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

4 December 2015
[30–15]

Call for submissions – Proposal P1024

Revision of the Regulation of Nutritive Substances & Novel Foods

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FSANZ has assessed a Proposal to investigate the regulation of nutritive substances and novel foods in the Australia New Zealand Food Standards Code. Pursuant to section 72 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist further consideration of the Proposal.

For information about making a submission, visit the FSANZ website at information for submitters.

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at information for submitters.

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on documents for public comment. You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

EXTENDED DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 24 March 2016

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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Supporting documents

The following documents which informed the assessment of this Proposal are available on the FSANZ website at http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1024revisio5756.aspx.

SD1 Qualitative Assessment of Costs and Benefits
SD2 Assessment of Risks and Safety Data Requirements for New Foods
SD3 Eligible Food Criteria
SD4 Overview of International Regulatory Approaches
SD5 Consideration of Policy Guideline on Substances other than Vitamins and Minerals

Executive summary

The *Australia New Zealand Food Standards Code* (the Code) prohibits food for sale in Australia and New Zealand from containing nutritive substances or novel foods unless an express permission is listed. Nutritive substances are those substances that are intended to be added to food to achieve a nutritive purpose, and include vitamins, minerals, amino acids and electrolytes. Novel foods encompass a broader range of foods, including substances that are intended to be added to foods (or sold as foods themselves) for a variety of reasons, including beneficial health effects. Permissions in the Code are listed only after FSANZ has conducted an assessment and is satisfied the foods are safe for consumption.

The Proposal seeks to improve the regulation of nutritive substances and novel foods to ensure appropriate pre-market safety assessment of these foods before they are sold in Australia and New Zealand. The Proposal aims to develop provisions that protect public health and safety while being objective, enforceable and proportionate with risk so that industry is not subject to an unreasonable regulatory burden. The Proposal relies on an evidence base that is informed by more than ten years of applying the current novel food and nutritive substance provisions. International approaches have also been taken into account in developing the options.

The current Code provisions relating to nutritive substances and novel foods, particularly the definitions associated with them, are creating uncertainty in the market place. The uncertainty relates to whether particular foods require permission in the Code before they can be sold in Australia and New Zealand; and therefore whether the foods should be subject to pre-market assessment by FSANZ. This presents different risks for industry and food enforcement agencies in particular.

FSANZ has assessed these risks and considers the status quo (option 1) is not an option that will address the risks associated with the uncertainty with the current Code provisions. Two options that may address the risks are presented in this assessment summary. Option 2 involves a minor amendment of the current standard: to amend the current provisions, primarily the definitional elements associated with nutritive substances and novel foods. The third option is more innovative: to develop an alternative approach based on the level of risk inherent in various types of novel food (a graduated risk approach). This is FSANZ's preferred option.

To facilitate stakeholder input into the development of an alternative approach and to inform a decision on whether to prepare a draft variation, FSANZ has prepared a draft framework for discussion. The graduated risk approach is a significant change from the current Code approach; and is presented in this report for discussion with stakeholders about potential alternative approaches. The approach includes draft criteria to identify low risk foods that would not require regulatory pre-market approval. These foods could be sold, subject to basic pre-market self-assessment requirements being satisfied by industry. Foods not meeting the criteria would be subject to additional pre-market assessment, either an industry pre-market assessment and notification pathway or the FSANZ pre-approval assessment process.

The Proposal includes consideration of the potential for closer alignment with the New Zealand Food (Supplemented Food) Standard 2013 and a review of the exclusive permission provision in Standard 1.5.1 – Novel Foods.

There will be two rounds of public comment for this Proposal. This is the first call for submissions relevant to the proposal in order to assist FSANZ's decision in relation to the preparation of a draft variation. Submitters are encouraged to provide comment on all aspects of this Proposal. FSANZ also seeks submissions on potential costs and benefits to inform development of a consultation Regulation Impact Statement, which can be included in a second call for submissions.

1 Introduction

1.1 The Proposal

The purpose of this Proposal is to develop an improved framework for the regulation of nutritive substances and novel foods in the *Australia New Zealand Food Standards Code* (the Code).

Nutritive substances and novel foods are foods that typically do not have a history of safe human consumption. Nutritive substances are those substances that are intended to be added to food to achieve a nutritive purpose, and include vitamins, minerals, amino acids and electrolytes. Novel foods encompass a broader range of foods, including substances that are intended to be added to foods (or sold as foods themselves) for a variety of reasons, including beneficial health effects. These may be newly developed foods that have not previously been consumed by humans, foods from other countries that do not have a history of consumption by Australian and New Zealand populations, or components of foods (or other sources) that have been extracted and refined and are added to foods in a way that differs from their traditional consumption.

Foods without a history of safe human consumption may pose a variety of risks to consumers. FSANZ's primary objective is the protection of public health and safety. The Code includes requirements for these foods to be subject to pre-market assessment of the risks, including toxicological, nutritional and microbiological risks, to determine if the nutritive substance or novel food is safe for consumption. In order to ensure these foods are subject to pre-market assessment, the Code prohibits the sale of novel foods and the use of nutritive substances as ingredients or components of foods, unless permission is included in the Code. Definitions of nutritive substances and novel foods are included in the Code to assist in identifying the type of foods that should be subject to pre-market assessment.

However, it has become apparent that these definitions are not effectively achieving their intended purpose. The definitions include ambiguous terms that create uncertainty in the market place. This uncertainty creates difficulties for industry and food enforcement agencies in determining whether particular foods require specific permission in the Code before they can be added to, or sold as, foods.

This Proposal assesses the impacts of this uncertainty in the market place and how the Code's nutritive substance and novel food provisions could be improved. FSANZ considers improvements to the regulation of nutritive substances and novel foods should be made in keeping with certain principles. In addition to the protection of public health and safety, an approach should be proportionate to the varying levels of risk posed by different types of foods; should be clear, objective and enforceable; should provide industry with the opportunity to access the market quickly and without undue regulatory burden, when appropriate; and should aim to be consistent with international regulations where appropriate.

In assessing the Proposal, FSANZ considers a shift away from the current approach to regulating nutritive substances and novel foods would provide the best opportunity to address these principles. FSANZ has developed a draft framework, based on a graduated risk approach, aimed at addressing these principles. The draft framework has been developed by FSANZ as a starting point for discussion with stakeholders. Comments received from stakeholders will inform the decision to prepare a draft variation to the Code which, if prepared, will be included in the second call for submissions.

Standards 2.9.1 – Infant Formula Products and 2.9.2 – Foods for Infants are excluded from consideration in this Proposal. The Ministerial Policy Guideline on the *Regulation of Infant Formula Products*[1] provides guidance on the pre-market assessment of substances added to infant formula products that will be considered separately by FSANZ as part of Proposal P1028 – Regulation of Infant Formula. Additional proposals may follow on from Proposal P1028 to address other formulae regulated by Standard 2.9.1. Standard 2.9.5 – Food for Special Medical Purposes is also excluded from this Proposal.

1.2 The current regulatory framework

Food businesses are responsible for ensuring the foods they sell are safe and suitable for consumption in Australia and New Zealand. All food sold must meet the requirements of the Food Acts in each Australian state and territory and in New Zealand. The Food Acts include provisions that make it an offence to sell food that is unsafe or unsuitable. A food is unsafe if it would be likely to cause physical harm to a person. A food is unsuitable if it, in brief: is damaged, deteriorated or perished; comes from a diseased animal; or contains an organism or chemical that is foreign to the nature of the food. For the purposes of this proposal we are concerned only with the unsafe food offence.

The Food Acts do not set out objective criteria for what constitutes an unsafe food. Food standards (in the Code) provide that level of objective criteria. Each Food Act provides for the application of the Code in each jurisdiction. Selling a food that does not comply with the Code is an offence under each Food Act. Noting the criteria that standards in the Code provide to support the Food Acts, the Code has an important role in the Australia New Zealand food regulatory system; assisting in ensuring that foods supplied in each country are safe for consumption. The Code provides a measure of certainty, for producers and consumers, about the safety or suitability of food. Food that complies with a standard will not be considered unsafe or unsuitable for the reason dealt with by that standard.

The Code's nutritive substance and novel food provisions should enable food enforcement agencies to rely on non-compliance with the Code for these types of foods when supplied to the market without permission in the Code. Food enforcement agencies should therefore not need to rely on the broad 'unsafe food' provisions in the Food Acts for these types of foods.

1.2.1 The Code provisions

Standard 1.1.1 - Structure of the Code[2] and general provisions - sets out basic requirements for food for sale in Australia and New Zealand. This Standard provides that, unless expressly permitted by the Code, food for sale:

- must not be a 'novel food' (paragraph 1.1.1– 10(5)(b)); and
- must not have as an ingredient or a component a substance that is 'used as a nutritive substance' (paragraph 1.1.1– 10(6)(b)).

Standard 1.5.1 – Novel foods contains permissions for the sale of novel foods that have been assessed and approved by FSANZ. These permissions are listed in Schedule 25. A number of standards contain permissions for the use of nutritive substances.

[1] http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx

[2] All references to the Code in this assessment summary and related SDs are to the revised Code which takes effect and replaces the current Code on 1 March 2016. This is because the gazettal of any draft variation resulting from this Proposal is not expected until after this date, and FSANZ therefore considers it is unnecessary to amend the current Code.

Vitamins and minerals can be used as a nutritive substance if they are permitted in Schedule 17 or in standards in Part 2.9 which relate to special purpose foods. Permissions for the use of other substances as nutritive substances are included in Part 2.9 standards and include substances like amino acids, nucleotides and electrolytes.

Standard 1.1.2 – Definitions used throughout the Code - includes definitions of 'novel food' and 'used as a nutritive substance'. These definitions are intended to identify those foods that should be subject to the pre-market approval requirements of the Code. The definitions are reproduced in Attachment D.

1.3 Rationale for the current framework

Foods without a history of safe consumption may pose a variety of risks to consumers, including toxicological, nutritional and microbiological risks. There are a number of factors which may affect toxicological and nutritional risks, including:

- cultivation, harvest and processing methods
- the composition of the food, particularly the presence of nutrients, toxicants and anti-nutrients or allergens
- levels of consumption of the food
- the metabolism and fate of the food in the human body
- whether the food will be added to multiple foods and the potential for cumulative effects which may result in consumer intakes above levels considered safe for that substance.

Microorganisms can also pose specific risks, which may need to be assessed to ensure they are safe for consumption.

The Code's provisions are intended to identify the foods that should be subject to FSANZ pre-market approval. FSANZ's assessment of these foods, once they have been identified, is not set out in the Code. The FSANZ Application Handbook sets out the type of data that is required to inform the assessment of the risks that apply specifically to nutritive substances and novel foods. More detail on these risks and the type of data that may be needed to assess them is explored in Supporting Document 2 – Assessment of risks and safety data requirements for new foods (SD2).

As part of this Proposal, FSANZ has conducted road-testing of the risks of potential novel foods identified by the FSANZ Advisory Committee on Novel Foods (ACNF) and its predecessor, the Novel Food Reference Group (NFRG)[3]. The ACNF includes representatives from food enforcement agencies and provides opinions on whether certain foods are likely to meet the definition of novel food. These opinions are not legal decisions and are provided for advisory purposes only to assist stakeholders in considering whether certain foods are likely to be subject to the Code's pre-market approval requirements for novel foods.

The views of the ACNF/NFRG highlight some foods with identified or potential safety concerns, based on risks such as those identified above. Table 1 lists some of these foods as examples of foods likely to be considered novel and should therefore be subject to pre-market assessment and approval. The identification, by the ACNF/NFRG, of foods with identified or potential safety concerns highlights the importance of adequate provisions in the Code to ensure foods with these characteristics are assessed for safety before they are supplied to consumers.

[3] The NFRG was a FSANZ internal group that provided updates to food enforcement agencies

Of the 208 foods considered by the ACNF/NFRG, 61 were considered novel, with the remaining 147 considered to be either traditional foods (62) or non-traditional, but not requiring pre-market approval (85). More detail on the road-testing of ACNF/NFRG views is provided in SD3 – Eligible Food Criteria.

Table 1: Examples of some foods considered novel by ACNF

Food	Comments / reason considered novel
Acacia rigidula	This plant was intended to be added as an alternative to DMAA in sports supplement products (see case study at Attachment B). The ACNF noted that *Acacia rigidula*, like DMAA, is likely to have stimulant properties and that the potential for adverse effects should be subject to further assessment of safety.
Dieffenbachia	The ACNF noted this plant had the potential to elicit hallucinogenic properties upon consumption and therefore had the potential for adverse effects that should be subject to further assessment of safety.
Rhodiola rosea, Siberian chaga	The ACNF noted these herbs have a traditional medicinal use and that some are also permitted to be added as active ingredients in complementary medicines in Australia. These herbs are associated with a number of potential therapeutic effects.
Hydroxycitric acid, African mango seed extract	These ingredients were derived from foods that had a tradition of use in certain areas of the world. However, the substances or extracts were either sourced from different parts of the plant that were not normally consumed or were extracted rather than being traditionally consumed. The ingredients were purported to have weight loss effects and the ACNF considered these effects and the potential for adverse effects should be subject to further assessment of safety, particularly for non-target population groups in which weight loss may not be a desired effect.

