revising the definitions in Standard 1.5.1.
- Increased transparency will be achieved by the establishment of an Advisory Committee on Novel Foods with a clear structure and role and detailed information on its operation on the FSANZ website. The development of a guidance tool for determining whether a food is novel or not to be used by the proposed Advisory Committee on Novel Foods and provided on the website will further increase transparency. Transparency will also be increased by the inclusion of justifications of views formed in relation to whether a food is novel or not on the FSANZ website.
- Timeliness has been addressed through recommendations from the FRSC steering committee addressing the FSANZ assessment and approval process. Specifically, that many novel food applications will be required to be assessed within 9 months and with only one round of public comment, in accordance with amendments to the FSANZ Act.
- Standard 1.5.1 is consistent with minimum effective regulation as highlighted by the fact that over 200 potential novel foods have been considered and only approximately 25% have been considered to be subject to the pre-market requirements of the Standard.
- The revised definitions should encourage fair trade by increasing the consistency of determining whether a food is novel or not. Industry growth, innovation and international trade may be encouraged by the increased availability of information regarding the process for determining whether a food is novel or not and outcome views on the website.

In response to the specific principles:

- The maintenance of public and industry confidence in the food system was considered in the impact analysis of the regulatory options and in increasing transparency with respect to determining whether a food is novel or not through the proposed establishment of an Advisory Committee on Novel Foods.
- Commercially sensitive information is protected to the extent possible under the FSANZ Act. Options for addressing the issue of data protection have been considered by the FRSC steering committee addressing the FSANZ assessment and approval process. In accordance with the recommendations to this process, changes to the FSANZ Act will result in most novel food applications being assessed in nine months with one round of public comment only. Another recommendation of this work was to allow applicants to seek exclusive permissions for novel foods for a 15-month period. Proposal P305 has been raised to consider exclusivity of novel foods.
- Conditions of use for novel foods can be specified to provide consumers with appropriate information on novel foods or novel food ingredients that may assist them in understanding the functionality of the ingredients. This provision coupled with the general labelling requirements including full disclosure of the name of the novel food ingredient should ensure that consumers are not misled by novel foods or novel food ingredients which appear similar to existing foods but may differ in terms of nutrition or function.

In response to the policy guidance:

- FSANZ is reviewing Standard 1.5.1 through a Proposal.
- FSANZ has held discussions with stakeholders, including jurisdictions, on the purpose of the Standard and also sought views from submitters. There was support for the purpose of the Standard – that novel foods undergo a risk-based assessment to ensure their safety prior to sale.
- The SDAC was established to provide advice to FSANZ during the review comprising members representing industry, consumers, public health and government. The government enforcement agencies represented include New South Wales Food Authority, South Australian Department of Health, Queensland Health, the Australian Quarantine and Inspection Service and New Zealand Food Safety Authority.
- Consideration has been given to the subjectivity and scope of the definitions (through Proposal P291), protection of information (through the implementation of recommendations in relation to the FSANZ assessment and approval process) and level of assessment to be commensurate with level of risk (through the implementation of recommendations in relation to the FSANZ assessment and approval process), and the issues raised by stakeholders during the FRSC consultation (through Proposal P291).
- FSANZ has reviewed the guidelines for novel foods. There are separate documents that cover the information relevant to novel foods. The *Application Handbook* sets out the required data to be submitted by applicants and provides categories of novel foods so that applicants have detailed information on the specific data required for the varied categories of novel foods.

The guidance tool for determining whether a food is novel or not will be used by the proposed Advisory Committee on Novel Foods in making recommendations in relation to potential novel foods. This will be provided on the website in conjunction with detailed information on the Advisory Committee on Novel Foods, once established.

## International Regulations for Novel Foods

### European Union

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

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

- (a) foods and food ingredients with a new or intentionally modified primary molecular structure;
- (b) foods and food ingredients consisting of or isolated from micro-organisms, fungi or algae;
- (c) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating and breeding practices and having a history of safe food use; and
- (d) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances.

