Attachment 2

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

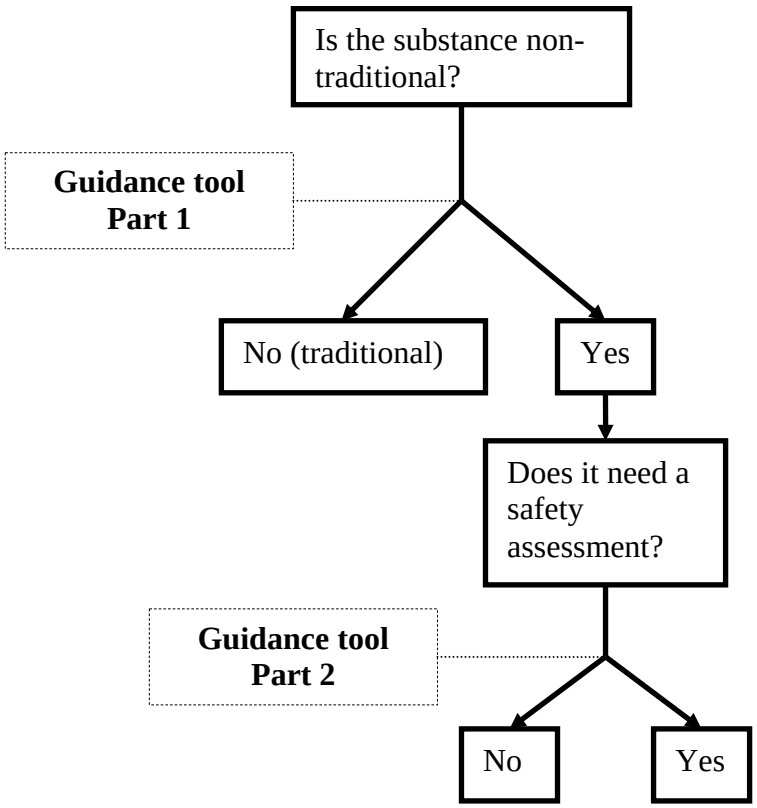
2. whether an assessment of public health and safety considerations should be required for the non-traditional food to confirm there is reasonable certainty that no harm will result from the intended use of the food and to determine whether any risk management strategies are warranted to ensure the safe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

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*[1].

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].

[1] 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).

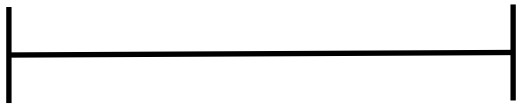
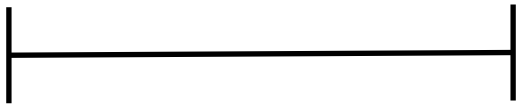
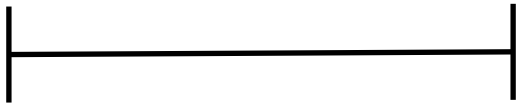
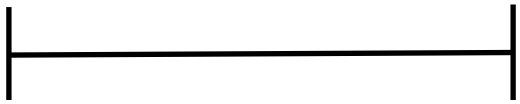
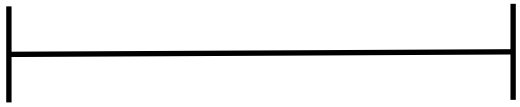
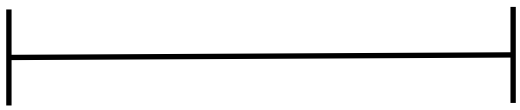
Questions 4.12, 4.13 and 4.14 of the questionnaire relate to the process by which the food is produced and the source from which the food is derived. If the answer to either question 4.13 or 4.14 is yes, then length of use would generally be considered to be short, extent of use would generally be considered 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.