The requirements for pre-market assessment in the Australian and New Zealand food regulatory system for new foods and substances added to foods are consistent with regulatory requirements in international jurisdictions, such as the European Union, the United States and Canada. That is, there is a common recognition that foods new to the food supply require some regulatory oversight. Additional detail on these international regulatory approaches is provided in SD4 – Overview of International Regulatory Approaches.

1.4 Procedure for assessment

The Proposal is being assessed under the Major Procedure[4] (which means it includes two rounds of public consultation). Stakeholder submissions to this assessment summary will inform a decision on preparation of a draft variation to the Code.

2 The problems with the current Code provisions

2.1 Used as a nutritive substance

The Supreme Court of New South Wales (2009) identified a number of ambiguous terms in the current definition of nutritive substance that made interpretation very difficult[5]. These terms are still included in the revised Code's definition of 'used as a nutritive substance'.

[4] The Major procedure is used when the variation of the food regulatory measure being considered involves a significant change to the scope of the measure and is of significant technical and scientific complexity.
[5] The revised Code definition of 'used as a nutritive substance' replaces the definition of 'nutritive substance'. However, the revised definition maintains the terminology referred to by the Court. Addressing the issues associated with these terms has been reserved for this Proposal.

The terms themselves are not clearly defined elsewhere in the Code. In particular, terms like *normally consumed* and *nutritional purpose* are not defined in the Code. The lack of clear meaning of these terms creates uncertainty and ambiguity in the overarching definition of 'used as a nutritive substance'. This uncertainty makes it difficult to be certain whether particular substances require specific permission in the Code before they can be added to, or sold as, foods.

The major difficulty arises for substances that may be subject to the definition. Vitamins and minerals and other substances that are specifically referred to or have specific permissions in the Code as nutritive substances are straightforward as they are clearly identified as nutritive substances. However, it is a matter of interpretation as to whether substances that are not specifically identified in the Code constitute nutritive substances.

New food substances are being developed as the food industry continues to innovate in the area of functional foods. Many of these substances may be considered to be added for nutritional purposes. It is not possible to predict the exact nature of nutritive substances that may be developed in the future. The current definition attempts to overcome the absence of knowledge of substances yet to be developed by the inclusion of terms like 'normally consumed as a food', and 'achieve a nutritional purpose', which provide flexibility at the expense of certainty.

2.2 Novel foods

'Novel food' is defined in the Code as a *'non-traditional food' that requires an assessment of public health and safety considerations having regard to* (a number of matters which are set out in the definition). Therefore, a novel food must first be considered a 'non-traditional' food. 'Non-traditional' food is also defined.

The definition of 'non-traditional food' includes the term *history of human consumption*, which is not defined in the Code. As such, the definition of non-traditional food is subject to a similar level of uncertainty and ambiguity as the definition of nutritive substance. Therefore, it is difficult to be certain which foods should be considered non-traditional and subsequently whether they should be subject to the second arm of the definition of novel food i.e. whether a non-traditional food *requires an assessment of the public health and safety considerations*. This italicised phrase is also considered to be ambiguous and not clearly defined elsewhere in the Code. However, this ambiguity raises an additional problem to those identified above for the definitions of nutritive substance and non-traditional food. Applying the phrase means that it is a matter of judgment or estimation as to whether an assessment is required. This leads to uncertainty for any particular food (as for nutritive substances and non-traditional foods), but also means that the requirements of the standard itself are based on uncertainty when they should be objective and clearly interpretable.

In addition, the Standard fails to make it clear who is responsible for determining whether an assessment is required and subsequently who should undertake the assessment. Food enforcement agencies have advised FSANZ that this aspect of the definition presents difficulties when determining whether a food is novel or not, particularly in relation to who makes that decision. While a food enforcement agency may consider that an assessment is required (i.e. the food is novel), it is possible for a food business to argue that they have done the relevant assessment and on that basis the food they are supplying is safe and therefore not novel.

The current definition of novel food was included in Standard 1.5.1 after the completion of Proposal P291 – Review of Novel Food Standard. Another outcome from Proposal P291 was to establish the FSANZ Advisory Committee on Novel Foods (ACNF).

The ACNF includes representatives from food enforcement agencies in Australia and New Zealand and was established to provide recommendations with respect to whether foods may meet the definition of novel food. The ACNF's recommendations are published on the FSANZ website. The recommendations provided to FSANZ by the ACNF provide some guidance on whether a food may be considered novel or not. However, the recommendations are not legal decisions and have no legal status.

The existence of the ACNF is an acknowledgement that the definitions of non-traditional food and novel food rely on uncertain concepts, and accordingly, the standard fails to deliver the level of certainty and objectivity required for effective operation of the standard in the food regulatory system.

2.3 Definitional overlap

FSANZ has observed that an increasing number of substances intended to be added to food to achieve a health effect could be considered under both the nutritive substance and novel food definitions. A number of enquiries to the ACNF have been for substances that may be considered in the context of either definition. This overlap is also reflected in the data requirements for applications to amend the Code, in the FSANZ Application Handbook. All applications to amend the Code must meet the requirements of the Application Handbook. The data requirements for applications for nutritive substances and novel foods are very similar, particularly in relation to establishing safety.

3 Risk Assessment

Foods which are new to the food supply may present microbiological, toxicological or nutritional risks, as discussed in SD2. The problems identified in section 2 mean that it is difficult to determine whether a substance or food should be subject pre-market approval by FSANZ in order to determine if these risks have been assessed and managed prior to marketing. It is also not clear who is responsible for determining whether an assessment is required, nor who should undertake the assessment. These difficulties create uncertainty in the market place. The impact of this uncertainty, particularly in relation to risks faced by food enforcement agencies and industry, is explored in this section.

3.1 Food enforcement agencies

Uncertainty creates challenges for food enforcement agencies in determining compliance of food products with the Code and in taking action against food products that are considered by the agency to be non-compliant. This can be particularly problematic when a product being sold to consumers contains an ingredient that a food enforcement agency considers to be a nutritive substance or a novel food that is not listed in the Code. A food enforcement agency may advise the food manufacturer or supplier of this view and recommend the company cease supply and submit an application to FSANZ to have the food assessed for safety.

However, if the food company disagrees with the food enforcement agency's view, the matter may need to be decided in court, which can be costly and time consuming. The absence of objective clarity in the definitions in the Code may make it difficult for a food enforcement agency to establish clearly that a particular ingredient meets one of the definitions. It is possible that even if a food enforcement agency is of the view that a particular food or ingredient meets one of the definitions, the agency may not be willing to take court action to ensure the food or ingredient undergoes a regulatory pre-market assessment before it can be sold.

The risk of court proceedings being decided in favour of the food company, due to the ambiguous nature of the definition(s) in the Code, may be too high for the food enforcement agency to be willing to pursue court action. A case study is provided in Attachment B to illustrate the practical impact of the problems enforcement agencies have faced in relation to taking action against a product containing an ingredient that was likely to be novel.

If the food enforcement agency is concerned that the food or ingredient poses a threat to consumer safety, it may decide to take action based on provisions in other legislation such as the Food Act requirements relating to the supply of unsafe or unsuitable food. However, effective enforcement action for unsafe food can be difficult. The onus of proof is again on the food enforcement agency to establish, beyond reasonable doubt, that the food or ingredient poses an obvious and irrefutable safety concern. It is possible that a court will find in favour of a defendant if there is any uncertainty in relation to a direct causal link between consumption of the food and harm to a consumer. This can be a barrier to successful prosecution in the absence of objective criteria for safety and may discourage a food enforcement agency from pursuing court action.

Food enforcement agencies have advised FSANZ that their ability to remove foods from the market which they consider non-compliant is largely determined by the willingness of food businesses to co-operate and voluntarily withdraw products. Some food businesses may refuse to cease supply or remove from supply products that a food enforcement agency considers non-compliant, knowing that enforcement action is unlikely to progress to court if there are no obvious adverse effects in consumers that can be directly linked with the product.

FSANZ has recently conducted a search on food products being offered for sale on the internet containing ingredients considered by the ACNF/NFRG to be novel but did not have permission in the Code. The search identified a number of the foods considered novel by the ACNF/NFRG that were present in food products offered for sale in niche markets Australia and New Zealand. As noted above the current standard does not clearly identify who is responsible for determining whether a food requires a safety assessment, and therefore should be considered as novel and captured under the requirements for pre-approval. A manufacturer may consider the food to be safe, despite the opinion of the ACNF or may have additional information on safety not available to the ACNF at the time their opinion was issued. As discussed above, this limits the ability of food enforcement agencies to determine compliance with the standard.

3.2 Food industry

The difficulty in interpreting the definitions also creates problems for industry. Food companies may not be certain whether a new food or ingredient requires permission in the Code before it can be sold as food, or as an ingredient in food in Australia and New Zealand. It is therefore difficult to be certain whether a new food may require the submission of an application to FSANZ for regulatory pre-market assessment if there is no current permission for the food in the Code. Even if a food company considers their product is not a nutritive substance or novel food they may be subject to enforcement action if a food enforcement agency has an opposing view. This can create uncertainty for the food company in relation to compliance and potentially interrupt or delay the supply of their product.

Despite this uncertainty, industry has indicated to FSANZ that the current ACNF process is, in their view, a useful avenue for providing clarification on the regulatory status of foods that may potentially be subject to the novel food standard. This is particularly the case for foods that the ACNF does not consider to be novel. The expectation is that for foods the ACNF does not consider to be novel, a regulatory pre-market assessment is not required and the food can be supplied on the market (assuming it meets any other relevant requirements in

food legislation). Over two-thirds of the enquiries submitted to the ACNF have been for foods the committee did not consider to be novel. This suggests that some food industry businesses see the need to seek clarification from the ACNF that their foods are unlikely to be novel, either because they seek assurance or because they are genuinely uncertain. The preparation of enquiries to the ACNF, and the consideration of these enquiries by the committee places a cost on industry and government (participants of the ACNF) that not be present if the Code's provisions were more clearly objective, efficient and proportionate to risk.

Compared to the number of enquiries to the ACNF and international approvals of novel foods, FSANZ receives few applications for the assessment of novel foods. This may be partly due to the problems associated with interpreting and enforcing the novel food provisions (i.e. why submit an application for assessment if it is arguable as to whether your food meets the definition of novel food?) as well as the cost of supporting an application for a novel food, taking account of the relatively small size of the Australian and New Zealand food market in a global context.

3.3 Summary of risk assessment

The risk assessment shows that there is a risk that the current regulatory regime is not adequately identifying foods requiring pre-market approval and that this creates uncertainty for food enforcement agencies and industry.

Questions:

How do the current novel food and nutritive substance definitions affect your organisation, either as a food business or a food enforcement agency?

Do you believe there are problems with the current definitions in addition to those outlined in the assessment summary? If so, describe the problems.

Do you believe there are problems with the current provisions more broadly (not just the definitions) in addition to those outlined in assessment summary? If so, describe the problems.

4 Risk Management

4.1 Risk management considerations

This section identifies the risk management considerations taken into account in developing options to improve the management of risks of unapproved foods entering the food supply due to the deficiencies noted in the current regulatory approach. The purpose of pre-market assessment approaches is to determine the safety and required mitigation measures prior to food entering the food supply. This is a fundamental principle in the Australia New Zealand food regulatory framework and ensures that the potential risks posed by certain foods (such as those without a history of safe consumption) are adequately addressed before these foods are sold to consumers. Section 1.3 (and SD2 and SD3) identifies the potential risks posed by new foods. The evidence from the consideration of new foods by the ACNF, from incidents relating to unsafe foods in Australia and New Zealand and the safety concerns that have been raised during assessments of applications by FSANZ and other regulators, indicate that novel foods can pose safety concerns which need managing. As noted above, reliance on the Food Acts or the existing standard to manage these risks is an inadequate risk management measure.

FSANZ's primary objective in standards development is the protection of public health and safety and this is the primary consideration FSANZ has taken into account in developing and assessing options. FSANZ has taken other secondary considerations into account, noting that options should be proportionate to the varying levels of risk of new foods entering the market; should be objective, clearly understood and enforceable; and should provide industry with the opportunity to access the market quickly and without undue regulatory burden. Compatibility with international approaches to the regulation of novel foods is also a consideration in formulating an amended approach.