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

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

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

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

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

### **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.

### **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 micro-organism, 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 micro-organism that has been genetically modified such that
  1. the plant, animal or micro-organism exhibits characteristics that were not previously observed in that plant, animal or micro-organism,
  2. the plant, animal or micro-organism no longer exhibits characteristics that were previously observed in that plant, animal or micro-organism, or
  3. one or more characteristics of the plant, animal or micro-organism no longer fall within the anticipated range for that plant, animal or micro-organism.

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<sup>®</sup> and ARASCO<sup>®</sup> 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.

## United States

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

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

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

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

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

- tomato lycopene extract (pending);
- $\alpha$ -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);
- $\beta$ -cyclodextrin (FDA has no questions);
- trehalose (FDA has no questions); and
- hempseed oil (notice does not provide a basis for a GRAS determination).



## Impact Analysis

### Option 1: Retain the *status quo*

- Retain the current Standard 1.5.1 – Novel Foods.
- Retain the current assessment process for novel foods.
- Retain the current supporting documents on the website but continue to update the considerations by the NFRG in the guidelines as is the case currently.
- Retain the current operation for determining whether a food is novel or not i.e. NFRG working in conjunction with jurisdictions.

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

- Retain the current Standard 1.5.1 – Novel Foods.
- Retain the current assessment process for novel foods.
- Amend the supporting documents as required. Review the categories of novel foods referred to in the guidelines.
- Review and amend operating procedures for determining whether a food is novel or not.
- Develop a guidance tool to assist in the interpretation of the definitions.
- Undertake targeted education for stakeholders in response to demand. This may assist in reducing the load with respect to determining whether a food is novel or not.

### Option 3: Amend Standard 1.5.1 and operating procedures

- Maintain the intent of the current Standard, but review the wording of the purpose clause and the definitions for ‘non-traditional food’ and ‘novel food’.
- Amend the definition for novel foods to capture foods produced using new technologies with altered characteristics that raise safety concerns.
- Amend the supporting documents as required. Review the categories of novel foods referred to in the guidelines.
- Review and amend operating procedures for determining whether a food is novel or not.
- Developing a guidance tool to assist in the interpretation of the definitions.
- Undertake targeted education for stakeholders in response to demand. This may assist in reducing the load with respect to determining whether a food is novel or not.

### *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 Standard is reasonably successful in supporting minimum effective regulation. For example, more than 200 enquiries have been received in relation to the Standard with approximately 25% of these being considered to be novel and therefore subject to the pre-market assessment requirements of the Standard.

The identified costs are as follows:

- Because of the broad nature of the standard, it may not be clear to industry which foods are captured by the standard and therefore subject to the pre-market assessment requirements.
- Applicants incur a resource and monetary cost in applying to FSANZ to amend the Code to permit a novel food.
- Competitors in the industry sector can take advantage of a novel food permission once gazetted and therefore remove the commercial advantage of the applicant.

## Government

The identified benefits are as follows:

- The Standard prohibits the sale of novel foods unless they 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 considered 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 whether a food is novel or not is resource intensive for government agencies – both FSANZ and enforcement agencies.

## *Option 2*

### Consumers

The potential costs and benefits to consumers listed for Option 1 apply to this Option. The amendment of the operating procedures (e.g. inclusion of a guidance tool) would give greater clarity as to how it is determined whether a food is novel or not. This potentially provides an additional benefit to consumers in comparison with Option 1, if the time taken to determine whether a food is novel or not is less, and novel foods are available on the market earlier.

### Public health professionals

The potential costs and benefits to public health professionals listed for Option 1 apply to this Option. The amendment of the operating procedures may provide an additional benefit to public health professionals because of greater clarity as to how it is determined whether a food is novel or not.

### Industry

In comparison with Option 1, amending the operating procedures would benefit industry by providing greater clarity as to how it is determined whether a food is novel or not. The development of a guidance tool for determining whether a food is novel or not, would assist industry in judging whether or not an application is required. An education initiative targeted toward industry would provide an additional benefit.

