AUSTRALIAN FOOD & GROCERY COUNCIL

AFGC SUBMISSION

P1024 – REVISION OF THE REGULATION OF NUTRITIVE SUBSTANCES AND NOVEL FOODS

MARCH, 2016

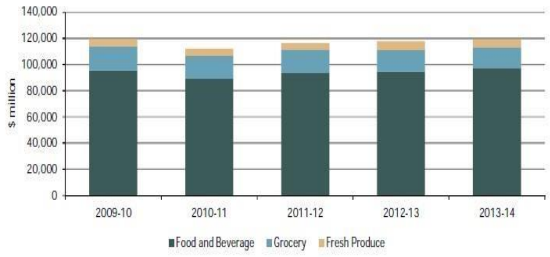
Sustaining Australia

Preface

The Australian Food and Grocery Council (AFGC) is the leading national organisation representing Australia's food, drink and grocery manufacturing industry.

The membership of AFGC comprises more than 190 companies, subsidiaries and associates which constitutes in the order of 80 per cent of the gross dollar value of the processed food, beverage and grocery products sectors.

Figure 3.1: Composition of the defined industry's turnover ($2013-14)[11]



Source: Based on ABS, catalogue number 8221.0, 8159.0 and 8155.0

Australia's food and grocery manufacturing industry takes raw materials and farm products and turns them into foods and other products that every Australian uses every day. With an annual turnover in the 2013-14 financial year of $118 billion, Australia's food and grocery manufacturing industry makes a substantial contribution to the Australian economy and is vital to the nation's future prosperity. It adds over $32 billion to the value of the products it transforms.

Manufacturing of food, beverages and groceries in the fast moving consumer goods sector is Australia's largest manufacturing industry. The diverse and sustainable industry is made up of over 26,651 businesses and represents 30% (almost one third) of the total manufacturing industry in Australia.

The food and grocery sector accounts for over $61.7 billion of the nation's international trade in 2014-15, with a trade surplus worth over $10 billion to the Australian economy in 2014-15. These businesses range from some of the largest globally significant multinational companies to family-based small and medium enterprises.

The food and grocery manufacturing sector employs more than 322,900 Australians, paying around $16.1 billion a year in salaries and wages.

Many food manufacturing plants are located outside the metropolitan regions. The industry makes a large contribution to rural and regional Australia economies, with over 40% of the total persons employed being in rural and regional Australia. It is essential for the economic and social development of Australia, and particularly rural and regional Australia, that the magnitude, significance and contribution of this industry is recognised and factored into the Government's economic, industrial and trade policies.

The contribution of the food and grocery sector to the economic and social well-being of Australia cannot be overstated. Australians and our political leaders overwhelmingly want a local, value-adding food and grocery manufacturing sector.

Data source: *AFGC and EY State of the Industry 2015: Essential Information: Facts and Figures*

Contents

1. Executive Summary

The Australian Food and Grocery Council (AFGC) provides this submission in response to Food Standards Australia New Zealand (FSANZ) Proposal P1024 *"Revision of the Regulation of Nutritive Substances and Novel Foods"* [30-15] (4 December 2015).

It is vital that Australian and New Zealand achieve two objectives in considering the future of novel food reform – the central objective of food safety, and the economic imperative to foster, or at least not unnecessarily impede, innovation. Novelty does not imply the absence of safety.

The AFGC strongly supports the principle of minimum effective regulation, and accordingly supports the graduated risk approach proposed under Option 3 of matching regulatory intervention to the nature and severity of the risk posed by a novel food or nutritive substance. A key element in Option 3 is that the tailored risk approach still provides strong protection for public health and safety. The AFGC and its members consider this an essential outcome of food regulation.

The AFGC does not support Options 1 or 2. Retaining the status quo (Option 1) fails to address the significant legal and policy questions that have arisen in relation to the current Standard, while changing definitions (Option 2) fails to address the need to moderate regulatory intervention proportionate to risk as an element of minimum effective regulation.

The AFGC therefore supports the draft framework which takes a proportionate approach to risk and has three main elements:

1. Identifying novel foods which do not require regulatory approval before market entry;
2. Pre-market self- and regulatory assessment routes for market entry of other novel foods; and
3. A description of data and dossier requirements needed to establish public health and safety under the various assessment routes.

While the AFGC is supportive of the approach in option 3, the "devil is in the detail" and this submission identifies opportunities for refinement of the proposal in relation to:

- A simplified pathway to market process under which the eligible food criteria (EFC) are significantly modified;
- Alternative mechanisms to assure the transparency and integrity of the risk assessment process in relation to novel foods and nutritive substances; and
- Formalisation of recognition of approvals by comparable economies for novel foods and nutritive substances without imposing additional self- or regulatory assessment processes.