FSANZ considered the option of relying on the Food Acts and a post-market approach only (in the absence of Code requirements), but rejected this for the reasons outlined in section 4.1.1.

Consideration of how regard can be given to policy guidance provided to FSANZ by Ministers is introduced in section 4.1.2.

4.1.1 Post-market versus pre-market approach

If the nutritive substance and novel food provisions were not included in the Code the foods and substances intended to be covered by these provisions would no longer be subject to pre-market assessment requirements in the Code. These foods would be subject to the general safe and suitable provisions of Food Acts and there would be a heavy reliance on post market measures to determine compliance with these provisions. Section 3.1 has identified the difficulties faced by food enforcement agencies in relying on the safe and suitable provisions of Food Acts to take enforcement action. Section 1 has identified the important role the Code plays in supporting the Food Acts by providing criteria for what constitutes an unsafe food.

The identification of adverse effects is not likely to be straightforward in a post market environment. Serious acute adverse effects may be identified if they are reported to appropriate authorities. However, the identification of chronic adverse effects is difficult in a post market environment. It is unlikely that chronic adverse effects will be reported to food authorities, as the cause of the chronic effect may not be identified. This highlights the limitations of relying on post-market measures without the support of clear and enforceable pre-market requirements. The potential for foods to cause chronic toxicity can be identified and incorporated into pre-market assessment requirements.

Therefore FSANZ considers a pre-market assessment approach to the regulation of nutritive substances and novel foods remains valid. The approach FSANZ has developed is focussed on a pre-market approach.

4.1.2 International regulation of new foods

FSANZ has identified the approaches taken in comparable international jurisdictions to address the safety of new foods. These are described and assessed in SD4. The European Union, Canada and the United States of America each have regulations that take a pre-market regulatory approach to establishing the safety of new foods in the food supply. The nature of the pre-market approach differs in each jurisdiction, including the types of foods captured by the regulations, the reliance on definitions and the balance between self-assessment and regulatory approval. FSANZ has taken account of these in developing its proposed approach to manage the risk of new foods entering the food supply. In particular, FSANZ has utilised the following aspects in developing the alternative graduated risk approach presented in section 4.2.3 of the assessment summary:

- A cut-off date for presence in the market (EU, USA) can provide an objective parameter to assist in identifying new foods and substances that require pre-market assessment.

- Industry self-assessment of safety can provide a more streamlined process for industry in relation to the time it takes to get a new product into the market (US, Canada), although the levels of transparency and regulatory oversight are important considerations to take into account.

- A demonstrated history of safe use of a food in other markets can provide a level of confidence in the assessment of safety of new or novel foods (EU, Canada).

- Combining nutritive substances and novel foods, as in Canada, may address some of the difficulties associated with distinguishing these types of substances.

4.1.3 Self-assessment and pre-approval pathways

FSANZ considers that there are graduated levels of risk arising from new foods entering the market. This has been addressed in SD3. A graduated risk management approach may therefore be appropriate to manage those risks. A proportionate approach could include options for a graduated approach to pre-market assessment requirements, including self-assessment by industry, through to a full pre-approval process involving independent risk analysis by FSANZ, dependent on risk.

4.1.4 Ministerial policy guidance

The FSANZ Act requires FSANZ to have regard to ministerial policy guidelines (subsection 18(2)) when developing or reviewing food standards. The Ministerial Policy Guideline on the *Addition of Substances other than Vitamins and Minerals*[6] (the Policy Guideline) is relevant to this Proposal because it provides guidance on the intentional addition to food of substances (other than vitamins and minerals) that are not intended to be consumed as foods in their own right. Substances in the policy context could be as broad as foods that are always used as ingredients or as crude or refined extracts or as highly refined extracts that are sufficiently pure to be chemically specified. Only the latter category is regarded as 'substances' in the context of this Proposal.

The Policy Guideline states:

The addition of substances other than vitamins and minerals to food where the purpose of the addition is for other than to achieve a solely technological function should be permitted where:

a) the purpose of adding the substance can be articulated clearly by the manufacturer (i.e. the 'stated purpose'); and
b) the addition of the substance to food is safe for human consumption; and
c) the substance is added in a quantity and a form which is consistent with delivering the stated purpose; and
d) the addition of the substance is not likely to create a significant negative public health impact to the general population or sub population; and
e) the presence of the substance does not mislead the consumer as to the nutritional quality of the food.

[6] http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx

More detail on these specific principles, including how they are currently addressed in the context of amending the Code to add permissions for new substances, is provided in SD5 – Consideration of Policy Guideline on Substances other than Vitamins and Minerals. How these principles may be addressed in the context of the alternative approach presented by FSANZ (section 4.2.3) is provided in section 4.3.2.

4.2 Options

Taking into account FSANZ's assessment (section 3), the risk management principles identified in section 4.1, and comments received in response to the consultation paper released in March 2012 (section 8.1.1) FSANZ has investigated potential options to improve the regulation of the type of foods intended to be captured under the existing nutritive substance and novel food provisions in the Code.

Three options are outlined below. FSANZ prefers option 3 and has presented a draft framework for discussion as a possible way of developing an alternative approach to the current regulation of nutritive substances and novel foods.

The costs and benefits of each option are discussed in more detail in SD1 – Qualitative Assessment of Costs and Benefits.

4.2.1 Option 1: Status quo

In any consideration of changes to regulation the status quo must be a part of FSANZ's assessment. Maintaining current provisions for nutritive substances and novel foods in the revised Code would not address the lack of legal clarity and enforcement issues discussed earlier. The continuation of current provisions would not effectively manage the current uncertainty associated with them.

The status quo could maintain a reliance on an ACNF type process to provide advice on whether certain foods are likely to be considered novel or not. The status quo would also maintain the requirement that industry should submit applications to FSANZ for the approval of all nutritive substances and novel foods, which is an approach that may not be commensurate with the risk of all these substances and foods and therefore may impose undue regulatory burden on industry for foods that are low risk. The ineffectiveness of the current provisions highlights the opportunity to investigate alternative options that are based on risk and an evaluation of previous experience.

Questions:

Are there elements of the status quo that you support maintaining in the Code? If so, please provide details and reasons for your support.

Can you identify any problems with the status quo in addition to those highlighted in this report? If so, please provide details.

4.2.2 Option 2: Amend the current definitions

Under this option the reliance on definitions of nutritive substance and novel food to identify the foods that would be subject to pre-market approval would be retained. However, the definitions would be amended to improve identification of these foods and substances as far as possible.

When it was added to the Code in 2000, the definition of nutritive substance did capture most nutritive substances in the regulatory sphere at the time. Indeed, a number of these nutritive substances are specifically listed in the definition of nutritive substance in Standard 1.1.1 or by virtue of the permissions for substances to be 'used as a nutritive substance' in other standards. It is therefore quite straightforward to identify those vitamins, minerals, amino acids, electrolytes and nucleotides as nutritive substances (and therefore prohibited from being added to food unless they are permitted elsewhere in the Code). As noted in section 2.1, the major difficulty with the current definition of nutritive substance arises for other substances that are not listed.

The current definition of novel food was an outcome of P291, which took account of significant stakeholder input, particularly into the definition of novel foods. The approach relies on identifying foods which require a pre-market approval. The ACNF was established to provide a way to consider whether certain foods were likely to meet the definition of novel food. The ACNF uses a guidance tool[7] to help interpret the definition, particularly the term 'history of human consumption'. The guidance tool outlines the type of information that can influence the consideration of whether there is a history of human consumption, including the length of use, the extent of use in the population, the quantity of the food consumed in a traditional context and the context of use (e.g. food versus traditional medicinal use).

However, the need for the ACNF and the guidance tool highlights the difficulty in objectively defining terms like 'history of human consumption' in a way that ensures consistency of interpretation while also ensuring that a definition does not capture too much or too little in terms of foods requiring pre-market approval. Attempting to refine the problematic terms included in the definition of nutritive substance would also be subject to similar difficulties, particularly as the nature of these substances and novel foods is likely to continue to change as the food industry continues to innovate. This option could use a cut-off date, as used in the EU and US, in addition to amended definitions, to partly improve the clarity of capture of foods requiring pre-market approval.

It may be possible to draft definitions that are either quite broad (and therefore capture low risk foods) or narrow and specific. Noting the increasing overlap between substances that could be considered to meet both definitions (section 2.3) it would be possible to combine them into one definition.

The use of a definition to capture foods requiring pre-approval may not foresee future developments in food production, which could result in new foods not being captured by the definition. These issues may result in similar problems to those currently being experienced by food enforcement agencies and/or the need to constantly update the definition to include new developments.

It is noted that the use of definitions by other international jurisdictions has also proven to be problematic.

FSANZ has not drafted new definitions for nutritive substances and novel foods at this stage of the Proposal, but encourages suggestions from stakeholders.

[7] Available from FSANZ website: http://www.foodstandards.gov.au/industry/novel/Pages/default.aspx (click on link under heading "How do I enquire about whether a food is novel?")

Questions:

Do you support amending the definitions of 'novel food' and 'used as a nutritive substance' in the Code? If so, FSANZ welcomes reasoned suggestions for amended definitions that will address the problems identified in sections 1 and 2.

4.2.3 Option 3: Develop an alternative framework

The review of the existing novel food standard provides an opportunity to address the deficiencies identified in terms of the lack of clarity of capture of foods requiring regulatory approval and who is responsible for making the assessment of novelty It also provides an opportunity to build on many years of experience with considering the safety of new foods to develop an approach which is proportionate to risk.

Different foods have different risks. The safety of low risk foods can be managed through measures other than requiring pre-market regulatory approval. Higher risk foods might require a mix of measures including pre-market assessment. FSANZ considers an alternative to the current Code approach may be required to provide improved clarity and certainty in relation to the regulation of nutritive substances and novel foods.

FSANZ has developed a draft framework as an example of what could be achieved with an alternative approach (described below, with additional detail in Attachment C). The draft framework is intended to provide greater clarity in the identification of foods that require pre-market approval and greater opportunity for proportionate and streamlined assessment processes to assess the safety of new foods entering the marketplace in Australia and New Zealand. The draft framework would only apply to new foods not previously marketed. It would not be applied retrospectively to foods that were marketed under the existing Code requirements for nutritive substances and novel foods. It would therefore improve clarity by not relying on a definition of traditional use.

The draft framework takes a proportionate approach to risk and has three main elements:

1. Identifying foods which do not require regulatory approval before market entry

    - The Code would permit the sale of new foods that meet 'eligible food criteria'. The criteria would be set out in the Code. A draft set of criteria have been developed for discussion.

2. Pre-market assessment routes for market entry of all other foods

    - Foods that do not meet the 'eligible food criteria' would require pre-market assessment before they could be supplied in the marketplace in Australia and New Zealand. The pre-market assessment may be an industry self-assessment process or a regulatory assessment process.

3. A description of data and dossier requirements needed to establish safety and impact on public health of new foods

    - The type of information that is needed for each pre-market assessment route; and how this information should be analysed and interpreted to determine whether a food is safe for human consumption and its potential impact on public health.

Each of these elements of the draft framework is summarised below. More detail on the development of the draft EFC is provided in SD3.

More detail on the second and third elements of the draft framework is provided in Attachment C.

The graduated risk approach is presented as an example of an approach that could work in the context of the existing legislative requirements of the food regulatory system in Australia and New Zealand. FSANZ has presented detail on identifying foods that require regulatory approval while presenting principles of alternative assessment processes for these foods. FSANZ is presenting this approach to encourage discussion among stakeholders on potential alternatives that will improve the regulation of nutritive substances and novel foods. FSANZ encourages stakeholders to provide submissions in response to this assessment summary, which will be used to inform a decision in relation to the preparation of a draft variation to the Code and a second call for submissions.

4.2.3.1 Identifying foods that do not require regulatory approval

Pre-market approval is currently required for novel foods and new nutritive substances. A graduated risk approach could retain this general approach but with a requirement for pre-market assessment of a more limited range of novel foods (including novel nutritive substances).

Eligible food criteria

One method of identifying foods that do not require regulatory approval is to establish criteria. FSANZ has developed a draft set of criteria for discussion based largely on the considerations of the NFRG and the ACNF over more than a decade. The draft set of criteria have been termed 'eligible food criteria' (EFC). The EFC could be an initial risk management measure under an alternative framework to ensure foods of unknown risk do not enter the food supply without appropriate pre-market assessment while also ensuring that known low risk foods can be sold to consumers without undue regulatory requirements. In this context, the intent of the EFC is the same as the current nutritive substance and novel food provisions in the Code. However, while the existing provisions rely on definitions to prohibit certain foods, the EFC would more objectively identify foods that are permitted to be sold without regulatory pre-approval. The EFC identify microorganisms, whole foods, minimally processed whole foods, extracts and substances that are considered to be low risk.