### Government

Amending the operating procedures and the development of a guidance tool would benefit government in comparison with Option 1 by providing greater clarity.

It is expected that any initial impact on resources in relation to amended operating procedures or education for stakeholders, is expected to provide a benefit to government in the long-term.

### Comments on Option 2

This Option provides a benefit to all affected parties in comparison with Option 1 due to greater clarity around the process for determining whether a food is novel or not and the operating procedures generally.

### *Option 3*

#### Consumers

Option 3 provides the additional benefit to consumers in comparison with Option 2 in that the amended definitions will provide further clarity. Improved clarity in the definitions may decrease the time taken to determine whether a food is novel or not in comparison with only amending the operating procedures.

Regulating foods produced using new technologies that have altered characteristics, and the altered characteristics raise safety concerns, 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.

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

#### Government

Enforcement agencies would also clearly benefit from clear and workable definitions, in combination with a clear process for determining whether a food is novel or not. Officers would have greater confidence in enforcement decisions and actions and would be able to act quicker if the definitions were less ambiguous.

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

### Comments on Option 3

Option 3 affords a clear benefit to consumers, public health professionals and government in comparison with Option 2 due to the opportunity to provide increased clarity around the definitions in addition to the process for determining whether a food is novel or not. Option 3 should benefit industry in comparison with Option 2 in most regards, specifically in relation to increased clarity around definitions. However, the introduction of regulation for foods produced from new technologies with altered characteristics may be viewed as a cost. Option 3 also supports the implementation of the Ministerial Council Policy Guidelines.

### **Conclusion**

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

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

Option 3 affords a clear benefit to consumers, public health professionals and government in comparison with Option 2 due to the opportunity to provide increased clarity around the definitions in addition to the process for determining whether a food is novel or not. Increased clarity around definitions would increase industry confidence in determining which foods are captured by the Standard and improve the efficiency of government enforcement agencies. Regulation of foods produced using new technologies would benefit consumers and public health professionals, and any cost to industry is likely to be minimal since only those foods with altered characteristics would be considered to be novel. Option 3 is the only option which allows FSANZ to adequately address and implement the Ministerial Council Policy Guideline on novel foods.

Overall, Option 3 is the preferred regulatory Option.

**Standard Development Advisory Committee Membership  
and  
Terms of Reference**

SDAC Membership

FSANZ (Chair)  
NSW Food Authority  
South Australian Department of Human Services  
Queensland Health  
Australian Quarantine and Inspection Service  
New Zealand Food Safety Authority  
Office of Complementary Medicines, Therapeutic Goods Administration  
Department of Agriculture, Fisheries and Forestry  
Department of Health and Ageing  
Australian Food and Grocery Council  
New Zealand Food and Grocery Council  
Australian Chamber of Commerce and Industry  
Complementary Healthcare Council  
Dietitians Association of Australia  
Public Health Association of Australia  
New Zealand Dietitians Association  
New Zealand Consumers Institute  
Maori Reference Group

Terms of Reference

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

1. the review of Standard 1.5.1 – Novel Foods in accordance with:
  - a. the requirements of the *Food Standards Australia New Zealand Act 1991*; and
  - b. the Australia and New Zealand Food Regulation Ministerial Council Policy Guideline on Novel Foods; and
2. any scientific, technical, policy, regulatory/enforcement, cost benefit or other information that may be relevant to the review process.