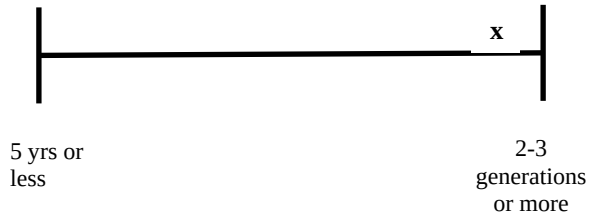
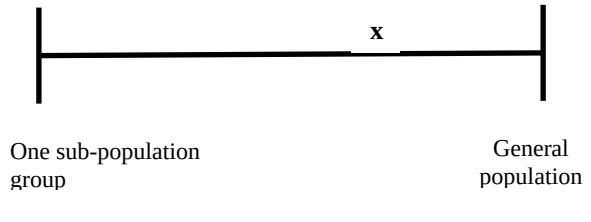
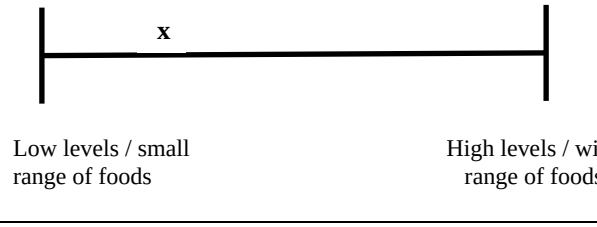
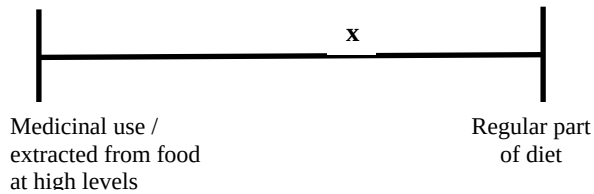
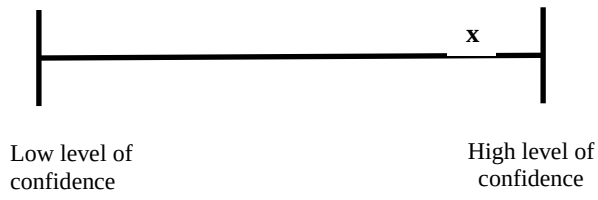
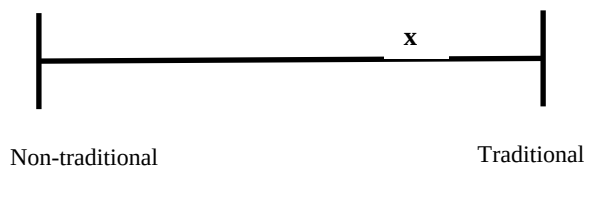
So while a particular fruit may have been consumed extensively in another part of the world, the extent of use in Australia and New Zealand may be very limited, if any.

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		 5 yrs or less — 2-3 generations or more
2. Extent of use		 One sub-population group — General population
3. Quantity of use (level of intake)		 Low levels / small range of foods — High levels / wide range of foods
4. Purpose or context of use		 Medicinal use / extracted from food at high levels — Regular part of diet
5. Confidence in information provided		 Low level of confidence — High level of confidence
6. Overall consideration		 Non-traditional — Traditional

Recommendation

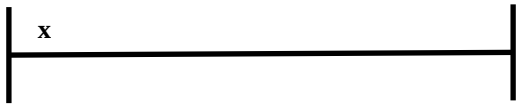
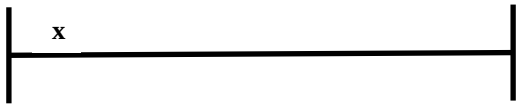
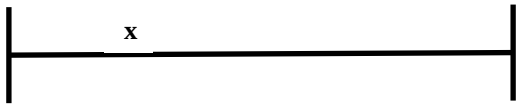
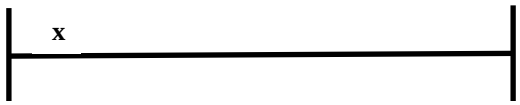
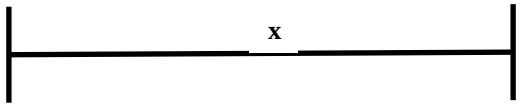
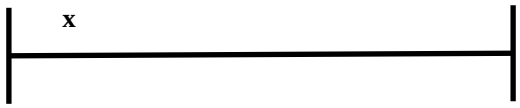
Example: Plant ingredient – *Hibiscus sabdariffa* (flower)

History of human consumption	Notes	Rating
1. Length of use	Appears to be a long history of use in Australia.	
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.	
3. Quantity of use (level of intake)	Used as an ingredient in jams and jellies and in champagne for decoration and flavour.	
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.	
5. Confidence in information provided	Information provided was supplemented by knowledge of committee considering this food.	
6. Overall consideration	There is a history of consumption in Australia.	

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.

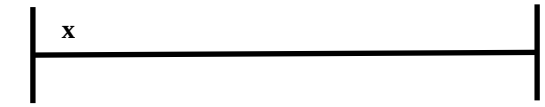
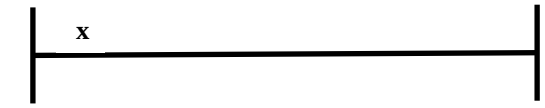
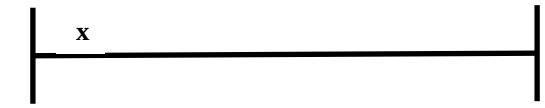
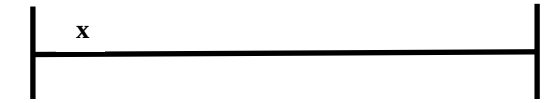
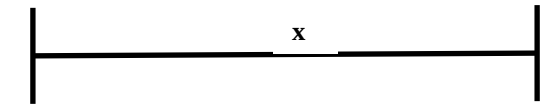
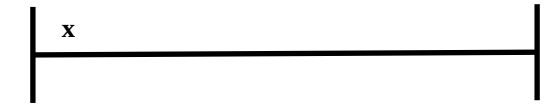
Example: Plant ingredient – Hoodia gordonii