Although the EFC are intended to identify known low risk foods, food businesses are still required under the Food Acts to ensure that the food they intend to supply is safe. For compliance purposes the Code would need to include specific record keeping requirements that food businesses would need to meet to support the safety of their eligible food. For example, a history of safe consumption of the product in another country could be information that would help establish that an eligible food is safe for Australian and New Zealand consumers.

The Code would list the EFC and include a provision that novel foods that meet any of the EFC can be sold in Australia and New Zealand without being subject to regulatory pre-market assessment requirements in the Code.

The Code would also include record keeping requirements that food businesses would need to meet to support the safety of an eligible food that is supplied for sale. Failure to hold these records would mean a food business would be supplying a food in contravention of the Code's requirements.

Exclusions to the EFC

Some foods that would otherwise meet the EFC may have characteristics that warrant pre-market assessment. For example, there are foods that the ACNF has consistently identified as:

- requiring pre-market assessment to establish safety (e.g. foods with purported weight loss and/or pharmacological properties),
- having the potential for adverse effects if consumed by non-target population sub-groups (e.g. children, pregnant and lactating women, elderly, immunocompromised), and/or
- being a segment of the market prone to misuse by certain suppliers (e.g. foods marketed as weight loss products have been observed to contain illegally added prescription medicines).

On this basis, FSANZ has developed exclusions to the EFC. These foods must undergo pre-market assessment along the potential pathways described in section 4.2.3.2 even if they would otherwise meet the EFC.

Questions:

Are the EFC appropriate for identifying foods that do not need regulatory approval?

Are there foods that may meet the EFC that you consider should be subject to pre-market assessment? If so, please describe the properties of these foods.

Are there foods that would not meet the EFC, but you consider should be eligible? If so, please describe the properties of these foods.

What type of information should be held by food businesses to support the safety of eligible foods? Please describe the type of information and why this would support safety.

Are the exclusions to the EFC appropriate in identifying foods that should be subject to pre-market assessment, despite otherwise meeting the EFC?

What do you consider would constitute a 'reasonable potential' for a food to have pharmacological effects at the intended levels of consumption? See SD3 for discussion on this issue.

4.2.3.2 Pathways for market entry of foods not meeting the EFC

Under FSANZ's draft framework, foods that do not meet any of the EFC would be subject to more extensive pre-market assessment than eligible foods before they could be sold in Australia and New Zealand. FSANZ has considered whether an industry self-assessment pathway may be viable for these foods, or for at least a subset of these foods.

Industry self-assessment

At present, all nutritive substances and novel foods must be assessed and approved by FSANZ before they can be sold. An industry self-assessment pathway may provide industry with greater control over time to market for new foods and timing of the release of proprietary information relevant to establishing safety than is currently afforded by the FSANZ pre-approval assessment process.

As part of a framework for industry self-assessment, FSANZ considers 'non-eligible foods' should be subject to 'gateway tests' to determine an appropriate assessment pathway, i.e. industry self-assessment or assessment by FSANZ (discussed below in section 4.2.3.4). Appropriate gateway tests will need to be developed if this draft framework is to be progressed. However, it is possible the scope of foods that could progress down the industry self-assessment pathway would be narrow at first, with the potential to broaden the scope after further consideration, either as part of this proposal or after the implementation of a future standard in the Code.

There may be concern that an industry pre-market assessment pathway without any transparency and reduced regulatory oversight will reduce confidence in the safety of new foods supplied on the market. Therefore, the draft framework includes a condition that self-assessment would involve the preparation of a dossier by a food business that supplies the non-eligible food. FSANZ also considers that dossiers should be made public to ensure public accountability and confidence. This could be achieved by the food business submitting the dossier to food regulators/authorities, who then publish the dossier online. More detail on the content and publishing of dossiers is provided in section 4.2.3.3.

In summary, a self-assessment pathway to market for a non-eligible food could operate according to the following process:

1. The food meets a gateway test and is therefore suitable for self-assessment by a food business

2. The food business[8] establishes the food as safe for consumption at the intended levels of use (subject to the data and assessment requirements in the Code and guidelines)

3. The food business notifies food regulators/authorities of its intention to market the food and submits a dossier which is published online (dossier details discussed in section 4.2.3.3)

4. The food business markets / supplies the food to consumers or to food manufacturers who may use the food as an ingredient in processed foods.

4.2.3.3 Data and dossier requirements

Content of dossiers

FSANZ expects the requirements for dossiers establishing the safety of foods would be similar to those for applications submitted to FSANZ for approval of foods. In addition, the analysis and weighing up of data should also result in an outcome that would be consistent with a FSANZ (or other expert body) assessment, including consideration of risk management measures that may be required (such as preparation instructions or other labelling considerations). Dossiers would need to evaluate the safety of the food in the context of its intended use in foods, including levels of use and the type of foods it may be added to.

In order for an industry self-assessment process to work effectively, the data and assessment requirements would need to be clearly set out in the Code, with guidance material supporting these requirements.

[8] The nature of the food business (for example, manufacturer, supplier, retailer) required to establish the safety of the food and notify food regulators/authorities is discussed in more detail later in this section under the heading *Dossier requirements – publication'*

These requirements would need to be clear so that industry can effectively assess the safety of applicable 'non-eligible' foods, food enforcement agencies can assess the dossiers for compliance, and consumers are satisfied that an appropriate process is in place to ensure the safety of foods supplied in the Australian and New Zealand markets. More detail on this process will be developed as part of this proposal if the draft framework, or elements of it, is supported.

The type of food business that will need to develop a dossier and notify food regulators/authorities will vary. Ingredient manufacturers may prepare and submit a dossier for the safety of their ingredient. A final food manufacturer using the new ingredient in their final food would not need to prepare a dossier if the use of the ingredient was consistent with the data in the dossier prepared by the ingredient manufacturer. The final food manufacturer would need to verify the use of the ingredient in the final processed food product complies with the parameters assessed in the dossier (such as levels of use and any risk management measures that may be appropriate). This would be similar for retailers of final processed food products. The retailer would need to have assurance that compliance and verification with the Code has been established by the ingredient manufacturer. The detail of dossier requirements, including notification, will be developed if the graduated risk approach proceeds.

Publication of dossiers

FSANZ considers it may be necessary for submitted dossiers to be published online to provide an element of transparency, public accountability and a level of assurance for consumers and consumer groups that food being supplied for sale is safe. This dossier submission and publication process would mean that some proprietary information will be publicly available. However, unlike the FSANZ assessment process, the timing of the release of this information would be controlled by the food business and could be timed to coincide with the release of the product, rather than being foreshadowed before the marketing of the product (once approved by FSANZ). Consideration would need to be given to providing an option for confidential commercial information to be made available only to food regulators/authorities, rather than being included in the publicly available dossier.

The notification and submission of a dossier under the self-assessment pathway outlined above would not constitute an application to amend the Code. The outcome of the food business submitting the dossier is that the dossier is published and the food can be supplied. The dossier would not be assessed by FSANZ and no change to the Code would result from the submission. Food enforcement agencies could choose to take action if they consider a dossier does not meet the assessment requirements set out in the Code.

Implementation and compliance

Food enforcement agencies would be responsible for enforcing the requirements set out in the Code for foods that are self-assessed and for which dossiers have been submitted for publication. The assessment of dossiers in an enforcement context will require an element of knowledge and training for enforcement officers. However, enforcement will be simplified for eligible and non-eligible foods that are supplied without the food business holding sufficient records (for eligible foods) or preparing and notifying a dossier (non-eligible foods) because these situations would not be compliant with the Code's requirements for the supply of self-assessed foods.

The co-ordination of the dossier submission process as well as the determination of compliance and consideration of appropriate evaluation measures will be addressed at the second call for submissions.

The effectiveness of a self-assessment process will also need to be monitored post-implementation, to assess whether the Code's requirements and guidance material are effective or require refinement.

Questions:

Do you regard the investigation of an alternative approach to regulating nutritive substances and novel foods in the Code as a viable option?

In particular, taking account of FSANZ's primary objective of protecting public health and safety, is the draft framework presented in option 3 a viable option? What aspects of the draft framework do you think are viable or not viable? Please provide supporting statements for your view.

Do you have suggestions for the type of foods that would not meet the EFC, but may be suitable for industry self-assessment?

Please provide details of how a self-assessment pathway may or may not provide benefits to industry.

Would notification and publication of dossiers provide enough regulatory oversight and consumer confidence in relation to the safety of new foods? Please support your answer with detail of why you believe this is the case.

4.2.3.4 FSANZ assessment of applications

A food business could choose to follow the self-assessment pathway, or could submit an application to FSANZ to assess the food. An application to FSANZ would need to meet the requirements of the FSANZ Application Handbook, as is currently the case for applications to amend the Code. If the FSANZ assessment recommends the approval of the food, it would be listed in the Code as a permitted food, similar to the existing list of permitted novel foods in Standard 1.5.1.

Some non-eligible foods may require assessment by FSANZ, rather than being suitable for industry self-assessment. These could be foods that do not pass the gateway tests described in section 4.3.2.2 above, or certain exclusions to the EFC that warrant additional assessment by FSANZ.

It is possible that the Application Handbook could be amended to reflect a graduated approach to assessment of different types of 'non-eligible' foods. For example, the data and assessment requirements for foods that are suitable for industry self-assessment should be reflected in the *Application Handbook* for those food businesses that wish to submit an application to FSANZ rather than conduct a self-assessment. It may be possible that other changes to the Application Handbook could be developed as this Proposal progresses.

A flowchart representing a self-assessment pathway of a graduated risk approach is presented in Figure 1 below. The flow chart identifies decision points in considering whether a food can be self-assessed, outcomes based on self-assessment (including reference to where FSANZ guidelines will need to be consulted), points at which a FSANZ assessment is required and the role of post-market surveillance.

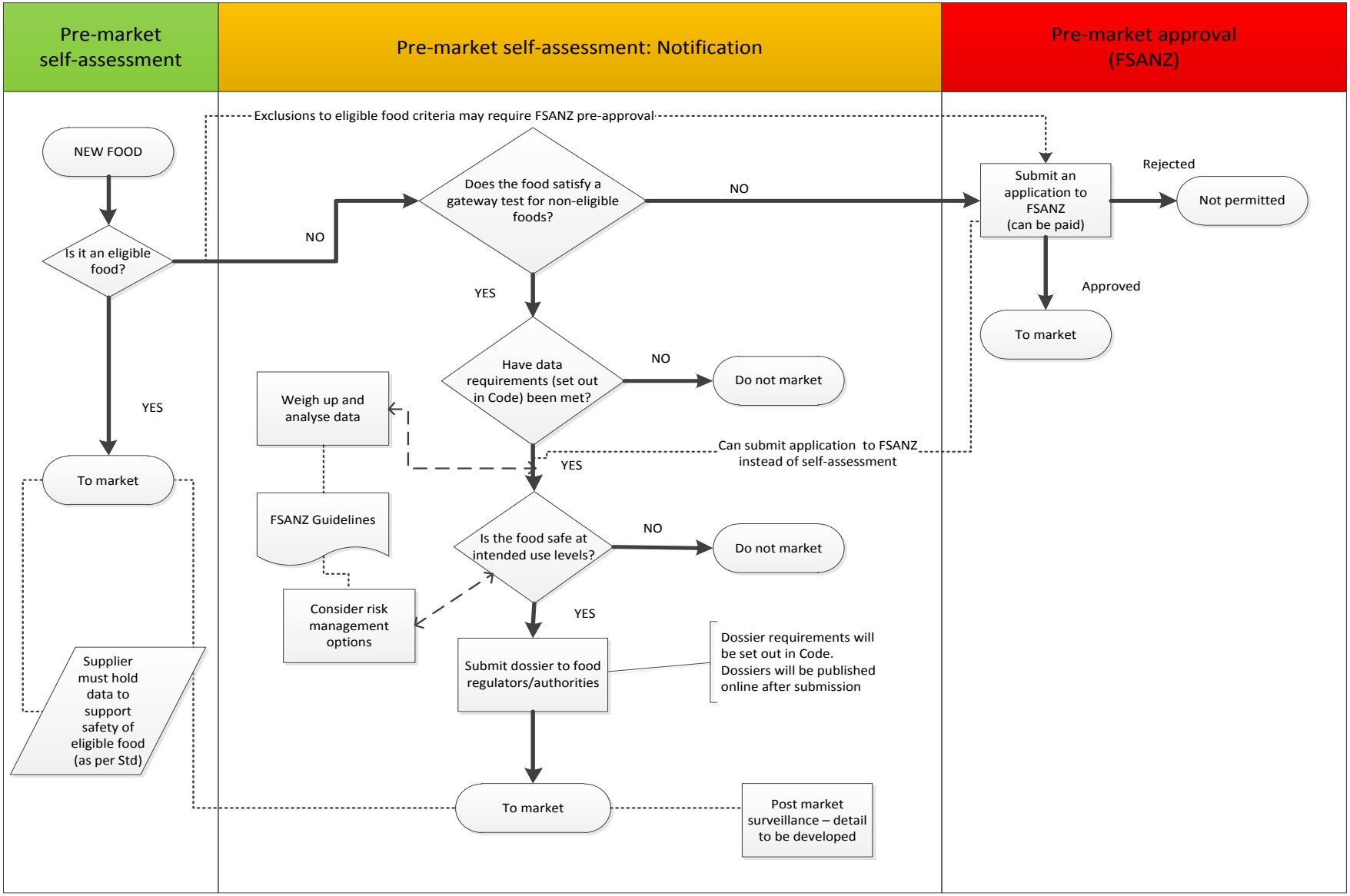

Figure 1. Framework for graduated risk approach – routes to market for new foods

4.3 Draft framework - other considerations

4.3.1 Impact of the draft framework on current standards

Under an alternative framework, the existing nutritive substance and novel food definitions, and the novel food standard, would be extensively revised. As noted in section 2.3, there is an increasing degree of overlap in relation to substances added to food to achieve a health effect that may meet both the definition of nutritive substance and novel food. In addition, the data requirements to establish safety of these substances are very similar (as evidenced in the *Application Handbook*).

