**16 June 2017**
**[15–17]**

# Consultation Paper – Proposal P1024

## Revision of the Regulation of Nutritive Substances & Novel Foods

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Proposal P1024 was prepared to review the regulation of nutritive substances and novel foods in the *Australia New Zealand Food Standards Code* (the Code). FSANZ is seeking stakeholder views in relation to a number of issues, which will inform FSANZ's 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 that we accept as confidential, 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 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.

**DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 28 July 2017**

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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# Table of contents



## Supporting document

The following document[1] which informed the assessment of this Proposal are available on the FSANZ website:

SD1 Summary of submissions

[1] http://www.foodstandards.gov.au/code/proposals/Pages/P1024.aspx

# 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. The current Code provisions relating to nutritive substances and novel foods, particularly the definitions associated with them, are creating uncertainty in the market place. This Proposal seeks to improve the regulation of nutritive substances and novel foods by making clearer which foods require regulatory oversight and approval before being sold in the marketplace.

FSANZ issued a Call for Submissions in December 2015. It sought feedback on a proposed alternative approach in the Code to the regulation of nutritive substances and novel foods. That approach involved different pathways to market for new foods, with criteria being included in the Code to identify foods which do or do not require pre-market approval. It also proposed removing the current definitions of nutritive substance and novel food from the Code and replacing them with alternative arrangements.

Stakeholders generally agreed that a new approach to regulating nutritive substances and novel foods was required. However, stakeholders had varying views on the proposed framework. Industry strongly supported the eligible food criteria and self-assessment components. However, there was strong government opposition to the self-assessment notification route. Government agencies were concerned about the lack of centralised, regulatory and scientific oversight as well as the potential for inconsistencies in determining compliance across jurisdictions (due to differing levels of resources and scientific expertise in jurisdictions).

In view of the above, FSANZ now seeks stakeholders' view on a possible modified framework. This modified framework does not include the self-assessment notification pathway. It only provides for the 'eligible food' criteria pathway and the FSANZ pre-market assessment pathway.

This paper also clarifies other aspects of the modified framework. In particular, FSANZ has expanded on the potential impact of the modified framework on existing Code provisions and permissions for novel foods and nutritive substances. The potential to streamline FSANZ's pre-market assessment process is also canvassed.

Stakeholder feedback is also sought on the review of the exclusive permission provision for novel foods in the Code and the proposed approach to grandfathering[2]. FSANZ has also clarified the scope of this Proposal with respect to standards in Part 2.9 of the Code and Proposal P1028 – Infant Formula.

Stakeholder feedback will inform a decision on whether to develop a draft food regulatory measure and on the content of any such measure. If a draft food regulatory measure is prepared, there will be a further call for submissions on the proposed draft measure.

[2] i.e. whether existing food products will be exempt from the requirements of a new framework

# 1 Introduction

## 1.1 The Proposal

The *Australia New Zealand Food Standards Code* (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 substance and novel food are included in the Code to help identify the type of foods that are subject to pre-market assessment. However, it has become apparent that these definitions include terms that create uncertainty. Uncertainty creates difficulties for industry and food enforcement agencies in determining whether particular foods require permission in the Code before they can be added to, or sold as, foods.

FSANZ prepared Proposal P1024 to develop an improved framework for regulating nutritive substances and novel foods. Following an assessment of the Proposal, FSANZ issued a Call for Submissions seeking stakeholder views on a potential framework for the pre-market safety assessment of nutritive substances and foods new to the food supply. Stakeholders raised a range of issues in relation to that framework. FSANZ has now prepared this consultation paper to obtain further stakeholder views on these and other issues before any decision is taken on development of a food regulatory measure.

This proposal is being assessed under the major procedure which includes a minimum of two (statutory) rounds of public consultation. This additional (non-statutory) round of public consultation is seeking stakeholder input on possible amendments to the Code to improve the regulation of nutritive substances and novel foods.

## 1.2 Issues

A number of key issues are included in this consultation paper for consideration. FSANZ is seeking feedback on these issues. The scope of the Proposal has also been clarified.

### 1.2.1 Framework

FSANZ's call for submissions and related assessment summary outlined a possible framework for regulating nutritive substances and novel foods.

Industry strongly supported the eligible food criteria and self-assessment aspects of that framework. However, government stakeholders did not support the self-assessment notification aspect. Government stakeholders advised that they would only support a self-assessment notification pathway if the framework incorporated centralised regulatory and scientific oversight (by FSANZ or another unspecified body), rather than the responsibility falling to individual jurisdictions as proposed.

The *Food Standards Australia New Zealand Act 1991* (Cth) (FSANZ Act) does not permit FSANZ to undertake such a role. Nor is FSANZ resourced for such a role.

Therefore, after having regard to stakeholder feedback, FSANZ has removed the self-assessment notification pathway from the framework. FSANZ now seeks input from stakeholders on a modified approach that provides two pathways to market for new foods; the eligible food criteria pathway and a FSANZ assessment pathway.

### 1.2.2 Other issues

FSANZ considers three other issues also require clarification and/or further stakeholder input before development of any food regulatory measure can occur. These issues are addressed in this paper and are listed below (more detail in section 3):

1. *Exclusive permission and the protection of investment in new product development (NPD).* Stakeholder responses to the first Call for Submissions highlighted the value of the current exclusive use provision. However, the issues of its limited duration and the possibility of using other means to protect NPD were raised and require further exploration.

2. *How foods which are being sold before gazettal of the revised standards should be addressed.* Stakeholders recommended that certain types of foods be excluded from the proposed 'grandfathering'. A possible approach to grandfathering is set out in this paper.

3. *The consideration of novel foods and nutritive substances applicable to Standards 2.9.1 and 2.9.2.* Stakeholders raised concerns on the exclusion of these standards from the scope of Proposal P1024 (and addressing them separately in Proposal P1028 – Infant Formula and subsequent proposals). FSANZ clarifies in this paper how the regulation of nutritive substances and novel foods will be progressed in Proposal P1028 and P1024.

FSANZ has also established a Novel Foods Standards Development Advisory Group, comprised of representatives from a novel food ingredient research entity, peak industry bodies, importers and jurisdictions. Their views have been considered in developing this paper.