## Summary of Submissions

### First Round of Public Comment

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

#### *Preferred regulatory options*

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

**Option 1** – Retain the *status quo*

**Option 2** – Retain the current standard but amend operating procedures

**Option 3** – Amend Standard 1.5.1 – Novel Foods, and operating procedures

**Option 4** – No specific regulation for novel foods

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

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

#### Purpose of the Novel Foods Standard

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

#### Definitions for ‘non-traditional’ and ‘novel’

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

### Regulation of foods produced using new technologies

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

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

### Categories of novel Foods

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

### Decision-tree

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

### Expert panel

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

### Education for industry

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

### Data protection

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

### Assessment process

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



## Full summary of submissions

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

### **5.1 General History and Operation of Standard 1.5.1**

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

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

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

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

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

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

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

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

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

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

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

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

## **5.2 Purpose of the Standard**

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

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

8. *Does the current Standard support this purpose?*

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

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

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

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

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

Two suggestions were made:

- The proposed wording be expanded to ensure the standard captures foods produced by new technologies including breeding, where safety concerns are known.
- The word ‘retail’ be removed such that it reads ‘the purpose of this Standard is to ensure that novel foods will undergo a risk-based safety assessment before they are offered for sale for direct consumption in Australia and New Zealand.’

### 5.3 Definitions for ‘non-traditional’ and ‘novel’ in Standard 1.5.1

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

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

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

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

How could a ‘generation’ be defined?

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

No additional issues were stated by enforcement agencies.

#### **5.4 Scope of novel foods regulation**

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

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

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

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

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

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

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

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

- Not all foods will fit within designated categories.
- Inclusion of categories in EU and Canadian legislation has given rise to difficulties.
- Inclusion of categories in regulations would be confusing.
- Guidelines are more easily amended than regulation and there will likely be a need to amend categories in the future.
- Inclusion of categories in regulations would be contrary to minimum effective regulation.

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

23. *Are the current classes in the guidelines helpful?*

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

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

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

## **5.6 Data protection for industry**

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

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

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

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

## **5.7 Assessment process for novel foods**

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

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

## **5.11 Uptake of existing permissions for novel foods**

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

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

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

## **6. Regulatory options**

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

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

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

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

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

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

31. *Would industry benefit from such an initiative?*

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

## **7. Impact analysis**

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

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

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

Option 3 was most strongly supported, with 8 submitters favouring this option, followed by Option 4, favoured by 5 submitters. Of the submissions received from government, all supported Option 3.



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

Reasons given in support of Option 3:

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

Reasons given in support of Option 4:

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

### **List of submitters to the Initial Assessment Report**

#### *Australia*

#### Public Health

Dietitians Association of Australia, Ms Sue Cassidy

#### Government

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

#### Industry

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

Consumer/Private

Mr Gary Bilton

*New Zealand*

Government

New Zealand Food Safety Authority, Ms Carole Inkster

Industry

New Zealand Food and Grocery Council, Ms Brenda Cutress

**Second Round of Public Comment**

The public consultation period on the Draft Assessment Report commenced on 5 October 2005 and closed on 25 January 2006.

**Overview of submissions received**

<b>Total number of submissions</b>	<b>18</b>
<b>Total from Australia</b>	<b>14</b>
<b>Total from New Zealand</b>	<b>4</b>
<b>Food Industry &amp; Business</b>	<b>12</b>
<b>Consumers</b>	<b>1</b>
<b>Government</b>	<b>5</b>

Six of the submissions received were from agencies/industry bodies or associations represented on the Standard Development Advisory Committee (SDAC). A full list of submitters is included at the end of this summary.

**Summary of key points raised in submissions**

The three options put forward in the Draft Assessment Report were:

**Option 1** – Retain the *status quo*

**Option 2** – Retain the current standard but amend operating procedures

**Option 3** – Amend Standard 1.5.1 – Novel Foods, and operating procedures

The majority of submitters supported Option 3 (13). One submitter favoured removing the standard and requiring new foods to be treated under the remaining provisions of the Code, but considered Option 3 to be the best of the options put forward. Another submitter supported Option 3 but re-iterated their suggestion made in response to the Initial Assessment Report, of adopting a GRAS system. Two submitters favoured Option 2 but because they did not support the definitions as proposed at Draft Assessment.