1. Length of use	Appears to be no history of use as a food in Australia or New Zealand.	 5 yrs or less — 2-3 generations or more
2. Extent of use	Not used as a food in Australia and New Zealand.	 One sub-population group — General population
3. Quantity of use (level of intake)	Use in Africa is apparently to chew the raw plant (cactus) when required (see purpose below).	 Low levels / small range of foods — High levels / wide range of foods
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.	 Medicinal use / extracted from food at high levels — Regular part of diet
5. Confidence in information provided	Information provided included interviews of African tribe members and use of hoodia in supplement type products overseas.	 Low level of confidence — High level of confidence
6. Overall consideration	Not a history of consumption in Australia and New Zealand.	 Non-traditional — Traditional

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.

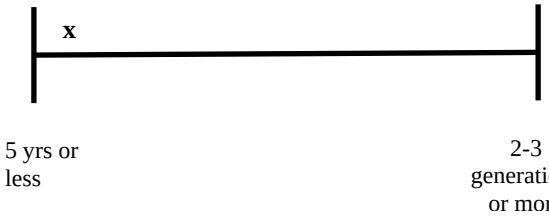
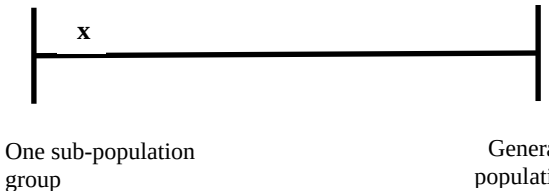
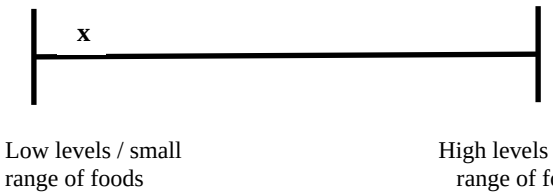
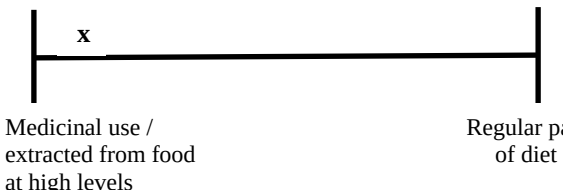
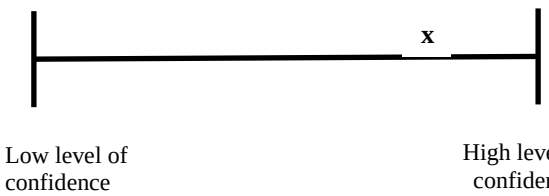
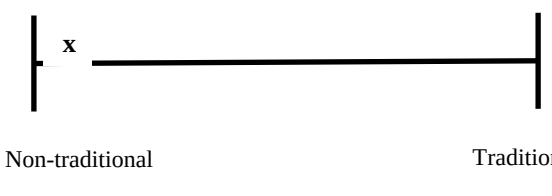
Example: Source of food ingredient –DHA sourced from *Schizochytrium* sp. (microalgae)

1. Length of use	There does not appear to be a history of consumption of Schizochytrium sp. or products derived from it in Australia or New Zealand.	 5 yrs or less — 2-3 generations or more
2. Extent of use	Does not appear to be use by any population group in Australia or New Zealand.	 One sub-population group — General population
3. Quantity of use (level of intake)	While there is a reasonably high level of intake of DHA in the diet from other sources, this is not from Schizochytrium sp.	 Low levels / small range of foods — High levels / wide range of foods
4. Purpose or context of use	While DHA is to be used in the food context, the marine microalgae is not used as food.	 Medicinal use / extracted from food at high levels — Regular part of diet
5. Confidence in information provided		 Low level of confidence — High level of confidence
6. Overall consideration	Not a history of human consumption in Australia and New Zealand.	 Non-traditional — Traditional

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.