## 1.3 Issues for subsequent consultation

This paper does not address all issues of relevance to this Proposal. If a draft food regulatory measure is developed, a number of issues will be dealt with in a further call for submissions, rather than in this paper, including:

- the criteria to determine which foods may be self-assessed (eligible food criteria)
- data requirements for eligible foods
- designation of responsibilities for holding dossiers for assessment against the eligible food criteria
- consideration of overseas approvals in the context of a new framework
- regulatory impact analysis.

The data requirements for foods which require an application to FSANZ will be addressed in a subsequent revision of the FSANZ Application Handbook.

## 1.4 Submitters' comments on the assessment

Submitter comments are noted throughout this paper. In addition, Supporting Document 1 (SD1) summarises the comments from submitters in relation to the issues included in this paper.

# 2 Regulatory framework

## 2.1 Summary of findings

In its 2015 call for submissions, FSANZ presented a framework that was an alternative to the existing Code provisions for nutritive substances and novel foods. The framework proposed three pathways to market for new foods (see diagram at Attachment A):

i. The first pathway permitted the sale of foods which are deemed to be of low risk because they meet defined criteria (eligible food criteria). Some safety data, which would be defined in the Code, would need to be held for these foods by the food or ingredient manufacturer or importer. No application to FSANZ would be required to seek approval of these foods.

ii. The second pathway was a self-assessment notification process for foods that did not meet the eligible food criteria. These foods would be subject to 'gateway' tests to determine whether they could be self-assessed or whether they would need to be assessed by FSANZ (via an application). For those foods that could be self-assessed, a dossier would be required to be notified to food regulators and available for review if needed. Again, no application to FSANZ would be required to seek approval of foods that meet the gateway tests and are assessed by industry to be safe. The self-assessment by industry would need to satisfy the assessment requirements that would be defined in the Code.

iii. The third pathway was the existing FSANZ application process that would apply to certain foods (e.g. pharmacologically active substances, foods added for weight management purposes and foods that did not meet the gateway tests described in point ii above). This route would also be available for those who wanted to have an approved food listed in the Code, rather than follow the self-assessment notification pathway (e.g. new ingredient manufacturers).

There was overall stakeholder support for developing a new framework, with stakeholders recognising the uncertainty associated with the current provisions. Some submitters considered the current approach of mandatory pre-market regulatory clearance for all novel foods and nutritive substances is anti-innovative and costly to industry. The development of a new framework was viewed as an opportunity to develop an approach that is proportionate to risk and provides opportunities for industry to access the market quickly.

There were a variety of stakeholder views on the proposed framework. Stakeholders generally supported the need for the Code to continue to include pre-market regulatory requirements of some form for the type of products intended to be captured by the existing nutritive substance and novel food provisions. Stakeholders noted that post-market enforcement alone (i.e. reliance only on Food Act offences prohibiting the sale of unsafe or unsuitable food) can be difficult to implement, particularly when attempting to remove a food from the market[3]. For this reason, stakeholders considered pre-market approval requirements in the Code for some foods to be appropriate.

However, government stakeholders did not support a self-assessment notification pathway and were mostly concerned about the lack of centralised regulatory and scientific oversight. The pathway was a notification type pathway (where individual jurisdictions could request and assess industry self-assessment dossiers). Government stakeholders were concerned that individual jurisdictions would be responsible for assessing dossiers and whether dossiers complied with relevant Code requirements. It was considered that the varying levels of scientific expertise and resources available to jurisdictions could lead to in inconsistent outcomes across Australia and New Zealand.

Submitters suggested various amended options in response to the eligible food criteria pathway and the self-assessment notification pathway. These suggested options and FSANZ's response to them are presented in Table 1. FSANZ notes that most exceed FSANZ's remit under the FSANZ Act.

[3] The assessment summary includes more detailed discussion of these enforcement problems: http://www.foodstandards.gov.au/code/proposals/Pages/P1024.aspx.

FSANZ must operate within the requirements of that Act when developing or varying food regulatory measures (such as changing the Code). Options or elements of options that can be considered further by FSANZ are expanded on in section 2.2.

**Table 1: Submitter suggested options for self-assessment pathways**

| |
|---|
| **Option 1**: Replace industry self-assessment with a streamlined application process. This option would not include a self-assessment pathway – all new foods would require an application, but FSANZ's assessment process may be streamlined for foods meeting eligible food criteria (for example, removing the requirement for FSANZ to seek public comment).[4]<br><br>**FSANZ comment**: A streamlined FSANZ assessment process that does not include public consultation would not comply with the FSANZ Act requirements. However, FSANZ intends to investigate opportunities for streamlining FSANZ assessments (section 2.2.4). |
| **Option 2**: Use a FSANZ-led committee to oversee self-assessment dossier ('amber' pathway).<br><br>**FSANZ comment**: As a statutory entity, FSANZ can only do what the FSANZ Act permits it to do. That Act does not permit FSANZ to undertake a regulatory role or to apply or enforce the Standards that it makes. Nor is FSANZ resourced for such a role.<br><br>Any opinion from a FSANZ-led committee would also lack regulatory certainty. This is the same limitation faced by the FSANZ Advisory Committee on Novel Foods (ACNF) and any reliance on its opinions. Stakeholders have noted that, while the ACNF process can provide guidance, its opinions remain opinions that lack any legal or regulatory status. This lack of legal certainty can create difficulties. For example, when enforcement agencies seek to rely on an ACNF opinion to enforce compliance with a Food Act requirement and the supplier in question contests that opinion and refuses to remove a product from the market.<br><br>Amendment of the FSANZ Act and / or the food laws in each jurisdiction is not within the scope of this Proposal. |
| **Option 3**: A group similar to the existing ACNF should perform an initial screening of the need for an application<br><br>**FSANZ comment**: See response to Option 2 above. |
| **Option 4**: Accept overseas approvals depending on listed criteria.<br><br>**FSANZ comment**: This option will be explored in a subsequent call for submissions. |
| **Option 5**: Use independent expert reviewers<br><br>**FSANZ comment**: FSANZ considers this option would be subject to the limitations that apply to Option 2. |
| **Option 6**: Give FSANZ or another regulatory body the power to provide a 'No objection' response to a self-assessment dossier or to require a novel food for which it deems the self-assessment dossier is inadequate to require a pre-market approval<br><br>**FSANZ comment**: See response to Option 2 above. |

[4] The Victorian Government submission suggested all new foods would require an application but this could be fast-tracked by FSANZ providing an expert view on compliance with eligible food criteria and determining if a more extensive assessment, particularly dietary modelling, is required. A public consultation may not be needed for this process.