Under an alternative framework, FSANZ considers there may be no need for the separate regulation of nutritive substances and novel foods in the Code other than vitamins and minerals which are specifically addressed by existing standards, particularly Standard 1.3.2 – Vitamins and Minerals. In addition, the need for maintaining definitions of nutritive substance and novel food would be removed. However, existing permissions for nutritive substances and novel foods in the Code would be maintained though these terms may not be used. Potential impacts of an alternative framework on current standards are explored in more detail in Attachment D.

Questions:

Can you identify any negative impacts that may result from combining the regulation of novel foods and nutritive substances (other than vitamins and minerals) that may occur under a graduated risk approach? Please explain these impacts.

4.3.2 Policy guidance

The draft framework primarily focuses on ensuring safety of the substance for human consumption, which is FSANZ's primary statutory objective. The Ministerial Policy Guideline (see section 4.1.4) also identifies three other issues to consider, namely:

- the stated purpose for adding the substance and the consistency to deliver this purpose
- the potential for the addition of the substance to create a significant negative public health impact to the general population or sub population
- the potential for consumers to be misled about the nutritional quality of the food containing the added substance.

How these issues might be addressed under the draft framework requires further consideration. Some initial considerations are provided in Attachment C and SD5.

4.3.3 International consistency

FSANZ has taken international approaches (to the regulation of nutritive substances and novel foods) into account in developing the draft framework. Although the legislative frameworks differ between international jurisdictions, some elements of international approaches have been incorporated into the draft framework. Additionally the draft framework may include as a 'gateway test' for the self-assessment route, the approval of a novel food by an overseas authority.

4.4 Assessment conclusion

After assessing the risks created by the uncertainty associated with the current provisions for nutritive substances and novel foods in the Code (section 3), and having regard to the criteria in section 59 and subsection 18(2) of the FSANZ Act and other risk management considerations, FSANZ considers option 3 will provide the greatest opportunity to address these issues. Maintaining the status quo will not address these risks (option 1). Amending the definitions of 'used as a nutritive substance' and 'novel food' may address these risks in part, but may also be subject to the existing issue of uncertainty faced by the current reliance on definitions to identify these foods (option 2).

Option 3 recognises an alternative approach may be required to more effectively address the risks identified in this assessment. The draft framework for an alternative approach presented by FSANZ in section 4.2.3, which would fit within the current food regulatory environment, illustrates one way of thinking about a new approach that would provide more objective identification of foods that do or do not require pre-market approval; risk-proportionate approaches to assessing foods that require pre-market assessment; and better enforceability. All foods would require a pre-market assessment but the routes to market, the data requirements and the level of regulatory oversight would be proportionate to risk or uncertainty. Eligible food criteria are used to identify low risk foods. A 'gateway' test will be developed to identify foods which may undergo a self-assessment with notification to regulatory authorities. Higher or unknown risk foods would require assessment by FSANZ as currently.

FSANZ has presented the draft framework to provide a starting point for meaningful discussion and input from stakeholders to inform a decision in relation to preparation of a draft variation to the Code.

A qualitative assessment of the costs and benefits of introducing a new approach to novel foods has been prepared (SD1). Insufficient information is available currently to determine the net benefit of the options to the community. However this preliminary analysis indicates that Option 3 may perform better than the other options against the objective of providing a cost-effective way of protecting public health and safety.

5 FSANZ Act assessment requirements

When assessing this Proposal, FSANZ has had regard to the following matters in section 59 of the FSANZ Act:

5.1 Section 59

5.1.1 Cost benefit analysis

FSANZ has prepared a qualitative assessment of costs and benefits of the options described in section 4.2 above (SD1). The cost benefit assessment suggests that maintenance of the status quo is not an option. The analysis also suggests that the potential costs of either of the two other identified options will not exceed the value of the anticipated direct and indirect benefits to the public. FSANZ seeks comments on this qualitative assessment in order to inform a decision in relation to preparation of a draft variation which, if prepared, will require development of a consultation Regulation Impact Statement and a 2nd call for submissions.

5.1.2 Other measures

FSANZ has not yet made a decision on the development of a food regulatory measure.

However, the preliminary cost benefit analysis suggests that Option 3, the alternative graduated risk approach measure, is the most cost-effective response to the regulatory issue that has been identified (see above). FSANZ at this stage remains unaware of any measure which would be more cost effective in addressing that issue. FSANZ seeks comments on this assessment to inform its decision on preparation of a draft variation.

5.1.3 Any relevant New Zealand standards

FSANZ has had regard to the *New Zealand Food (Supplemented Food) Standard 2013*, which is a New Zealand only standard. Standard 1.5.1 is a joint Standard.

5.1.4 Any other relevant matters

See matters considered below.

5.2 Addressing FSANZ's objectives for standards-setting

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

5.2.1 Protection of public health and safety

This Proposal is intended to improve protection of public health and safety by better managing the entry and removal of new foods or substances for which safety has not been established to or from the food supply.

5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

Not relevant.

5.2.3 The prevention of misleading or deceptive conduct

Not relevant

5.3 Subsection 18(2) considerations

FSANZ has also had regard to the matters listed in subsection 18(2):

- **the need for standards to be based on risk analysis using the best available scientific evidence**

The principle of pre-market assessment of certain foods, such as nutritive substances and novel foods has previously been established in the development of the existing standards in the Code and similar international regulations. FSANZ has assessed the risk associated with the uncertainty created by the current nutritive substance and novel food provisions in the Code. While FSANZ considers a pre-market assessment is warranted for certain foods, an alternative approach to the current regulation of nutritive substances and novel foods in the Code may better address the risks identified in FSANZ's assessment. The draft framework accompanying option 3 has been informed by the analysis of over a decade of experience with the novel food standard, including consideration of the views provided by the NFRG and ACNF. The responses to this call for submissions will inform the decision in relation to the preparation of a draft variation which, if prepared, will be subject to a second call for submissions and further risk analysis using the best available scientific evidence and experience of stakeholders.

- **the promotion of consistency between domestic and international food standards**

This proposal has drawn on elements of international regulatory systems and considered consistency with these where possible within the Australia New Zealand legislative environment. There is potential for closer alignment of the New Zealand *Food (Supplemented Food) Standard 2013* with the Code.

- **the desirability of an efficient and internationally competitive food industry**

An aim of this proposal is to facilitate efficiency and an internationally competitive market by creating a more level playing field for the New Zealand and Australian food industry and by being better prepared for future trends and development. The draft alternative framework for regulating nutritive substances and novel foods (option 3) aims to provide a regulatory environment that protects public health and safety while being proportionate with risk; more timely and cost effective; and consistent with minimum effective regulation. It also seeks to maintain the facility for protection of commercially sensitive information and recognition of industry's intellectual property, as far as possible.

- **the promotion of fair trading in food**

The potential for closer alignment of the Code's requirements with the New Zealand *Food (Supplemented Food) Standard* is being investigated in this Proposal. Closer alignment of these regulations will provide a more level playing field between Australian and New Zealand food manufacturers (section 6.1). Improved Code provisions that are clearer and more enforceable will also promote consistency in requirements that need to be met by industry.

- **any written Policy Guidelines formulated by the Ministerial Council**[9]

The Australia and New Zealand Ministerial Forum on Food Regulation has approved two policy guidelines applicable to this Proposal; the Policy Guideline on Novel Foods, and the Policy Guideline on the Addition to Foods of Substances other than Vitamins and Minerals[10]. These guidance documents have been taken into consideration in the development of this proposal.

6 Other matters

FSANZ will be including consideration of other matters in this Proposal. In particular, the potential for closer alignment of the Code with the New Zealand Food (Supplemented Food) Standard 2013 and a review of the exclusive permission provision in Standard 1.5.1 will be incorporated into this Proposal. More information on these two matters is provided below.

6.1 The New Zealand *Food (Supplemented Food) Standard 2013*

The New Zealand *Food (Supplemented Food) Standard 2013*[11] (the New Zealand Standard) is a New Zealand only standard that applies outside the joint trans-Tasman food standards regulatory system.

[9] Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)
[10] http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx
[11] The New Zealand Food (Supplemented Food) Standard 2013. Available at http://www.foodsafety.govt.nz/elibrary/industry/nzfood-supplementedfood-standard-2013.pdf

It was developed as an interim regulatory arrangement for supplemented food and to specifically regulate 'food-type' dietary supplements that were previously regulated under the New Zealand *Dietary Supplement Regulations (1985)*.

Supplemented food is defined in the New Zealand Standard as:

> *A product that is represented as a food that has a substance or substances added to it or that has been modified in some way to perform a physiological role beyond the provision of a simple nutritive requirement.*

Although it is a New Zealand only standard, supplemented foods that comply with this Standard in New Zealand may be sold as foods in Australia under the Trans-Tasman Mutual Recognition Arrangement (TTMRA) provided the Australian Therapeutic Goods Administration does not conclude that a particular supplemented food is regarded in Australia as a complementary medicine. However, Australian food manufacturers cannot produce and sell supplemented foods in Australia. The products would have to be produced or imported into New Zealand in order to be subject to the TTMRA.

6.1.1 New Zealand Standard versus the Code

The New Zealand Standard provides more liberal permissions than the Code, particularly for the range and amounts of added substances. It adopts the approach of 'permitted unless restricted' or prohibited by reference. Therefore, unless specifically restricted or prohibited, any substance may be added to a supplemented food if the manufacturer/packer for sale/seller determines that it is safe and suitable for the purpose for which it is being added.

Clause 8 of the New Zealand Standard lists the standards in the Code that also apply to supplemented foods. However, the key standards in the Code that regulate use of nutritive substances and novel foods do not apply to supplemented foods, specifically clause 9 of Standard 1.1.1 (the prohibition on addition of nutritive substances to food unless expressly permitted in the Code) and Standard 1.5.1 (Novel Foods, except clause 3 relating to the exclusive use of novel foods). Standard 1.4.4 – Prohibited and Restricted Plants and Fungi of the Code applies to supplemented foods, excluding references to *Hypericum perforatum*, St John's wort, or Hypericine.

Clause 11 of the New Zealand Standard prohibits the presence of any intoxicating substance in supplemented foods. Clause 13 places restrictions on use of certain substances, for example St John's Wort may be used only in herbal infusions and the label must contain a prescribed warning statement. Clause 14 prohibits the use of certain substances (e.g. Black Cohosh and Kava).

Vitamin and mineral permissions in the New Zealand Standard are also more liberal than those in the Code. Vitamins and minerals may be added to supplemented foods with restrictions on the maximum per one day quantity for some vitamins and minerals, which in most cases equate to 50% adult Upper Level of Intake (clause 15). In contrast, the Code permissions in Standard 1.3.2 – Vitamins and Minerals are more moderate and relate to specific food and nutrient combinations[12] with prescribed maximum claims per reference quantity as appropriate of 10-50% of the rRDI (as listed in Schedule to Standard 1.1.1).

Clause 9 of the New Zealand Standard prohibits supplemented foods specifically formulated or marketed for infants or young children under the age of four years. This provision intends that food products specifically for this age group must comply with the relevant standards in

[12] For example, pasta may contain thiamin, iron and 7 other vitamins and minerals.

the Code, including Standard 2.9.1 – Infant formula products), Standard 2.9.2 – Foods for infants and Division 4 of Standard 2.9.3 – Formulated supplementary foods for young children, defined in the standard as being a formulated supplementary food for children aged one to three years).