The majority of submitters focussed their comments around the proposed definitions for non-traditional food and novel food. In relation to the proposed definition for non-traditional food, comments centred on the perceived ambiguity associated with terms used in the definition of non-traditional food such as ‘generally available’, ‘broad cross-section’ and ‘history of human consumption’. There was general support for (a), (b) and (c) of the proposed definition for novel food, however there were a number of comments on parts (d), (e) and (f) which relate to the process by which the food has been prepared, the source from which the food has been derived and any other relevant matters.

Submitters generally supported the provision of a guidance tool, suggesting that it would be a valuable tool for industry and consumers. A number of submitters provided specific and helpful comments for improving the proposed tool. There was general support for the inclusion of categories of novel foods in the novel foods guidelines, but that they should be non-exclusive since it is possible that some foods may fall outside the listed categories. Those submitters who commented on the operation of the Novel Foods Reference Group (NFRG) were supportive of its function and some submitters made useful comments to assist in improving the visibility of its operation and outcomes. Two jurisdictions commented on the difficulties in enforcing views of the NFRG on the novel status of foods or food ingredients. Other comments related to data protection, review of novel food permissions and education.

## Full summary of submissions

### 1. Definition of non-traditional food

There was some support for the definition of non-traditional food proposed at Draft Assessment. However, most submitters suggested some amendments, with a number of submitters considering that the proposed definition is problematic and that greater clarification was still required for various components of the definition. There was general concern that the definition would be difficult to interpret with particular attention drawn to difficulty in determining what constituted ‘generally available’, ‘broad cross section of consumers’ and ‘a history of human consumption’. Some concerns and/or suggestions for amending or clarifying these terms include:

#### *Generally available*

- Requires clarification.
- Suggest ‘freely available’ rather than generally available. For example, available in supermarkets or health food stores in at least one jurisdiction in Australia and/or New Zealand.

#### *Broad cross-section*

- Too broad or vague to enforce.
- Any gender or age group that is likely to consume the food or food ingredient should be considered.
- Not applicable to population groups with special needs and may impact on special purpose foods.
- Should not be limited to consumers in Australia and New Zealand, particularly if consumed extensively in overseas markets without any known detrimental effect.

- Foods consumed by ethnic groups should be considered.

#### *History of human consumption*

- Should refer to a history of SAFE human consumption.
- Should not be limited to consumption in Australia and New Zealand.

Other comments by submitters included the need to clarify parts of the definition to ensure certain substances would be explicitly covered by the definition. For example:

- Amend part (c) to include reference to ‘any synthetic substance’.
- Amend part (b) to add reference to where a substance is intended to be used a significantly greater concentrations than naturally present in foods.
- Part (a) should take into account the amount of the product used. If intended to be used at much greater quantities than traditionally used, the traditional use should not be relied upon to form the basis of evidence of traditional use.

Two submitters raised concerns that the definition could affect some special purpose foods used for specific population subgroups. It was suggested that special purpose foods should be excluded from consideration under Standard 1.5.1.

## **2. Definition of novel food**

There was general support for parts (a), (b) and (c) of the proposed definition for novel food. Most submitters considered these parts of the definition were adequate to define novelty. Some submitters suggested that it may be difficult to predict patterns and levels of consumption of the food (part (c)), particularly given the lack of current nutrition survey data. Most submitters supported the inclusion of part (c) in the definition.

However, there was a lot of comment on parts (d), (e) and (f) of the definition. Most submitters suggested that the process by which a food has been prepared (part (d)) should not be subject to regulation under Standard 1.5.1. Submitters were of the opinion that it should be the final food that should be regulated under the Standard, and then only if the characteristics of the final food are sufficiently different (and raise safety concerns) from an equivalent food produced using a traditional process. Some submitters suggested that this was adequately covered by parts (a) and (b) of the definition.

A similar approach was suggested for part (e) of the definition. The source from which a food has been prepared should not be subject to regulation under the Standard, but rather the final food if it is not identical in composition to a food sourced from a traditional food source, and only if there are concerns regarding safety.