**Option 7**: Give regulatory certainty to novel foods considered to be safe to market without requiring listing in the Code by publication of a list on the FSANZ website

**FSANZ comment**: A list on the FSANZ website alone would have no legal or regulatory status, unlike a list or permission included in a standard in the Code. This option is subject to the same limitations as identified in option 2.

**Option 8**: Give regulatory certainty to novel foods that FSANZ or another over sighting body had not raised an objection by permitting these to be listed in the Code without an application process

**FSANZ comment**: The FSANZ Act requires that amendment of the Code (for example, to include a food in a list of permitted novel foods) can only occur by means of an application or a proposal, which must in turn be assessed in accordance with that Act.

## 2.2 Proposed approach

The modified framework outlined in this paper focusses on developing the eligible food criteria concept to provide greater clarity and certainty about the regulation of new foods and substances, particularly in relation to which new foods and substances require pre-market regulatory approval. FSANZ intends to further develop the eligible food criteria in considering options for any food regulatory measure and has not included detailed discussion on this issue in this paper.

Other elements of the modified framework, based on submissions and other targeted stakeholder consultations, are listed below and described in more detail in this section:

- the concept of a novel food in the new framework
- existing permissions for novel foods
- consideration of nutritive and related substances
- amended data requirements for applications.

A diagram depicting the broad elements of the modified framework is at Attachment B. Although the broad elements of the modified framework are discussed in this paper, the detail of the framework, including how the Code may be amended to enable the framework, will be considered at the next stage of the assessment.

### 2.2.1 The concept of a novel food in the modified framework

The current definition of novel food will be removed from the Code.

Instead, the new framework will apply to foods that:

(a) have not been marketed in Australia and New Zealand before the date of gazettal of the Code provisions enacting that framework; and

(b) are not subject to another Code pre-market assessment requirement. That is, the food or substance is not a food additive, processing aid, vitamin or minerals (or another named nutritive substance – see section 2.2.3), a food produced using gene technology, an irradiated food etc.

These foods will be subject to the eligible food criteria, which will be set out in the Code. If a food meets any of the eligible food criteria, and if data requirements are met, the food can be sold in Australian and New Zealand. Data requirements for foods meeting the eligible food criteria will also be set out in the Code. Suppliers would need to hold records to substantiate that the data requirements have been met and food enforcement agencies could request this information from suppliers. The actual eligible food criteria and data requirements themselves remain under consideration by FSANZ and will be the subject of further public consultation.

Those foods that do not meet the eligible food criteria will require assessment and approval by FSANZ before being marketed. That is, an application or proposal would be required.

### 2.2.2 Existing permissions for novel foods

Permitted novel foods are listed in Schedule 25 – Permitted novel foods. Some of these foods have specified conditions of use and may only be sold as foods or used as an ingredient in food for retail sale in accordance with those conditions. For example, phytosterols, phytostanols and their esters are only permitted to be added to specified foods and at certain levels.

In addition, recent FSANZ assessments of novel food applications have included consideration of the appropriateness of the generic nature of novel food permissions, particularly for infant formula products, infant foods and toddler supplementary products. The outcome of these assessments is the approved permissions for these foods are subject to conditions of use, rather than being permitted to be added to all foods. Application A1123 – Isomalto-oligosaccharide as a Novel Food has resulted in FSANZ approving permissions to apply to all foods, except certain part 2.9 standards. Application A1124 – Alternative DHA-rich Algal Oil for Infant Formula Products has resulted in FSANZ drafting the permission to apply for certain Part 2.9 standards.

Where no conditions are specified, novel ingredients may be used in any food for retail sale. For example, algal oil sources of docosahexaenoic acid (DHA) which are used in infant formula products are listed without specified conditions. This is also the case for isomaltulose, trehalose, and D-tagatose. Alpha-cyclodextrin, gamma-cyclodextrin and diacylglycerol oil may be used in any food for retail sale but must be declared in a specific manner in the statement of ingredients.

#### 2.2.2.1 Proposed approach

Novel foods listed in Schedule 25 with specified conditions of use will be retained in the Code. An extension of use or other change to these permissions would require an application to FSANZ. Although such foods will no longer be ‘novel’ under the modified framework, retaining these permissions in the Code will be consistent with the risk management options identified in FSANZ’s assessment of these respective foods (such as the labelling requirements for cyclodextrins and control of levels and types of foods to which phytosterols can be added). If the conditions relate only to certain special purpose foods, such as approved under A1124, then the permissions may be relocated to other relevant standards.

Stakeholders (particularly industry) have for some time questioned how long a food needs to remain ‘novel’ after it has been approved and how long a permission needs to be maintained in the Code. At present, there is no mechanism to remove novel food permissions from the Code after a certain period of time. Novel foods listed in Schedule 25 without any conditions of use could be considered to no longer be novel foods because they have been assessed to be safe (i.e. no further assessment of public health and safety is required).

FSANZ seeks stakeholder views on the potential effects of removing these permissions from the Code. For example, if a novel food is used in certain special purpose foods would removal of the permission from Schedule 25 create uncertainty in relation to using the food in those products? Additionally, the specification requirements for identity and purity in Standard 1.1.1 – Structure of the Code and general provisions (section 1.1.1—15) and Schedule 3 – Identity and purity may be relevant for novel foods listed in Schedule 25. Would removal of the permissions from Schedule 25 create unanticipated identification/specification issues for these foods? Is there a need for food listed in Schedule 25 to continue to be subject to identity and purity specifications?

**Questions for submitters:**

Will the removal of permissions from Schedule 25 create problems relating to requirements for specifications for these foods?

Which of the novel foods listed in Schedule 25 are used only in foods regulated by specific Part 2.9 standards?

Are there other issues associated with removing permissions from Schedule 25? Please elaborate.