6.1.2 Potential alignment of trans-Tasman regulations for the addition of substances to foods

The New Zealand Government aims to retain the New Zealand Standard as an interim regulatory arrangement for supplemented food until appropriate permissions are incorporated in the Code. This Proposal may address some of the issues associated with the need for the New Zealand-only standard, and provide a framework for better alignment of trans-Tasman food regulations[13]. This aim aligns with the FSANZ Act that requires FSANZ to have regard to any relevant New Zealand standards when developing or varying a regulatory measure.

The base regulatory approach for the addition of substances to foods differs – the Code prohibits unless permitted (pre-market approach) whereas the New Zealand Standard is open and prohibits by reference (post market approach).

It is possible that improved regulation of nutritive substances and novel foods in the Code may assist in more closely aligning the Code and the New Zealand Standard. The ideal outcome is for the New Zealand Standard to be repealed because it is no longer required. Whether this ideal can be achieved as a result of this Proposal remains to be seen. If achieved, this would resolve the current inconsistency in permissions for substances that can be added to supplemented foods under the New Zealand Standard and to other foods regulated under the Code.

FSANZ will continue to work with the New Zealand Ministry for Primary Industries (MPI) throughout this Proposal to address the issues that currently impede alignment of the New Zealand Standard with the Code. MPI has advised FSANZ that it is undertaking further work in relation to the New Zealand Standard, including a survey of existing supplemented foods on the market, which may be of benefit to the assessment of this Proposal.

6.2 Exclusive permission for brand and class of food

Standard 1.5.1 includes a provision that novel foods can be granted exclusive use on the basis of brand and class of food. This provision was added to Standard 1.5.1 when the review of the novel food standard (P291) was completed in 2007. A separate proposal was prepared to consider adding the exclusive use permission provision (Proposal P305). At the time, the then Australia New Zealand Food Regulation Ministerial Council requested FSANZ review this provision within three to five years after that date. FSANZ is including a review of this provision in its consideration of P1024. There is no other section of the Code providing specifically for exclusivity.

The permission for exclusive use provision was introduced to Standard 1.5.1 in recognition of the investment made in developing a novel food or ingredient and the need to achieve return on this investment, thereby supporting innovation. The Standard provides that an applicant requesting approval of a novel food may also apply for a period of ‘exclusive’ use to apply to a brand or class of food for 15 months.

[13] Vitamin and mineral permissions are not being addressed in this proposal except for possible editorial consequential changes.

At the end of the initial 15-month period, the exclusive use permission reverts to a generic permission for the novel food, and competitors can then market that food under their own brands. However, the Standard does not and cannot prevent approval of second or subsequent applications within that 15-month period for the use of the same novel food (or containing the approved ingredient) by other food companies, providing the application process is undertaken. This situation has occurred once, with two applications being received for conjugated linoleic acid at a similar time, both of which requested exclusive permission for different brands. These applications were rejected on safety grounds, so concurrent exclusive permissions were never gazetted in the Code.

FSANZ has prepared questions for submitters relating to the current exclusive use provision, to ascertain whether the provision achieves its intention, provides value to industry and whether there may be alternative methods of achieving similar effects in the context of the Code, or through other means. FSANZ notes that the European Union proposal for amending the novel food regulation proposes an element of data protection, whereby newly developed scientific evidence or data supporting an application may not be used for the benefit of a subsequent application for a period of five years from the date of authorisation of the novel food (without the agreement of the initial applicant).

Only three novel food applications assessed by FSANZ to date have requested exclusive use permission. As noted above, two of these were rejected. The other application, for the use of phytosterols in cheese, has resulted in the only exclusive permission being gazetted in the Code, which has now expired. There are no current exclusive use permissions for novel foods in the novel food standard.

Under the draft framework presented in section 4.2.3, a potential industry self-assessment pathway for new foods has been included. The self-assessment pathway would not result in a specific permission in the Code for a food that has been assessed as safe by a food business (in accordance with prescribed assessment requirements). Therefore, the current exclusive permission provision in the Code would not apply to the industry self-assessment pathway. However, having greater control over the timing of placing a product on the market and not having to undergo the transparent assessment process (via an application to FSANZ) may provide an alternative benefit for food businesses.

FSANZ will consider the review of the exclusive permission provision in more detail after submissions have been received and during development of a preferred option for the 2nd call for submissions. The revised Code has amended Standard 1.5.1 to recast the exclusive use provision as a condition attaching to approval; however the intent of the provision will still be reviewed as part of P1024.

Questions:

Do you support retaining the provision to grant exclusive permission in the Code for foods approved by FSANZ? Please provide reasons for your view.

Can you identify any issues that may arise if exclusive permissions are available for FSANZ approved foods (with permission provided in the Code), but not available for industry self-assessed foods? Would the self-assessment process for non-eligible foods provide a trade-off against the lack of an exclusive permission for self-assessed foods (section 4.2.3)?

7 Transition and implementation

7.1 Proposed transitional period

Arrangements for the transition from the Code's current nutritive substance and novel foods provisions regime to a new alternative regime will be required for options 2 and 3 considered above.

Given the above-mentioned difficulties with definition, FSANZ considers a cut-off date could be specified – similar to the cut-off date approach for novel foods in the EU and USA. A cut-off date would objectively identify foods that would be subject to an alternative framework in the Code. The cut-off date could, for example, be the gazettal date of a new standard in the Code.

There is also the option of grandfathering provisions applying to foods on the market before that cut- off date. One option may be a 6-month transition period to allow sufficient time to implement new processes to comply with new provisions.

A stock in trade provision may not be required depending on the nature of the grandfathering provisions.

Questions:

Do you support a cut-off date? Please provide reasons for your view.

Do you see a need for grandfathering provisions? Please provide reasons for your view.

Do you see a need for a stock in trade provision? Please provide reasons for your view.

7.2 Implementation

7.2.1 Enforcement and compliance

All suppliers and retailers of the food in question need to comply with the revised provisions. For the self-assessment pathways identified in the draft framework accompanying option 3, it is proposed that the food supplier e.g. the new food ingredient manufacturer or supplier of the whole food needs to meet assessment requirements in the Code. The Code would stipulate the food supplier must satisfy record keeping requirements (for foods meeting EFC for low-risk foods) or prepare and notify / submit a dossier to food regulators/authorities (foods not meeting the EFC). The retailer has to have documentation that compliance and verification with the Code has been established by the supplier.

Further discussions with jurisdictions responsible for enforcement of any new provisions will be required to develop an approach to the implementation of the record-keeping and notification arrangements, should the graduated approach proceed.

7.2.2 Awareness of the new provisions

For both option 2 and 3, in order to achieve efficient and fit-for-purpose implementation of the new provisions, industry, including small and medium enterprises (SMEs), need to become familiar with the new provisions. To address this, FSANZ considers it would be appropriate to work with peak bodies to disseminate the information. This implementation issue can be further explored in a second call for submissions.

FSANZ is also aware that as part of the implementation process, there may be need to include some training for enforcement officers to raise their awareness of, and expertise in dealing with the new provisions.

7.2.3 Post-market surveillance

Post-market surveillance will be a key-issue for Options 2 and 3. This issue can be addressed in consultation with food regulatory agencies and in a 2nd call for submissions.

Questions:

Do you have any concerns regarding the proposed 6 month transition period? Please explain your concerns, noting the length of time the development of any future standard is likely to take and will therefore be clearly signposted before changes are made to the Code.

Do you have any comments regarding the proposal not to allow a stock-in-trade provision during the transition period?

Do you have any suggestions as to which peak bodies should be involved in familiarising industry of the new provisions?

Do you have any suggestions on how the implementation process could be approached, especially with respect to enhancing awareness and understanding of the potential new provisions under Option 3?

Are there any particular comments you feel are appropriate to ensuring satisfactory post-market surveillance?

8 Communication

Consultation is a key part of FSANZ's standards development process. FSANZ has prepared a communication strategy for this Proposal, which includes targeted communication with key stakeholders and preparing information for the broader community.

All calls for submissions are notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and Food Standards News. Subscribers and interested parties are notified about the availability of reports for public comment.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Proposal. The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on the draft variation to the Code. FSANZ places all related Proposal documents and submissions on the FSANZ website. All public comments received are reviewed and considered by the FSANZ Board in making its final decision.

8.1 Consultation

8.1.1 Preliminary Consultation 2012

Before preparing this Proposal, FSANZ released a consultation paper[14] in March 2012.

[14] http://www.foodstandards.gov.au/media/Pages/mediareleases/mediareleases2012/26march2012fsanzcons5467.aspx

The objective of the consultation paper was to seek feedback on a proposed alternative approach to the regulation of nutritive substances and novel foods in the Code. During the consultation period, FSANZ held targeted conversations with the Australian Food and Grocery Council (AFGC) and industry members and with other government agencies responsible for food regulation.

FSANZ presented an alternative approach aimed at providing greater clarity and regulatory certainty for industry and regulators, while also protecting public health and safety. The concept of criteria being included in the Code to identify foods which do or do not require pre-market approval was introduced, along with different assessment processes. The consultation paper described the approach in principle and sought comments on specific aspects of the approach.

FSANZ received 22 written submissions with varying levels of support and opposition to the proposed approach. The following six key issues were distilled from the submissions to the consultation paper.

1. A number of submitters suggested the case for changing the current Code provisions was not well established in the consultation paper.
2. Any change to the regulatory system should be proportionate to the risk/benefit for consumers, industry and government.
3. Any new regulatory system should improve the protection of consumer health and safety.
4. Any new regulatory system should not be an unnecessary burden on business, hamper innovation and/or affect confidentiality.
5. Any new regulatory system should result in an efficient, responsive and effective process that identified those substances that required pre-market risk assessment, and was consistent with international processes for novel foods.
6. Any new regulatory system provided regulatory certainty for enforcement agencies.

Given the range of opinions, FSANZ considered that it would be prudent to consult further with industry and government with a view to better understanding these issues. FSANZ hosted a workshop with industry and government agencies to discuss a number of issues pertaining to the future regulation of nutrient substances and novel foods (Sydney, 26 June 2012). This workshop was attended by 20 delegates from Australia and New Zealand, including six officers from FSANZ.

The workshop concluded that the current regulatory system for the addition of nutritive substances to food and the sale of novel foods was not viable in the longer term. The workshop also included a broad discussion of potential elements of an alternative approach to the current Code provisions.

8.1.2 Cost/benefit consultation

FSANZ commissioned a survey to examine potential costs to industry associated with complying with bringing a new nutrient or novel food to market in Australia and New Zealand. The survey was conducted by Catalyst Ltd. This survey included consideration of gaining approval of a nutrient or novel food via the FSANZ application process as well as the submission of enquiries to the ACNF for consideration. The results of the survey were varied and are examined in more detail in SD1 (a copy of the final survey report is included as an attachment to SD1).

8.1.3 Food enforcement consultation

Before the release of this call for submissions, FSANZ requested information from food enforcement agencies in Australia and New Zealand on the difficulties faced when attempting to enforce the current nutritive substance and novel food provisions in the Code. The information provided by these agencies has been used in developing sections 2.1 and 3.1 and includes evidence of the difficulties in interpreting the Code's requirements and relying on Food Act safe and suitable provisions and the limitations these difficulties place on the confidence of food enforcement agencies taking successful action on non-compliance, including when there are concerns in relation to safety.

8.1.4 Future consultation

This proposal will include two periods of public comment. This call for submissions requests input from stakeholders on the options, including costs and benefits, in order to inform a decision on whether to prepare an food regulatory measure for this proposal and, if so, to further develop options for improving the regulation of nutritive substances and novel foods, particularly in relation to all elements of the graduated risk approach presented in section 4.2.3. Preparation of a food regulatory measure will require a 2nd call for submissions which will request public comment on proposed drafting of regulatory measures developed following consideration of submissions on this assessment summary and related supporting documents.

Should the alternative graduated risk approach be progressed, the drafting for consultation at this stage will need to cover:

- description of EFC
- requirement for suppliers of novel foods which meet the EFC to hold supporting safety data and these data requirements
- description of types of foods which can follow a self-assessment / notification pathway
- description of the data requirements for this pathway
- description of the notification process
- requirement for all other foods to seek pre-approval
- exclusivity provisions
- transition provisions

Workshops with stakeholders will be held early in the consultation period after this call for submissions and there may be further targeted consultation with key stakeholders before a 2nd call for submissions.

8.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged 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.