Part (f) of the definition was generally considered too open ended and non-specific to be enforceable. The inclusion of ‘any other relevant matters’ was considered by most submitters to add considerable uncertainty and subjectivity to the definition.

### **3. Purpose clause**

Less than half of submitters addressed the proposed purpose clause. However, all of these submitters supported the wording of the clause. Two submitters suggested that it was not necessary to include the words ‘in Australia and New Zealand’ in the purpose clause.

### **4. Guidance tool for determining whether a food is novel or not**

Submitters supported the provision of a guidance tool for determining whether a food is novel or not, suggesting that it would be a valuable tool for industry and consumers.

Comments on the guidance tool proposed at Draft Assessment included:

- The open ended questions included in the guidance tool should be amended to provide ‘yes’ or ‘no’ answers in order to reduce subjectivity. Under Step 2 a ‘yes’ answer could equate to ‘traditional’ and a ‘no’ answer could equate to ‘non-traditional’.
- In Steps 2 and 3, further clarity is required to determine what would contribute to an overall yes or no answer. It is not transparent regarding how yes and no answers will, or should, be interpreted.
- The questions in Step 3 relating to parts (d), (e) and (f) should be removed or amended to reflect the comments provided in relation to those parts of the definition of novel food.
- Support from one submitter for a tool with flexibility, which leaves it open to a total consideration of whether a food is novel or not, rather than a strict priori criteria.

### **5. Guidelines for novel foods**

There was general support for the inclusion of categories of novel foods in the novel food guidelines, but not in Standard 1.5.1 itself. It was suggested that the categories should be non-exclusive as it is possible that some foods may fall outside of the defined categories. One submitter did not support the use of categories for novel foods, however suggested that if used, they should only be included in the guidelines and should be a non-exclusive list.

One submitter commented that the development of data requirements for each of the identified classes of novel foods is worthy of support provided industry agrees that the requirements will assist in developing submissions and/or applications to amend the Standard.

Two submitters suggested that probiotics should not be considered a category of novel foods, and that they should be considered traditional foods or food ingredients based on the history of consumption in fermented products.

### **6. Novel foods reference group (NFRG) operation**

Those submitters who commented on the operation of the NFRG were supportive of its function. The record of views formed by the NFRG in response to enquiries, published on the FSANZ website, was considered a valuable resource. It was also suggested that stakeholder education on how the NFRG makes a determination would be helpful. This could be done on the FSANZ website, with examples of how determinations were made. The reasons for a determination should also be published as this would be useful.

Some submitters suggested that wider representation from jurisdictions should be considered on the NFRG, with provision being made for the use of additional experts as appropriate.

In general, the use of an expert panel was not supported. However, there was support for the use of an expert panel convened by the private sector, such as that used in the US Food and Drug Administration's Generally Recognised As Safe (GRAS) notification system. The use of an expert panel would only be required where the novel food guidance tool was not sufficient to arrive at an outcome for the novel status of a food. Such use of an expert panel would help manufacturers to self determine the safety of a food.

## **7. Enforcement issues**

Two submitters suggested that there are difficulties in enforcing the views of the NFRG on the novel status of foods or food ingredients. Where a novel food appears in the table to clause 2 of Standard 1.5.1 enforceability would not seem to be an issue. However, it was suggested that where a food has been considered by the FSANZ NFRG and considered to be novel, there can be problems with enforcement. If a food business or another jurisdiction does not agree with a 'novel' determination of the NFRG a successful prosecution for a breach of the Standard may be problematic.

These submitters suggested that for consistency of enforcement, all NFRG determinations should be included in a schedule that is referenced by the Standard (or the schedule should be included directly in the Standard). This is seen as providing a binding document that jurisdictions can choose to enforce upon.

One submitter highlighted that the process for determining novelty of a food or food ingredient outlined in the guidance tool should reflect the requirements of the Standard and be robust enough to improve the enforceability of the Standard. The outcome of any guidance tool consideration should provide a direction as to whether the Standard applies to a particular food or food ingredient.