### 2.2.3 Consideration of nutritive and related substances

#### *2.2.3.1 Current regulation of nutritive and related substances*

'Used as a nutritive substance' is defined in section 1.1.2—12. The definition refers to use of a substance that occurs through addition to food for a nutritional purpose. The definition also specifically includes vitamins and minerals and any substance[5] that has been concentrated, refined or synthesised to achieve a nutritional purpose when added to a food.

The Code recognises substances identified as vitamins and minerals and certain other collectively identified substances as nutritive substances. The Code also identifies electrolytes, L-amino acids and certain other substances by their specific name or as collectively identified 'substances' which may fall within the definition of used as a nutritive substance if such substances are added to food for a nutritional purpose. The same entity may be identified in the Code as a vitamin or a substance; a nutritive substance or a substance; or be specifically identified without specific reference to substance or nutritive substance.

Standard 2.6.2 – Non-alcoholic beverages and brewed soft drinks, Standard 2.6.4 – Formulated caffeinated beverages and the special purpose food standards in Part 2.9 of the Code are the only standards that currently permit use of nutritive substances (identified as such) or permit addition of other specified substances that may serve a nutritional purpose.

Schedule 29 – Special purpose foods identifies the use of specific nutritive substances identified as such, or specific electrolytes, L- amino acids (including glycine) and other substances and/or their chemical forms that are permitted by the following Standards:

2.9.1 – Infant formula products
2.9.2 – Food for infants
2.9.3 – Formulated meal replacements and formulated supplementary foods
2.9.4 – Formulated supplementary sports foods
2.9.5 – Food for special medical purposes
2.9.6 – Transitional standard for special purpose foods.

In addition, section 2.6.2—10 identifies mineral (and electrolyte) compounds permitted for addition to electrolyte drinks and bases, whereas Schedule 28 – Formulated caffeinated beverages identifies substances permitted for addition by Standard 2.6.4 that may serve a nutritional purpose.

[5] other than an inulin-type fructan, galacto-oligosaccharide or a substance normally consumed as a food

#### *2.2.3.2 Approach following assessment*

Discussion of nutritive substances following the assessment focused on the limitations of the definition of 'nutritive substance'/'used as a nutritive substance'[6] and the potential overlap with the definition of novel foods. The similarity of data requirements in applications for pre-market approval of novel foods and nutritive substances was also discussed. It was noted that a food used as a nutritive substance must have permission in the Code whereas a non-traditional food that did not meet the requirement for an assessment of public health and safety (i.e. it was not a novel food) would not require a specific permission in the Code.

The proposal to combine the concepts of nutritive substances and novel foods was widely supported by submitters. However, the specific detail of how nutritive substances and novel foods could be combined into a single designation had not been developed at that stage.

#### *2.2.3.3 Proposed approach*

The current definition of 'used as a nutritive substance' will be removed from the Code.

The modified framework outlined in section 2.2.1 will apply to all foods (including substances used a nutritive substance) not marketed before the date of gazettal of the Code provisions enacting that framework.

However, vitamins, minerals, electrolytes and L-amino acids that are currently used for a nutritional purpose will continue to require pre-market approval for inclusion in the standards that currently contain these permissions. This is to ensure a consistent and moderate approach to adding these substances will support public health nutrition policies and ensure the safety of permitted chemical forms.

Nutritive substance permissions listed in Standard 1.3.2 – Vitamins and minerals or Standards 2.6.2 and 2.6.4, or Part 2.9 standards will remain. The use of the term 'nutritive substance', including in section 2.9.5—13 (labelling of nutrition information), may be altered if the definition of 'used as a nutritive substance' is removed from the Code.

**Question for submitters:**

Do you consider other nutritive type substances (in addition to vitamins, minerals, electrolytes and L-amino acids) should always be subject to pre-market approval by FSANZ? Please provide reasons for your view.

### 2.2.4 Amended data requirements for applications

#### *2.2.4.1 Current situation*

The FSANZ *Application Handbook* sets out mandatory requirements for applications for novel foods and nutritive substances. There are different data requirements for different types of novel foods (such as plant and animal products, dietary macro components and single chemical entities). However, the Handbook does not include an explicit tiered approach to data requirements in relation to varying levels of risk that consumption of different foods or substances may present.

[6] The 'nutritive substance' definition was replaced with 'used as a nutritive substance' when the Code was revised (2016)

#### *2.2.4.2 Proposed approach*

FSANZ is considering whether the FSANZ assessment process could be streamlined by amendments to the Handbook's data requirements. That is, for the assessment of new foods which require a pre-market assessment by FSANZ (i.e. those not meeting the eligible food criteria).

If the modified framework is supported, amending these data requirements will be explored during the next stage of the assessment. For example, the Handbook could more explicitly set out different levels of data required for different types of foods; with data requirements increasing with complexity or risk that may be presented by a food. Amendments to the Handbook are conducted via a separate process, so any potential changes to the Handbook identified as part of the assessment of this Proposal will need to be progressed separately.

FSANZ will also investigate other administrative, business and risk assessment processes that may provide opportunities for streamlining the application and FSANZ assessment process. For example, an application template may reduce the time spent by FSANZ in preparing a risk assessment. This and other opportunities will be explored during the next stage of the assessment.

### 2.2.5 Summary of modified framework

The modified framework on which submissions are sought is at Attachment B.

The major elements of this proposed framework are:

- all foods (other than those covered by other parts of the Code) not previously marketed in Australia or New Zealand before the date of gazettal of the amendments arising from this Proposal will be subject to the framework;

- there are two pathways to market for new foods:

  - foods meeting the eligible food criteria can be sold without regulatory approval subject to industry meeting safety requirements that will be set out in the Code
  - foods not meeting the eligible food criteria will require assessment and approval by FSANZ before being marketed (eg, via an application to amend the Code).

- vitamins, minerals, L- amino acids and electrolytes will continue to require pre-market approval by FSANZ
- other potential nutritive substances will be subject to the requirements of the modified framework
- foods currently listed in Schedule 25 with specified conditions of use will continue to be specifically permitted
- foods currently listed in Schedule 25 with no conditions of use may be removed from the Schedule
- FSANZ will explore the streamlining of its pre-market assessment process.

# 3 Other issues

FSANZ considers the following three issues require clarification and/or further stakeholder input before options are considered for a possible food regulatory measure. The issues are discussed below.