There are many other areas in the Code where mandatory pre-market regulatory clearance is the mechanism to control food and ingredient access to the Australian and New Zealand market. The AFGC considers that the tiered risk approach should be progressed through all such areas of the Code, including for example the regulation of processing aids and food additives, where ANZ regulation already lags behind international markets.

Mechanisms to assure the transparency and integrity of the risk assessment process in relation to novel foods and nutritive substances are critical, and the AFGC proposes further work to identify and refine such processes.

Recommendations

Recommendation 1: That FSANZ progress Option 3 in relation to P1024, and consider a similar tiered risk approach for all other areas of the Code where mandatory pre-market assessment mechanisms currently apply.

Recommendation 2: That FSANZ include standards in Part 2.9 of the Code within the scope of Proposal P1024.

Recommendation 3: That FSANZ adopt a simplified process for 'green channel' free-to-market novel foods involving the recognition of approvals by comparable economies for novel foods.

Recommendation 4: That FSANZ Consider alternative mechanisms to provide transparency and integrity of self-assessments.

Recommendation 5: That FSANZ remove the ill-defined and duplicatory concept of nutritive substance from the Food Standards Code, and instead regulates specific substances of concern, such as amino acids, as considered necessary for minimum effective regulation.

Recommendation 6: That novel food assessment be independent of potential product claims.

2. Key Issues and Considerations

2.1 Matching Regulation to Risk

The AFGC strongly supports the regulatory principle of minimum effective regulation, and accordingly supports the concept, introduced in Option 3, of matching regulatory intervention to the nature and severity of the risk posed by a novel food or nutritive substance. The AFGC queries whether there is an evidence base for the assumption that novel foods as a class pose any special risk (as distinct from particular issues relating to some sports foods and weight loss products that are formulated with active therapeutic constituents), but recognises the practical reality that abandoning novel food regulation in its entirety is unlikely to develop any better regulatory outcome compared to the general approach proposed in Option 3.

In recognising the impediments to innovation posed by the regulatory pre-market assessment required by the existing novel foods regulation, FSANZ demonstrates a commendable level of understanding of the difficulties, costs and delays faced by industry in relation to the current regulatory processes for nutritive substances and novel foods. Any reduction in the regulatory burdens that currently hamper industry's ability to innovate is welcomed.

A key element in Option 3 is that the tailored risk approach still provides strong protection for public health and safety. The AFGC and its members consider this an essential outcome of food regulation.

There are many other areas in the Code where mandatory pre-market regulatory clearance is the mechanism to control food and ingredient access to the Australian and New Zealand market. The AFGC recommends that the tiered risk approach should be progressed through all such areas of the Code, including for example the regulation of processing aids and food additives, where ANZ regulation already lags behind international markets.

Recommendation: That FSANZ progress Option 3 in relation to P1024, and consider a similar tiered risk approach for all other areas of the Code where mandatory pre-market assessment mechanisms currently apply.

2.2 Scope of the review

The AFGC notes that of the eight standards in the Code that refer to 'nutritive substances', five of these standards are in Part 2.9 and three of those Standards (Standards 2.9.1, 2.9.2 and 2.9.5) are specifically excluded from the scope of Proposal P1024.

It is not clear why this is so or how it has been justified given that if this proposal is to proceed, the regulation of nutritive substances and novel foods for these foods will effectively default to the current arrangements. It is likely that it will take up to 2 years to prepare and process another Proposal to cover these foods. This will delay innovation in these food categories.

The AFGC considers it inappropriate to develop a system for the future regulation of nutritive substances when the bulk of the application of the term is in Standards that are excluded from scope. The AFGC therefore strongly supports the inclusion of standards in Part 2.9 within the scope of Proposal P1024. Applying the same framework for the future regulation of new substances (currently nutritive substances and novel foods) with appropriate amendments to address special requirements is the most sensible way to proceed and recommends the scope of Proposal P1028 be amended to exclude consideration of nutritive substances and novel foods.

Recommendation: That FSANZ include standards in Part 2.9 within the scope of Proposal P1024.

2.3 Eligible food criteria (EFC)

Option 3 seeks to establish Eligible Food Criteria (EFC) for the 'free-to-market' path, as a means of identifying those novel foods for which a pre-market assessment is not necessary. The AFGC does not support the proposed Eligible Food Criteria (EFC) and our comments on the criteria proposed by FSANZ are set out below.

In particular, the AFGC does not support positive lists for the EFC – they can never fully cover all possibilities and will therefore require ongoing monitoring and updating and will generally lag creating impediments to innovation. This is neither an efficient nor effective regulatory approach and is a course that is intensely demanding on resources, never up-to-date and constraining on innovation and development.