## **8. Data protection**

Submitters who commented on this issue highlighted the importance of data protection and/or first to market advantage to ensure commercial advantage for the applicant and to avoid the potential for competitors to 'ride on the back' of generic applications.

One submitter suggested that enough information should be available in order to consider an application in a thorough manner.

Some submitters acknowledged the review of FSANZ's processes was likely to have an impact on data protection and market advantage.

### *8.1 FSANZ Response*

FSANZ has raised Proposal P305 – Exclusivity of Novel Foods to address the concerns expressed by industry in relation to data protection and in response to requests from the Food Regulation Standing Committee (FRSC) and the Ministerial Council.

The purpose of the Proposal is to consider the capacity for including a specific provision for exclusivity of use for novel foods in Standard 1.5.1 and if so, whether an exclusive permission should be limited to a period of 15 months. Proposal P305 is being progressed in parallel to this FAR.

The impact of amending Standard 1.5.1 to include specific provision for exclusive permissions would be to make clear that an applicant for a novel food is able to apply for a variation to the Novel Foods Standard for a specific brand and class of food. The specific brand may be applied to the class of food as a whole or to a particular product(s) within the class of food; a decision that is up to the applicant. The applicant would need to clearly state the brand and class of food, or product(s) within a class of food, for which they are seeking exclusivity.

## **9. Review of novel food permissions**

There was general support for a review of novel food permissions, however ten years was considered too long a period of time after a permission was granted; and five years was suggested as more appropriate. One submitter suggested that a review of a novel food permission should be a condition of approval. Submitters suggested that it was not clear how this review process would be conducted and that such a process needs to be clearly described to ensure transparency.

A number of submitters suggested that after review a clear distinction should be made as to whether a novel food was then permitted for general use, remained novel or if it was prohibited from use. Some submitters suggested that a novel food should be declared no longer novel after review if there were no concerns associated with that food. These submitters also suggested that a table should be included in the Standard to reflect either prohibited novel foods or approved novel foods that are now permitted for general use after review.

A small number of submitters did not support a review process. Such a process was viewed by these submitters as a potential waste of resources, given that the food had already gone through a full assessment process, and was considered unnecessary if no significant concerns had been raised by the public or regulators.

## **10. Education**

Some submitters supported stakeholder education programs to assist industry in understanding the process for determining novelty, which would decrease the workload of the NFRG and provide greater clarity. The FSANZ website was suggested as a medium to deliver such education, including examples of how a determination of novelty is conducted. One submitter highlighted the importance of educating consumers to ensure they had sufficient information to make informed and healthy food choices.

## **11. Policy guidance for the addition of substances other than vitamins or minerals**

Some submitters noted that work was being conducted on developing policy guidance for the addition of substances other than vitamins and minerals to food and that this could impact on the novel food standard.

### *11.1 FSANZ Response*

The development of policy guidance on the addition of substances other than vitamins and minerals to food is ongoing and is unlikely to impact on the scope of this review and the novel foods standard.

## **12. Food-medicine interface**

One submitter also noted that more discussion is required around the topic of the food-medicine interface, particularly for substances that may have a therapeutic aspect. One submitter suggested support for novel food consideration of substances traditionally used in complementary medicines or dietary supplements, to determine their suitability for inclusion in foods.

## **13. Consistency with national nutrition policies and guidelines**

One submitter suggested that the food vehicle should be considered for novel food ingredients and that dietary criteria for food vehicles should be considered to ensure the food vehicle is consistent with national nutritional policies and guidelines.

### *13.1 FSANZ Response*

The framework for the novel foods standard provides scope to consider public health and safety considerations associated with a food vehicle.

## **14. GRAS system for approval of novel foods**

One submitter questioned whether FSANZ would rely on a GRAS FSA approval in lieu of undertaking its own safety assessment for a food or food ingredient.

### *14.1 FSANZ Response*

The option of implementing a notification procedure similar to the US GRAS system was raised and considered at Draft Assessment, however such a system is not feasible under the FSANZ Act.