## 3.1 Review of exclusive permissions

### 3.1.1 Background

The Ministerial policy guidance for novel foods[7] includes the following specific policy principle: *To provide an assessment process that aims to protect commercially sensitive information and recognise industry's intellectual property to the maximum extent possible.*

An exclusive permission provision in the Code was introduced in 2007 under Proposal P305 – Permission for Exclusivity of Use of Novel Foods. This followed requests from the Food Regulation Ministers for FSANZ to consider the capacity for including a specific provision for exclusivity of use for novel foods in Standard 1.5.1 and to limit the period of exclusive permission as a novel food for a particular brand for up to 15 months, after which any exclusive permissions revert to a generic permission at the expiration of the approved period of exclusivity (see section 3.1.2). Ministers requested a review of the exclusive use permission provision be conducted 3–5 years after its introduction. This review is being addressed in this Proposal.

### 3.1.2 Current approach

The FSANZ Act permits FSANZ to make a standard that may relate to a particular brand of food (paragraph 16(2)(b)). This enables FSANZ to set exclusive permissions for a brand of food; i.e. only a particular brand or brands of a novel food may be sold during the exclusive permission period. In deciding whether to set an exclusive permission, FSANZ must have regard to specific assessment criteria prescribed by the FSANZ Act.

The decision of whether to set an exclusive use permission is taken as part of a more general consideration of whether a novel food, if approved, should have conditions of use imposed on it. This is described in the Note to section 1.5.1—3. The Code does not mandate specifying the brand of food and the class of food in which that brand/food may be sold when an exclusive permission is granted. It allows FSANZ, when appropriate, to impose a condition that the sale of the novel food be restricted to a particular food class or brand of food, either as a stand-alone condition or as part of a set of conditions, for a period of up to 15 months post-gazettal. At the end of that 15 month period, the permission becomes generic and non-brand specific. That is, the food may be sold under any brand.

An exclusive use permission is usually only considered by FSANZ if an applicant expressly applies for one. Such an application would usually be a paid application on the basis that its approval would confer an exclusive capturable commercial benefit on the applicant.

At present, any manufacturer can submit an application using data generated by others if that data is publicly available. Additionally, neither the FSANZ Act nor the Code prevents approval of second or subsequent applications within the 15-month exclusive permission period for the use of the same novel food by other food companies (i.e. under a different brand). Any subsequent applications must follow the same application process, including meeting the requirements of the FSANZ *Application Handbook* and payment of a charge, if applicable. A subsequent application for a different brand, if approved, would be likely to attract a limited period of exclusivity because the initial and existing exclusive permission would automatically revert to a generic and non-brand specific permission at the end of its exclusive use period.

Only a limited number of exclusive use permissions have been sought to date.

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

### 3.1.3 Stakeholder views

Many stakeholders supported exclusive use permissions as a means of protecting industry's commercial investment in new ingredients. Most of these stakeholders consider an exclusive use period of 15-months as insufficient to achieve the required return on investment. Some stakeholders provided data to suggest that 15 months was inadequate to cover administrative costs, the cost of producing the safety dossier and running manufacturing plant trials. However, the data provided was limited. Extending the exclusive permission period to three or five years was proposed by various submitters.

Stakeholders opposed to exclusivity (in submissions to P305) cited its effect on both domestic and international competition in the market; limiting consumer choices of products containing the novel food ingredient; and increased prices of novel food products with exclusive permissions. These stakeholders have also noted that there was no need for the Code exclusive use permissions as industry have other means available to protect new product development. In particular, intellectual property protection is available under patent law. However, other submitters suggested that intellectual property protections (e.g. patents and trade secrets) may not always be suitable in the context of new food products.

Industry stakeholders suggested that data protection is an important aspect of protecting new product development costs. The new European Union novel food regulation[8] provides a period of five years data protection for novel food approvals in certain circumstances. That is, newly developed scientific evidence and proprietary data used in a novel food application cannot be used for the benefit of another application for five years after the novel food has been approved. However, the FSANZ Act does not provide FSANZ with the authority to adopt this model of data protection, if it was considered warranted.

The FSANZ Act also requires that FSANZ decision-making processes be transparent and accountable and that material relevant to applications generally be published to inform and facilitate public participation in decision-making. The outcomes that result from FSANZ's assessment of applications are decisions that can touch the entire Australian and New Zealand community. Anyone who produces or consumes food in these countries has a strong interest in how those decisions are made. For these reasons, applications, their supporting documents and submissions are generally published on the FSANZ website or made publically available. Applications, supporting documents and submissions are also subject to freedom of information and other laws which can require their disclosure or publication.

### 3.1.4 Request for input

FSANZ has received limited information on the costs and benefits associated with the exclusive permission provision. However, more evidence is needed in order to undertake analysis of its effectiveness and to consider whether alternative options may be appropriate..

In deciding whether the Code should include measures relating to exclusive use, protection of investment in new product development etc., FSANZ is required by section 29 and 59 of the FSANZ Act to have regard to the following matters, among others:

- whether costs that would arise from such a measure outweigh the direct and indirect benefits to the community, Government or industry that would arise from that measure;

- whether other measures would be more cost-effective than such a measure;

[8] http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1449760581954&uri=OJ:JOL_2015_327_R_0001

- other relevant matters such as:
  - the need for any such measure to be based on risk analysis using the best available scientific evidence (which includes economic evidence);
  - the desirability of an efficient and internationally competitive food industry.

With these factors in mind, FSANZ is therefore seeking additional information from stakeholders.

**Questions for submitters:**

Does there remain a requirement to provide exclusive permission as a condition of use in the Code?

What costs to the community, Government and industry arise from the grant and use of exclusive permissions? Please provide data if possible.

What direct and indirect benefits to the community, Government and industry arise from the grant and use of exclusive permissions? Please provide data if possible.

Why should Australian and New Zealand food laws make Australian and New Zealand food regulators bear the onus and cost of protecting industry's intellectual property in products being sold commercially?

Why are other existing measures (such as intellectual property laws allowing a patent or innovation patent) not adequate to protect industry's investment in developing commercial food products?

What other alternatives exist to protect industry's investment in developing commercial food products (i.e. other than reliance on the Code and Australian and New Zealand food laws)?