This issue will be fully considered at the next stage of the assessment and, if necessary, notification will be made in accordance with Australia's and New Zealand's obligations under either the WTO Technical Barriers to Trade (TBT) or Sanitary and Phytosanitary Measures (SPS) Agreements. This will enable other WTO member countries to comment on any proposed amendments.

Attachments

A. Summary of questions for submitters
B Case study: Removing novel food from the market
C. Draft framework for alternative approach
D. Provisions for nutritive substances and novel foods in the Code

Attachment A – Summary of questions for submitters

Refer section 3.3
How do the current novel food and nutritive substance definitions affect your organisation, either as a food business or a food enforcement agency?

Do you believe there are problems with the current definitions in addition to those outlined in the assessment summary? If so, describe the problems.

Do you believe there are problems with the current provisions more broadly (not just the definitions) in addition to those outlined in assessment summary? If so, describe the problems.

Refer section 4.2.1
Are there elements of the status quo that you support maintaining in the Code? If so, please provide details and reasons for your support.

Can you identify any problems with the status quo in addition to those highlighted in this report? If so, please provide details.

Refer section 4.2.2
Do you support amending the definitions of 'novel food' and 'used as a nutritive substance' in the Code? If so, FSANZ welcomes reasoned suggestions for amended definitions that will address the problems identified in sections 1 and 2.

Refer section 4.2.3.1
Are the EFC appropriate for identifying foods that do not need regulatory approval?

Are there foods that may meet the EFC that you consider should be subject to pre-market assessment? If so, please describe the properties of these foods.

Are there foods that would not meet the EFC, but you consider should be eligible? If so, please describe the properties of these foods.

What type of information do you think should be held by food businesses to support the safety of eligible foods? Please describe the type of information and why this information would support safety.

Are the exclusions to the EFC appropriate in identifying foods that should be subject to pre-market assessment, despite otherwise meeting the EFC?

What do you consider would constitute a 'reasonable potential' for a food to have pharmacological effects at the intended levels of consumption? See SD3 for discussion on this issue.

Refer section 4.2.3.3
Do you regard the investigation of an alternative approach to regulating nutritive substances and novel foods in the Code as a viable option?

In particular, taking account of FSANZ's primary objective of protecting public health and safety, is the draft framework presented in option 3 a viable option? What aspects of the draft framework do you think are viable or not viable? Please provide supporting statements for your view.

Do you have suggestions for the type of foods that would not meet the EFC, but may be suitable for industry self-assessment?

Please provide details of how a self-assessment pathway may or may not provide benefits to industry.

Would notification and publication of dossiers provide enough regulatory oversight and consumer confidence in relation to the safety of new foods? Please support your answer with detail of why you believe this is the case.

Refer section 4.3.1
Can you identify any negative impacts that may result from combining the regulation of novel foods and nutritive substances (other than vitamins and minerals) that may occur under a graduated risk approach? Please explain these impacts.

Refer section 6.2
Do you support retaining the provision to grant exclusive permission in the Code for foods approved by FSANZ? Please provide reasons for your view.

Can you identify any issues that may arise if exclusive permissions are available for FSANZ approved foods, but not available for industry self-assessed foods? Would the self-assessment process for non-eligible foods provide a trade-off against the lack of an exclusive permission for self-assessed foods (section 4.2.3)?

Refer section 7.1
Do you support a cut-off date? Please provide reasons for your view.

Do you see a need for grandfathering provisions? Please provide reasons for your view.

Do you see a need for a stock in trade provision? Please provide reasons for your view.

Refer section 7.2.3
Do you have any concerns regarding the proposed 6 month transition period? Please explain your concerns, noting the length of time the development of any future standard is likely to take and will therefore be clearly signposted before changes are made to the Code.

Do you have any comments regarding the proposal not to allow a stock-in-trade provision during the transition period?

Do you have any suggestions as to which peak bodies should be involved in familiarising industry of the new provisions?

Do you have any suggestions on how the implementation process could be approached, especially with respect to enhancing awareness and understanding of the potential new provisions under Option 3?

Are there any particular comments you feel are appropriate to ensuring satisfactory post-market surveillance?

Refer Attachment C
The exclusions make reference to ‘reasonable potential’ and ‘reasonably expected’. FSANZ’s intent is to capture foods that are pharmacologically active or have biological activity beyond basic nutrition at the levels they are intended to be used. Can you make suggestions in relation to how such foods might be captured to ensure they are subject to pre-market assessment?

Why is it important for novel foods permitted in the Code to be declared 'not novel' after a certain period of time? Please explain the impacts on your business of novel food permissions remaining in the Code (as novel foods).

Refer SD1

1. What costs have you experienced in making novel food or nutritive substance applications (for permission in the Code) or enquiries to the ACNF under the current system? If possible, include information on size and types of costs (e.g. commissioning research, staff time spent preparing an application). If possible, indicate the costs which relate only to the Australian/New Zealand market. If this is not possible please clearly indicate these are the global costs of obtaining these data and which other regulatory authority they have been prepared for.

2. What other costs have you experienced as a result of the current novel food and nutritive substance provisions (i.e. costs not related to applications and enquiries)? For example, costs of obtaining legal advice on whether a substance is a novel food or a nutritive substance.

3. How (if at all) do the current provisions influence your business's decisions regarding developing and launching new products?

4. What (if any) kinds of opportunity costs have you experienced due to the time taken to assess applications? For example, missing a 'window' during which a retailer will accept new products within a particular category.

5. (For food regulators) What types of enforcement costs does your organisation experience as a result of the current nutritive substance and novel food standards? E.g. dealing with enquiries about whether a food is novel or a nutritive substance, notifying food businesses that their food is a nutritive substance or novel food and requires pre-market assessment by FSANZ.

6. (For food regulators) How would (if at all would) the types of enforcement costs change if Options 2 or 3 were introduced?

Attachment B – Case study: Removing novel food from the market

In June 2012, regulators became aware of a number of sports supplement products containing DMAA as an ingredient that were being supplied in Australia and New Zealand. DMAA is a stimulant that was originally developed in the 1940s as a nasal decongestant. However, its use in food and dietary supplement type products has occurred more recently in sports food and supplement products. FSANZ and food enforcement agencies noted the stimulant effect of DMAA and reports of adverse effects associated with the consumption of products containing the ingredient including deaths and serious illnesses overseas. Food enforcement agencies agreed that these products should be removed from the market. However, as noted above in section 3.1 there were limited options available to force products off the market without sufficient evidence to prove that consumption of DMAA containing products would categorically cause harm or adverse effects.

There was evidence to suggest that consumption of DMAA at higher levels could cause significant adverse effects. However, at the time, there was a lack of clear scientific evidence to show a direct causal link between the consumption of DMAA at the levels added to sports food and supplement products and adverse health effects.

Food enforcement agencies noted that DMAA would likely be considered a novel food in accordance with the definition in Standard 1.5.1. However, noting the difficulties in enforcing the novel food provisions, regulators were reluctant to rely on this to take action. Food enforcement agencies also noted the potential difficulty in relying on 'unsafe' provisions in the Food Acts. In the first instance, food enforcement agencies notified suppliers that the use of DMAA may be 'unsuitable' and requested removal of products from the market.

In addition, during this time, the Therapeutic Goods Administration (TGA) was taking action to include DMAA in Appendix C of the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). The SUSMP, legally referred to as the Poisons Standard, is given legal effect through state and territory legislation, similar to the way the Code is given legal effect. Entry in Appendix C of the SUSMP prohibits a substance from being sold, possessed or supplied in Australia. DMAA was included in Appendix C, with the prohibition taking effect on 8 August 2012. This was almost two months after the DMAA incident was first identified by regulators. In March 2012, DMAA was classified in New Zealand as a temporary class drug, which made it illegal to import, export, manufacture, supply or sell the substance, or products containing the substance[15]. This temporary order resulted in a more rapid removal of products from the New Zealand market than in Australia.

The DMAA example highlights the difficulties that food enforcement agencies can experience when attempting to remove products from the market that are considered to present potential harm to consumers. The Food Act provisions in relation to the supply of 'unsafe' foods are broad to ensure they can apply to a range of situations. However, the novel food provisions in the Code are intended to provide more specific requirements in relation to the safe supply of certain types of foods. Ingredients like DMAA, that would appear to clearly meet the intent of the novel food provisions, are currently caught up in the issues relating to uncertainty that have been highlighted above. Therefore, rather than being able to rely on the novel food provisions to assist in taking appropriate action, other means may need to be used by food enforcement agencies. These other means may not provide timely or suitable mechanisms to remove products from the market if this is considered necessary.

[15] Temporary class drug notice issued under the *Misuse of Drugs Act 1975*.

Attachment C – Draft framework for alternative approach – Option 3

This attachment includes additional detail on the draft framework prepared by FSANZ to support option 3 (section 4.2.3).

Eligible Food Criteria

Under the draft alternative framework, FSANZ considers foods that meet eligible food criteria (EFC) could be sold, provided the supplier of the food meets record keeping requirements that would be established in the Code. At this stage FSANZ has not developed the record keeping requirements in detail. However FSANZ does not expect these requirements to be overly onerous on food businesses that should already be ensuring the foods they supply are safe. The nature of the food business that is required to hold the records may vary. For example, food retailers and caterers may not be required to hold records that describe the full information package that supports safety, but would need to be able to reference who holds the information on the eligible food (the manufacturer / supplier of the eligible food). In this case, food control plans of food retailers / caterers would need to verify the information is held by the manufacturer / supplier of the eligible food. The draft EFC are listed below:

Eligible food criteria

1. Microorganisms are eligible if they are listed in the Standard (in the Code) and are cultured to maintain genetic stability.

2. Animal food commodities and plant commodities are eligible if they are included in the list of food classes[16]. Animal food commodities and plant commodities included in the list of food classes are also eligible if they are **physically fractionated, fermented** (using microorganisms that meet criterion 1), **and/or physically processed** (including chopping, cutting, peeling, grinding, squeezing, pressing, steeping, infusion, filtering and dehydration).

3. Extracts are eligible if they are prepared from foods described in criteria 2 when added to processed foods where the total concentration of the naturally occurring and added components in the target food is no higher than that present as if the source food were used as an ingredient.

4. Subject to criterion 2, substances are eligible if they are obtained from animal commodities when added to processed animal commodities from the same food class, or if they are obtained from plant commodities when added to processed plant commodities from the same food class provided that the concentration of the total of the naturally occurring and added substance is within the natural range in that food class.

Exclusions to the eligible food criteria

Despite meeting the EFC, the following foods require pre-market assessment:

1. Processed or unprocessed animal or plant commodities, including their extracts or substances, which have, or have reasonable potential to have, pharmacological effects at the intended levels of consumption.

[16] Food classes will be listed in the Code. More detail on food classes is provided in SD3. The food classes are based on those listed in Schedule 22 of the revised Code.

2. Processed or unprocessed animal or plant commodities including their extracts and substances that have, or are reasonably expected to have, weight loss purpose/properties at the intended levels of consumption.

The exclusion does not apply to foods without these properties that otherwise qualify to carry diet, low energy or similar claims, or that are regulated as meal replacements by Standard 2.9.3 or as food for special (medical) purposes by Standards 2.9.5 or 1.1A.6.

Question

The exclusions make reference to 'reasonable potential' and 'reasonably expected'. FSANZ's intent is to capture foods that are pharmacologically active or have biological activity beyond basic nutrition at the levels they are intended to be used. Can you make suggestions in relation to how such foods might be captured to ensure they are subject to pre-market assessment?

Industry self-assessment

The draft framework described in section 4.2.3 notes foods that do not meet the EFC would be subject to a greater level of pre-market assessment than eligible foods. However, the draft framework suggests an industry self-assessment process may be appropriate for a subset of foods that do not meet the EFC. In order to determine which foods can be self-assessed for safety by industry, 'gateway tests' may need to be developed. A food that satisfies a gateway test may be suitable for self-assessment. Other foods may require FSANZ assessment, via the existing application route, before they can be sold.

Gateway tests

FSANZ has not developed the detail of these gateway tests for the purposes of this assessment summary but will do so in more detail if this draft framework is considered to warrant further development. A couple of examples of potential gateway tests are illustrated below:

- Approval of the food by an international food regulatory agency that has similar regulatory and safety data requirements to FSANZ. The data used to gain approval of the food in another jurisdiction may be used as the basis for a self-assessment by industry for access to the Australian and New Zealand market. It is likely that the Code would need to set out such requirements. Depending on the nature of the assessment by the international food regulatory agency, and on any specific requirements for the Australian and New Zealand markets, some data may be required in addition to those considered as part of the international approval process.

- Carve outs: It may be possible to develop categories of 'non-eligible' foods that could be self-assessed by industry. For example, minor variations from the EFC could be categorised, such as certain types of substances or sources of substances. These carve outs would need to be defined in the Code.