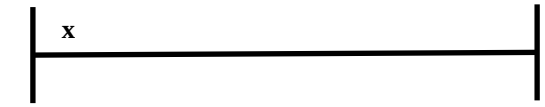
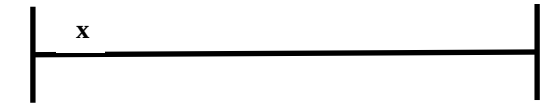
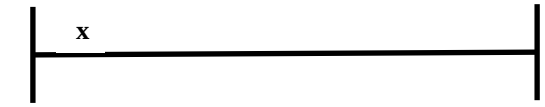
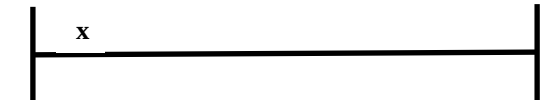
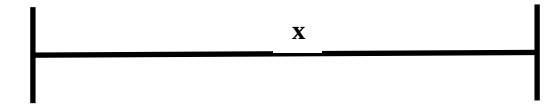
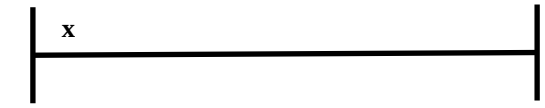
Example: Substance derived from food – Betaine (extracted from sugar beet)

1. Length of use	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.	
2. Extent of use	Does not appear to have been consumed by any population group in Australia or New Zealand in the context presented.	
3. Quantity of use (level of intake)	Natural levels are quite low in foods - less than proposed levels of addition to foods. Proposed to be extracted from sugar beet.	
4. Purpose or context of use	Extracted from sugar beet and added to other foods at higher levels.	
5. Confidence in information provided	Information provided was satisfactory and was supplemented by investigation into European Union consideration of same substance.	
6. Overall consideration	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

1. Length of use	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.	 5 yrs or less — 2-3 generations or more
2. Extent of use	Little or no use in Australia and New Zealand. Generally available in Jamaica.	 One sub-population group — General population
3. Quantity of use (level of intake)	Appears to be used in some traditional dishes in Jamaica. Little or no use in Australia or New Zealand.	 Low levels / small range of foods — High levels / wide range of foods
4. Purpose or context of use	Not used in Australia or New Zealand.	 Medicinal use / extracted from food at high levels — Regular part of diet
5. Confidence in information provided	Information provided seemed reputable, though not extensive.	 Low level of confidence — High level of confidence
6. Overall consideration	Not a history of human consumption in Australia and New Zealand.	 Non-traditional — Traditional

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
(a) The potential for adverse effects in humans	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[2]; 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) The composition or structure of the food	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.	
(c) The process by which the food has been prepared	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))?	
(d) The source from which it is derived	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).	
(e) Patterns and levels of consumption of the food	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?	
(f) Any other relevant matters	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

[2] 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.

Example: Plant ingredient – Hoodia gordonii

Matters to be considered	Explanatory notes	Evaluation
(a) The potential for adverse effects in humans	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) The composition or structure of the food	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.	
(c) The process by which the food has been prepared	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))?	
(d) The source from which it is derived	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).	
(e) Patterns and levels of consumption of the food	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.
(f) Any other relevant matters	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 (e).

Example: Source of food ingredient – DHA from *Schizochytrium* sp. (microalgae)

Matters to be considered	Explanatory notes	Evaluation
(a) The potential for adverse effects in humans	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) The composition or structure of the food	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.	
(c) The process by which the food has been prepared	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))?	
(d) The source from which it is derived	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, *Schizochytrium* sp. (marine micro algae) gives rise to potential safety concerns due to the potential for undesirable substances such as natural toxins and pathogens.
(e) Patterns and levels of consumption of the food	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?	
(f) Any other relevant matters	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 (d).

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

Matters to be considered	Explanatory notes	Evaluation
(a) The potential for adverse effects in humans	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) The composition or structure of the food	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.
(c) The process by which the food has been prepared	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))?	
(d) The source from which it is derived	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).	
(e) Patterns and levels of consumption of the food	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?	
(f) Any other relevant matters	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).

Example: Whole food – Ackee fruit

Matters to be considered	Explanatory notes	Evaluation
(a) The potential for adverse effects in humans	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) The composition or structure of the food	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.
(c) The process by which the food has been prepared	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))?	
(d) The source from which it is derived	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).	
(e) Patterns and levels of consumption of the food	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?	
(f) Any other relevant matters	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 <u>all</u> 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.

1. Identity of food or food ingredient	
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 <u>botanical characterisation</u>:	
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 therapeutic claims associated with its use?	
4.10 If the substance has been used for medicinal purposes in any country, what are the typical use levels prescribed?	
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?	

5. Public health and safety considerations	
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? Please detail the nature and extent of any such adverse effects.	
5.2 Does the food or food ingredient contain any substance known to cause adverse reaction or illness, including an allergenic response? Please detail the nature and extent of any such adverse effects	
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? Please provide copies of the referenced studies.	
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?	

6. Additional information	
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.	