Is the current 15-month period applied to exclusive permissions sufficient? If 15 months is not considered sufficient, please explain why this is the case and what period of time would be sufficient and why. Please provide data if possible.

Does the innovation activity your business undertakes typically occur in Australia or New Zealand? Will this change if the period for exclusive permissions are increased and, if so, how and why? Please provide data if possible.

Does your business typically place new products on the market at the same time or before placing them on the market in larger overseas markets? Please provide examples or data if possible.

## 3.2 Transition arrangements for currently marketed foods

### 3.2.1 General approach

#### *3.2.1.1 Approach following assessment*

Following the assessment, FSANZ's preferred option was to not rely on a definition of 'non-traditional food', but instead set a cut-off date by reference to 'new' foods that had not been marketed before that date. A new framework would apply to these 'new' foods, but would not to be applied retrospectively to foods already on the market before the cut-off date. Thus any food which was marketed before the cut-off date would be permitted to be sold without having to comply with the revised standard.

Some international jurisdictions have adopted a cut-off date for the requirement for pre-market assessment, including the European Union's novel food regulations and the United States Food and Drug Administration's generally recognised as safe (GRAS) approach. These cut-off dates provide an objective measure and appear to have been effective in these jurisdictions.

#### *3.2.1.2 Stakeholder views*

The concept of exempting foods currently marketed from the requirements of the new framework ('grandfathering') was supported by most stakeholders because it would not impose an additional regulatory burden and provided certainty on the legality of marketing existing foods. However, some submitters raised concerns about the safety of foods which would not have undergone rigorous safety assessment (i.e. nutritive substances and novel foods that are on the market before a cut-off date, but not approved by FSANZ) and suggested FSANZ should do a market scan to identify the extent of these foods.

One submitter requested that foods sold under the New Zealand *Food (Supplemented Food) Standard 2013* (the Supplemented Food Standard) be grandfathered. The New Zealand Ministry for Primary Industries acknowledged that P1024 could assist in aligning the Code with the Supplemented Food Standard, although it was likely the Supplemented Food Standard would continue to be needed because other standards in the Code did not apply to supplemented foods (for example, vitamin and mineral requirements in Standard 1.3.2).

#### 3.2.1.3 Possible proposed approach

FSANZ sees merit in an approach where foods on the Australian and New Zealand markets at the time of gazettal would be 'grandfathered', as initially proposed following the assessment. Only those foods supplied after the date of gazettal would be subject to the new framework.

Some submitters expressed concern around foods that the ACNF had considered novel, but were on the market without being permitted in the Code. ACNF opinions can be based on specific safety concerns. However, the opinions can also be based on the absence of sufficient safety information being provided to the ACNF, rather than any identified safety concerns. It is reasonable to expect food manufacturers to be able to confirm that their foods are safe and suitable, since this is a requirement under the Food Acts. The ACNF and its predecessor, the FSANZ Novel Food Reference Group, provide advisory opinions only. They have no legal status or standing. For these reasons, they have limited utility in identifying foods which should or should not be 'grandfathered' (ie, regulated).

Submitters also expressed concern around some ingredients which are uniquely present in foods sold under Standard 2.9.4 – Formulated supplementary sports foods. Foods sold under this Standard have been the subject of some food recalls and other post-market regulatory interventions. However, the compositional requirements of Standard 2.9.4 are quite broad and also subject to the existing nutritive substance and novel food provisions in the Code. Therefore, similar to the previous paragraph, without clear evidence of non-compliance or a safety concern, they can have limited utility in identifying foods subject to Standard 2.9.4 that should not be subject to grandfathering. FSANZ's future review of Standard 2.9.4 will consider the compositional aspects of this category of foods.

Foods sold under the New Zealand Supplemented Food Standard do not currently need to comply with Standard 1.5.1 or the requirement for permission for nutritive substances to be pre-approved in the Code. FSANZ acknowledges the desire expressed by some Australian submitters for a more even playing field in relation to the sale of foods currently produced in New Zealand under the New Zealand Standard and able to be legally sold in Australia under the trans-Tasman Agreement.

The New Zealand Government has indicated an intent, in time, to reduce, if not eliminate, foods sold under the New Zealand Supplemented Food Standard. However, the migration of products regulated under the New Zealand Supplemented Food Standard towards the Code is outside the scope of this Proposal.

In addition to legal obstacles to retrospectively applying the requirements of a new framework to existing foods, FSANZ is concerned about the practicality of an alternative approach to grandfathering which would involve some level of post-market surveillance or a retrospective production of a safety dossier compliant with the new standard. Such an exercise would be very costly and potentially very difficult to implement. Regulatory or legal action is problematic because of the onus of proof required when undertaking proceedings in relation to the safe and suitable provisions of Food Acts (see section 3.1 of the assessment summary for further discussion of this issue[9]).

In response to the suggestion that FSANZ develops a positive list of acceptable foods and ingredients, FSANZ considers the compilation of all existing foodstuffs and ingredients to develop a positive list in the Code would be a lengthy, complex and expensive task, disproportionate to risk and would be unlikely to be sufficiently comprehensive to be of value.

### 3.2.2 Microorganisms

#### *3.2.2.1 Current approach*

The use of microorganisms as food or ingredients in foods is specifically addressed in only a limited sense in the Code. Infant formula, infant foods and some dairy commodities in Chapter 2 are permitted to contain lactic acid producing microorganisms, without further clarification on particular species. New microorganisms or new uses of microorganisms in food may be subject to the novel food requirements in the Code.

#### *3.2.2.2 Approach following assessment*

FSANZ considered that specifically addressing the use of microorganisms (as food) in the Code would provide greater clarity and certainty than exists currently. The framework presented in the assessment summary included an eligible food criterion for microorganisms, namely that microorganisms were *eligible if they are listed in the Code and are cultured to maintain genetic stability*. FSANZ proposed developing a positive list of microorganisms with a known history of safe use. The positive list would have been included in the Code to support the eligible food criterion. More detail on the development of this criterion is available in Supporting Document (SD3) which accompanied the first Call for Submissions. A copy of SD3 is available on the FSANZ website.