An industry self-assessment route may provide industry with an alternative to the current FSANZ assessment process, for suitable foods. FSANZ has received feedback from industry suggesting that the current FSANZ assessment process places significant regulatory burden on food businesses, particularly with respect to the time it takes FSANZ to complete an assessment and therefore, the time it takes to get a product onto the market.

Industry has also noted the transparent nature of the FSANZ assessment process allows competitors to take advantage of the work done by the food business in preparing the application due to the time it takes FSANZ to complete its assessment. Competitors are able to market approved products without having to prepare and submit their own application. FSANZ recognises its assessment process is transparent and accountable. However, there are provisions in the FSANZ Act to permit certain information to remain commercial-in-confidence and not be published as part of FSANZ's assessment process. Applicants can also request exclusive permission to be attached to the approval of novel foods, so that only the applicant's brand of novel food can be sold for a period of 15 months following gazettal of the permission in the Code. The time FSANZ takes to assess applications compares favourably with those of other major regulators in respect to novel foods.

Dossier requirements

Section 4.2.3 notes that an industry self-assessment process would include a requirement that the food business assessing the safety of the food would need to prepare a dossier and submit it to food regulators/authorities. The dossier requirements would need to be set out in the Code and would include the type of data required to assess safety. The dossier would also have to include consideration of whether any risk management options may be required for the food. For example, the food may have similar characteristics to foods for which there are existing specific labelling requirements in the Code (such as including an advisory statement for a polyol that is not currently listed in Standard 1.2.3 or instructions/directions for use for foods that require specific preparation steps after purchase). Dossiers would need to evaluate the safety of the food in the context of its intended use in the food supply, including the types of foods and the levels at which it will be added to these foods. The requirement to consider risk management options would need to be specified in the Code and in guidance material for a self-assessment process.

Standard 1.2.7 – Nutrition, Health and Related Claims requires the substantiation of health food health relationships. Schedule 6 of the revised Code sets out the process of systematic review used to establish a relationship between a food or a property of a food and a health effect. Guidance material on establishing a food-health relationship has been developed to assist industry and food enforcement agencies. Although the health claims framework relates to the substantiation of food-health relationships, rather than establishing the safety of foods, FSANZ considers some aspects of the health claims framework may provide a basis for developing data requirements that would need to be met when establishing the safety of a new food.

Publication of dossiers

In addition to preparing and submitting a dossier under an industry self-assessment process, FSANZ notes that dossiers may need to be published to maintain a level of transparency and accountability that will ensure public confidence in the safety of foods supplied in Australia and New Zealand. FSANZ does not have the legal power under the FSANZ Act to maintain a register of foods in a similar way to United States Food and Drug Administration's (FDA's) Generally Recognised as Safe (GRAS) inventory, particularly in relation to assessing and responding to notifications. Upon receipt of a GRAS dossier from a food business, the FDA conducts a preliminary assessment to determine whether it has any questions in relation to the assessment of safety conducted by the food business. A similar approach is followed by Health Canada for Natural Health Products (see SD4 for more detail on international regulatory approaches). FSANZ can only assess a submission if it is an application to amend the Code. Therefore, similar to the health claims approach, FSANZ would not assess dossiers submitted under point 3 above.

Consideration may need to be given to introducing a mandated time period that must pass after submitting a dossier before the dossier is made available to the general public and a food business can supply a food. This time period may provide food enforcement agencies with the opportunity to conduct a preliminary assessment of the dossier and to raise concerns with a food business before the dossier is published and the food is marketed.

A requirement to submit a dossier for publication would allow food businesses to control the time to market for products and prevent other food businesses from selling the food unless they too have submitted a dossier. A food business could submit a dossier at a time that coincides with the intended release of a product. This may allay one of the concerns relating to the FSANZ assessment process outlined above. The information included in the dossier would then be publicly available online. A published dossier should include relevant data and analysis of data to clearly illustrate how the safety of the food was established. As noted previously, further consideration may be required to determine the type of information that can remain confidential to the food business and not be included in the dossier, while still ensuring the public has enough information to be satisfied with the food business' assessment of safety.

Other matters related to draft framework

Impact on current standards

Existing permissions for novel foods would be maintained in a revised standard or in commodity based standards in Chapter 2 of the Code (phytosterol permissions in Standard 1.5.1 are also highlighted in Chapter 2 standards, such as Standard 2.5.1 for phytosterols permitted to be added to milk). Nutritive substance permissions would remain in the respective standards in which those permissions are listed. To date, nutritive substances other than vitamins and minerals are permitted only in standards for special purpose foods. Whether these substances would still be referred to as nutritive substances, or a more generic description has not yet been determined. Further consideration of any impact on the wording of current permissions for nutritive substances will be undertaken if an alternative approach is developed as part of this proposal. A full list of Code permissions for the sale of novel foods and the addition of nutritive substances to food is included at Attachment D.

In relation to novel food permissions in the Code, some stakeholders have questioned when an approved novel food ceases to be novel; and therefore when permission in the Code is no longer required. At present novel food permissions in the Code do not have a date after which a permitted novel food is no longer considered novel; the permissions remains in the Code with no end date specified. In general, where novel food permissions have no conditions of use associated with the permission (this is the case for most novel food permissions in the Code) the foods may no longer need to be considered as novel because they do not require further assessment. However, where overall exposure may need to be assessed, then it may be necessary for permissions for extension of use to be subject to a pre-approval process. For example, in the case of phytosterols, permissions are restricted to certain foods and levels. In order to add phytosterols to other foods, food businesses would need to submit an application to FSANZ to request an extension of the phytosterol permissions. To date, FSANZ has not proposed amending novel food permissions to stipulate that a permitted novel food is no longer novel. FSANZ considers this would remain the case under a graduated risk approach when there are concerns or uncertainty about the potential impact in relation to levels of consumption of a novel food across the food supply.

Questions:

Why is it important for novel foods permitted in the Code to be declared 'not novel' after a certain period of time? Please explain the impacts on your business of novel food permissions remaining in the Code (as novel foods).

Policy guidance

The draft framework primarily focuses on ensuring safety of the substance for human consumption, which is FSANZ's primary statutory objective. The Ministerial Policy Guideline on substances other than vitamins and minerals (see section 4.1.4) also identifies three other issues to consider, namely:

- the stated purpose for adding the substance and the consistency to deliver this purpose
- the potential for the addition of the substance to create a significant negative public health impact to the general population or sub population
- the potential for consumers to be misled about the nutritional quality of the food containing the added substance.

How these issues might be addressed under the draft framework requires further consideration. Some initial considerations are provided below.

As a first step, the spectrum of potential measures to address each issue is outlined. The relevance of the measures for each of the three pathways under the graduated risk approach will require consideration in future reports.

Consistency with stated purpose

The approach could require food businesses to clearly articulate to regulators the purpose of adding a substance to a food. Whether any stated purpose is acceptable, or must fit a particular category of purpose needs to be considered.

Similarly, the quality of evidence required to demonstrate that the quantity and form of the substance in the food will deliver the stated purpose needs to be considered. The spectrum of measures ranges from requiring no evidence to substantiate the stated purpose (noting that the health claims standard would provide a level of control for those products that intend to make claims), to a method set in regulation that requires a certain quality of evidence to substantiate the stated purpose. The quality of evidence could be relatively low, as currently required by the *Application Handbook* to demonstrate consistency with stated purpose, or high, as required to substantiate food-health relationships under the health claims standard.

Safety and negative impacts on public health

A safety concern is that consumers may consume on a regular basis multiple foods that contain the same substance, resulting in an intake above levels considered safe for that substance (i.e. cumulative effect). The assessment of risks and safety data requirements for new foods includes initial consideration of cumulative effects of exposure to foods (SD2).

The concern that the presence of a substance in a food may influence consumer food choice towards an unhealthy consumption pattern (e.g. an increase in consumption of high fat, sugar or salt foods) could be approached in several ways.

Evidence from reports of consumer behaviour is used to determine likely impacts on public health. Where such impacts are likely to be unfavourable, consideration could be given to additional regulatory approaches. For example, the compositional requirements could be applied to foods permitted to contain added substances, or food businesses could be required to provide/hold information on actual and/or potential consumption behaviour changes (i.e. substitution, addition and avoidance) in response to the substance.

Potential to mislead

Existing labelling requirements in the Code will remain. The application of the generic labelling requirements to foods with added substances mitigates the potential for consumers to be misled about the nutritional quality of the food. These requirements relate to mandatory declarations in the statement of ingredients and to the presence or otherwise of voluntary nutrition content or health claims on food labels. The generic labelling requirements in the Code are intended to provide consumers with information to allow them to make informed purchasing decisions.

Attachment D − Code provisions for nutritive substances and novel foods

Standard 1.1.1 – Structure of the Code and general provisions sets out basic requirements for food for sale in Australia and New Zealand. In this Standard, food for sale must not be a 'novel food' (section 10(5)(b)) and must not have as an ingredient or a component a substance that was 'used as a nutritive substance' (section 10(6)(b)).

Standard 1.1.2 – Definitions used throughout the Code, includes definitions of 'novel food' and 'used as a nutritive substance'.

The definition of novel food is reproduced below:

novel food means a non-traditional food that 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.

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.

The definition of 'used as a nutritive substance' is reproduced below:

(1) In this Code, a substance is ***used as a nutritive substance*** in relation to a food if it is added to the food:

(a) to achieve a nutritional purpose; and
(b) it is a substance identified in subsection (2).

(2) For subsection (1), the substances are:

(a) any substance that is identified in this Code as one that may be used as a nutritive substance; and
(b) a vitamin or a mineral; and
(c) any substance (other than an inulin-type fructan, a galacto-oligosaccharide or a substance normally consumed as a food) that has been concentrated, refined or synthesised, to achieve a nutritional purpose when added to a food.

Code permissions for nutritive substances and novel foods

Provided below is a list of the permissions for novel foods, nutritive substances (other than vitamins and minerals) and other relevant substances in the Code.

Table D.1: Permissions in the Code for novel foods and nutritive and other substances

Item	Current Code	Revised Code
Permitted novel foods and conditions of use	Table to cl 2 of Std 1.5.1	S25–2
Edible oil spreads and margarine may contain no more than 82 g/kg of total plant sterol equivalents content	Paragraph 2(1)(g) of Std 2.4.2	Std 2.4.2–2(b)(vii)
Conditions for the addition of phytosterols, phytostanols and their esters to milk	Cl 5 of Std 2.5.1.	Std 2.5.1–6
Conditions for the addition of phytosterols, phytostanols and their esters to yoghurt.	Cl 4 of Std 2.5.3.	Std 2.5.3–5 .
Conditions for the addition of tall oil phytosterol esters to cheese and processed cheese	Cl 3 of Std 2.5.4	Std 2.5.4–4
Permission to add lutein from *Tagetes erecta L.* to formulated supplementary foods for young children (with conditions)	Cl 6A of Std 2.9.3	Std 2.9.3, Division 4, – 7 (4)
Conditions for the addition of fluoride to packaged water	Cl 2A of Std 2.6.2	Std 2.6.2–4
Conditions for the addition of caffeine to a formulated caffeinated beverage.	Subclause 2(1) of Std 2.6.4	Std 2.6.4–3 (a)
Formulated Caffeinated Beverages - Permitted[17] 'substances' (e.g. taurine, glucuronolactone and inositol), (with conditions)	Table to subclause 2(2) of Std 2.6.4	Std 2.6.4–3(b) permission to add 'substances' to FCB's. S28–2, table provides a list of those listed substances (with conditions)
Permissions to add inulin-type fructans and galacto-oligosaccharides (with conditions) to formulated supplementary foods for young children	Subclause 6(4) of Std 2.9.3	Std 2.9.3–7(3)
Permission to add specified amino acids to formulated supplementary sports foods, (with conditions)	Paragraph 2(b) of Std 2.9.4	Std 2.9.4–3(1)(b) permission to add. S29–18 lists the amino acids which can be added (with conditions).
Permission to add specified 'ingredients' (e.g. L-carnitine, choline, creatine, gamma-oryzinol) to formulated supplementary sports foods, (with conditions)	Paragraph 2(c) of Std 2.9.4	Std 2.9.4–3(1)(c) permission to add. S29–19 lists the permitted other substances (with conditions).
Permission to add substances(e.g. amino acids, L-carnitine, choline, inositol, taurine, nucleotides) and other substances regardless of their form, subject to the requirements of any Standard that applies to the substance or the food for special medical purposes	Paragraph 6(1) of Std 2.9.5	Std 2.9.5–6 permits the addition of substances. S29–20 and–7 provide details on substances which can be added.

[17] In the revised Code, 'permitted' is replaced by 'listed'