#### *3.2.2.3 Submitter views*

Submitters provided a variety of views in relation to the proposed approach following the assessment. The significant history of using microorganisms in foods and in the production of foods was noted. Submitters expressed concern that a positive list of microorganisms in the Code may present problems for fermentative and flavour producing food culture microorganisms (e.g. those used in production of alcohol, cheeses, salamis and other fermented foods). Food cultures of this type are sometimes not well characterised, but have not presented safety concerns. Concern was expressed that a positive list[10] that does not encompass the wide variety of microorganisms that may be present in food cultures may be unnecessarily restrictive and not be representative of risk.

[9] http://www.foodstandards.gov.au/code/proposals/Pages/P1024.aspx
[10] Proposed eligible food criterion 1 in the originally proposed framework

Submitters suggested that other reference sources should also be considered, in addition to the European Union's qualified presumption of safety list, if a positive list was to be introduced.

Submitters noted that a positive list may be appropriate for microorganisms intentionally added to food.

Some submitters commented on the proposed requirement for maintaining genetic stability of microorganisms, either asking for more clarification or providing suggested modifications to wording. FSANZ will investigate this aspect of microorganism requirements in the next stage of the assessment.

#### *3.2.2.4 Proposed approach*

The current generic references to microorganisms in various standards in the Code recognise the inherent safety of these fermentative and flavour producing food culture microorganisms (FCMs) to produce food. These microorganisms are selected for and maintained in culture, either as characterised single and mixed strain cultures or uncharacterised mixed cultures, to express specific phenotypic characteristics to produce foods with desirable, stable and reproducible characteristics. These FCMs, and the processes and methods used for selection, have a history of safe use.

Safety concerns may arise, however, if: microorganisms are used for a purpose in food without a history of safe use; there is a substantial change in the amount of the microorganism used as a component of the food during production; or there is a substantial increase in the amount and type consumed. For example,

- if a specific species of microorganism without a history of safe use at the proposed quantities ingested is developed for use as a food or food ingredient, rather than as an FCM
- if there are specific risk factors related to a genus or species, such as the presence of transferable virulence and antimicrobial resistance genes in *Enterococcus* spp.
- if a minor component of an uncharacterised mixed strain food culture is isolated and used as a major component.

The risk to the health and safety of consumers may arise due to the expression of virulence factors, the presence of transferable antimicrobial resistance genes or the expression of toxins or undesirable metabolites that would otherwise not have been consumed in sufficient quantities to cause a health problem.

FSANZ therefore sees merit in all foods produced with live food culture microorganisms sold in Australia and New Zealand at the time of gazettal being 'grandfathered' and not subject to the new framework.

FSANZ notes there may need to be exceptions to this approach. Stakeholder views are sought on the following possible exceptions to the grandfathering of foods produced with live food culture microorganisms:

- In instances where microorganisms are added for a purpose other than as a 'food culture microorganism' and where a history of safe use cannot be demonstrated, the microorganisms must be identified and evidence of an absence of virulence determinants, toxins, undesirable metabolites and transferable anti-microbial resistance (AMR) genes must be demonstrated.

- Standards 2.9.1 and 2.9.2 permit the addition of lactic acid bacteria to infant formula and infant foods respectively. FSANZ questions whether the addition of lactic acid bacteria to these products should be subject to the grandfathering of 'food culture microorganisms' as this may not be the purpose of adding these ingredients. Clarification may be required for these foods, depending on the purpose of addition of the lactic acid bacteria.

**Questions for submitters:**

Please indicate whether you support the 'grandfathering' of foods which are available for sale in Australia and New Zealand at the time of gazettal (of a new framework in the Code).

Do you consider there are categories of foods that should not be grandfathered? If so, please provide justification for your view.

Would the proposed approach for microorganisms present problems for your business? If so, please elaborate.

## 3.3 Part 2.9 standards – scope and timing

### 3.3.1 Proposed approach following assessment

FSANZ originally proposed that this Proposal would not consider Standards 2.9.1, 2.9.2 and 2.9.5 but would have regard to Standards 2.9.3, 2.9.4 and 2.9.6.

### 3.3.2 Submitter comments

Submissions in early 2016 on both P1024 and P1028 – Infant Formula consultation paper commented on the consideration of nutritive substances and novel foods. The P1028 consultation paper proposed that novel foods and nutritive substances relevant to infant formula would be included in scope of that Proposal and in due course, would be applied in some manner to all products regulated by Standard 2.9.1. This was to enable FSANZ to have regard to the Ministerial Policy Guideline on the Regulation of Infant Formula Products[11] especially policy principle (i) which states:

> *(i) Pre-market assessment … should be required for any substance proposed to be used in infant formula and follow-on formula that:*
>
> *i does not have a history of safe use at the proposed level in these products in Australia and New Zealand; or*
>
> *ii has a history of safe use in these products in Australia and New Zealand, but which, having regard to source, has a different form/structure, or is produced using a substantially different technique or technology.*

The approach that would be established for follow-on formula was proposed to be considered for infant food at a later time, since these two foods were consumed by the same vulnerable population group.

Submitters on the P1024 assessment (and the P1028 consultation paper) commented that P1024 should apply to the entire Code because it was inappropriate to exclude the bulk of standards that regulated nutritive substances (other than vitamins etc.) and that the current regulation of novel foods was no different for Standard 2.9.1 than for other standards (especially in regard to definitional issues).

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

The need for consistency across the Code was also emphasised and that regime alignment between Standard 2.9.1 and the Code's other standards was crucial. In response to FSANZ's question about how to incorporate foods regulated by Part 2.9, P1024 submitters suggested that novel foods approved for use in infant formula products should be listed as approved optional ingredients in Standard 2.9.1. Concerns were also expressed about the final integration of all new requirements across the Code when they are considered separately and may be completed at different times.

### 3.3.3 Proposed approach – Scope and timing of P1024 relative to P1028

FSANZ now proposes that the scope of P1024 should be expanded to include all standards in the Code except Standard 2.9.1, particularly as the latest proposed model is simpler than that originally proposed. The reason for exclusion of Standard 2.9.1 from P1024 relates to the policy guidance on infant formula products which outlines a more stringent approach than for other foods. Detailed consideration of infant formula products will therefore be needed under P1028 taking account of the sustained public interest in human milk research and in infant nutritional science, as well as the specific trends in formula composition and manufacturing of infant formula products. The inclusion of Standard 2.9.2 brings lactic acid producing microorganisms into consideration, but which are also permitted in Standard 2.9.1.

The P1028 consultation paper indicated that the model for general foods implemented under P1024 may be able to be considered for infant formula products. However, any proposed eligible food criteria for certain standards in Part 2.9 may differ in some respects from those applicable to general foods on the basis of the more vulnerable population groups to which these foods are directed. Further development of eligible food criteria will be undertaken in the next call for submissions.

FSANZ is aware of the developments and timing of both proposals and will take them into consideration as appropriate. In relation to the potential for both proposals to have different completion dates, the integration of the new requirements across the Code can be addressed after further progress provides firmer direction on both proposals and plans for the review of follow-on formula are developed.

# 4 Risk communication

Consultation is a key part of FSANZ's standards development process. All consultation papers and 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 documents and submissions on the FSANZ website. All public comments received are reviewed and considered by the FSANZ Board in making its final decision.

FSANZ also acknowledges the expertise of members of the Standards Development Committee comprising representatives from jurisdictions, enforcement agencies and industry, which has been established to provide advice on the next stages of the assessment of the Proposal.

## 4.1 Consultation

Before preparing this Proposal, FSANZ released a consultation paper[12] in March 2012. The objective of the consultation paper was to seek feedback on a proposed 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.

FSANZ received 22 written submissions with varying levels of support and opposition to the proposed approach. Given the range of opinions, FSANZ hosted a workshop with industry and government agencies to discuss a number of issues pertaining to the future regulation of nutritive substances and novel foods (Sydney, 26 June 2012). 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 and included a discussion of potential elements of an alternative approach to the current Code provisions.

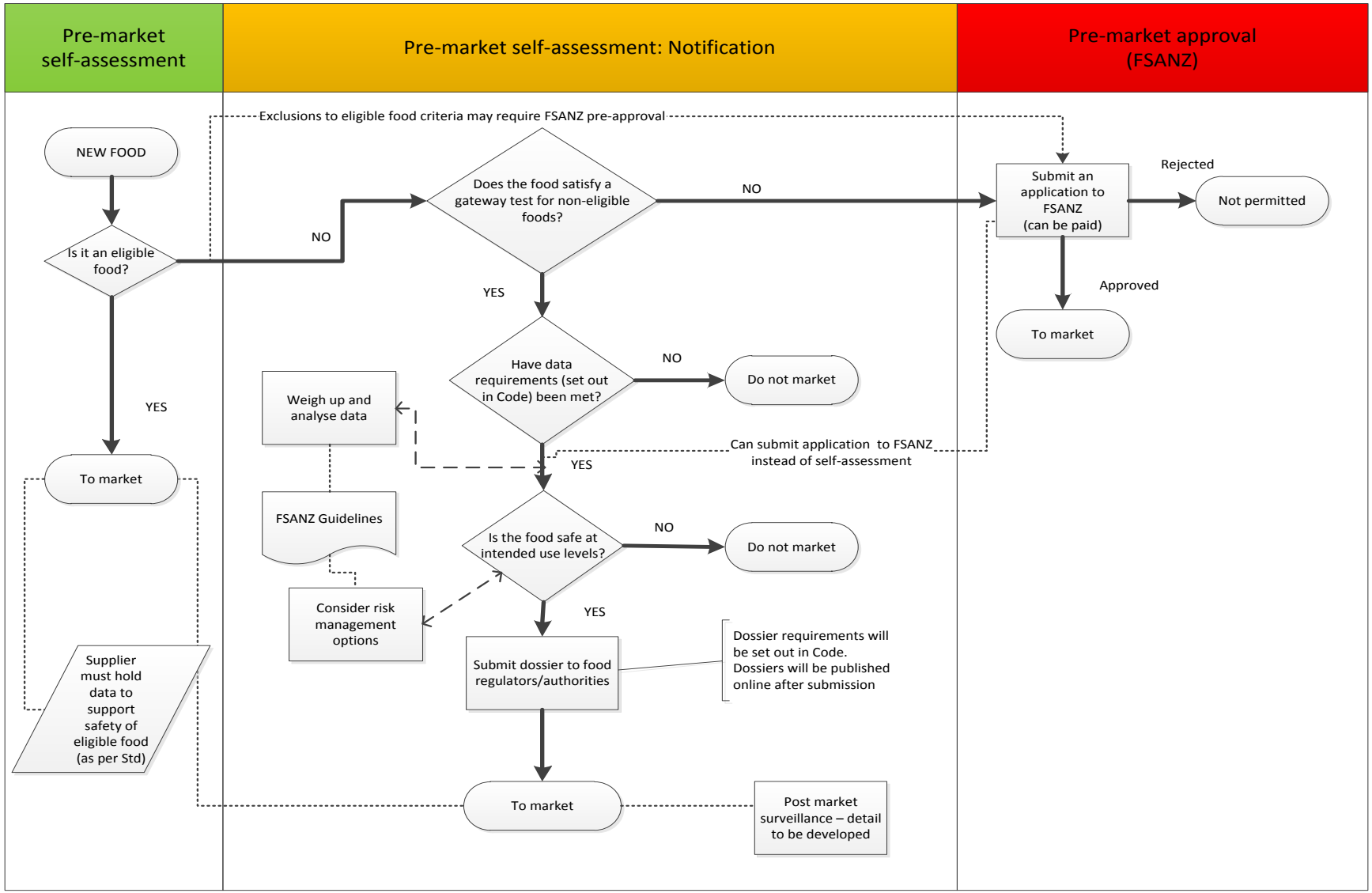
Based on those discussions and submissions, following the formal assessment of P1024, an assessment summary and related supporting documents which included an alternative approach to the regulation of nutritive substances and novel foods were released in December 2015 and workshops were held in various locations.

After considering responses to this paper, FSANZ will further consideration options to progress the Proposal. As part of its consideration as to whether or not the preparation of a draft food regulatory measure is appropriate, the following issues will be taken into account by FSANZ:

- description of eligible food criteria
- requirement for suppliers of novel foods which meet the eligible food criteria to hold supporting safety data and these data requirements
- requirement for all other foods to seek pre-approval
- exclusivity provisions
- transition provisions.

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

## Attachment A – Original proposed framework following assessment



## Attachment B – Modified framework – May 2017