The AFGC instead advocates the adoption of safety and risk assessments conducted by other jurisdictions with similar regulatory approaches. The Australian Government has implemented the principle of adopting international standards and risk assessments.[1] That is, where an international standard or risk assessment already exists, the Government has decided that this should be adopted unless it can be demonstrated that there is a good reason to maintain a unique Australian standard or risk assessment. There is little justification to continue to adopt an idiosyncratic posture of Australasian exceptionalism unless there is evidence that Australian and New Zealand diets are dramatically different from those in the assessing economy. A 'novel' product that has gained approval as a food or food ingredient in comparable economies such as the EU, USA, Canada and Asian countries such as Japan and Singapore should enjoy the 'free' path to market without further requirement for self- or regulatory assessment, and this should be the basis of the 'free' path to market.

Recommendation 3: That FSANZ adopt a simplified process for 'green channel' free-to-market novel foods involving the recognition of approvals by comparable economies for novel foods.

[1] https://www.cuttingredtape.gov.au/sites/default/files/files/International_Standards_FAQ.pdf, accessed 17.03.2016

2.4 Publication of Dossiers

The AFGC recognises and agrees with the principle that regulatory outcomes should be transparent. The AFGC further acknowledges that applications lodged with FSANZ, if accepted, are typically published as part of the call for submissions process, subject to the redaction of any commercial-in-confidence material. Finally, the AFGC recognises that there has been a degree of regulatory disquiet in relation to a lack of any supervisory function of the notification system for self-assessment of general level health claims

On the other hand, any requirement to disclose confidential information serves as a disincentive for companies to seek approval for innovative technology, and even to invest in developing such technology in the first place.

The AFGC considers there needs be a balance between these competing principles, and so does not support full publication of substantiation dossiers. In the AFGC's view, publication of scientific and technical dossiers provides no communication benefit to the general public who are not trained to do risk and safety assessments, and may be confused or misled by the highly technical papers.

The AFGC considers further work needs to be undertaken to identify mechanisms that facilitate regulatory oversight and assure the transparency and integrity of the self-assessment process in relation to novel foods. As a starting position, the AFGC proposes that the self-assessment route, on this point, involve the following elements:

- The company must notify FSANZ ahead of product entry into the ANZ market that it has undertaken a self-assessment, such notification including a statement as to the qualification of the food for the self-assessment process, and a summary and the conclusions of its assessment against mandated data requirements.
- The company must publish the notice to FSANZ on a publicly available website no later than product entry into the ANZ market.
- The company must, from the time of the FSANZ notice, make the full dossier available to regulators on request, subject to safeguards around the protection of commercial-in-confidence material.

This model ensures that regulators, through FSANZ, have both the awareness of novel foods and nutritive substances entering the market. The public has access to information about the novel food and its evaluation, while at the same time the confidentiality of sensitive information can be protected.

Recommendation: That FSANZ consider alternative mechanisms to provide transparency and integrity of self-assessments.

2.5 Combining nutritive substances with novel foods

The AFGC considers that the regulation of nutritive substances was misconceived from the start, covering substances that were already regulated (vitamins and minerals) as well as having a confusing and complex overlap with novel food regulation. A more objective regulatory definition for

'novel food' would largely negate the need for continued, separate regulation of nutritive substances, the possible exception being the regulation of amino acids. The AFGC believes appropriate consequential amendments to those few standards that reference nutritive substances (largely special purpose foods and formulated caffeinated beverages) could address all outstanding concerns such that the definition and concept of 'nutritive substance' could be removed from the Code entirely, or at least constrained to specific use in the 2.9 standards.

The definition would need to considering variations of non-novel foods (e.g. lime vs. bush lime) and novel foods in new matrices (e.g. as per Standard 1.3.2 Vitamins and Minerals unable to add vitamin C to Milk, will this Standard allow as a novel food?)

Recommendation: That FSANZ remove the ill-defined and duplicatory concept of nutritive substance from the Food Standards Code, and instead regulate specific substances of concern, such as amino acids, as considered necessary for minimum effective regulation.

2.6 Distinction between food approval and health claims

The AFGC notes the Application Handbook section relating to novel foods effectively asks about the claims that are being made in relation to the novel food in overseas jurisdictions, or are being considered in the Australian context. Such concerns might arguably have been justified prior to the commencement of Standard 1.2.7, but now reflect a confusion between the regulatory objectives of the two classes of standards – Standard 1.2.7 is the appropriate mechanism to regulate claims, whereas the focus of novel foods regulation must, in the AFGC's view, be centred on safety. The claims that might be made should be irrelevant in a novel food safety assessment process.

The AFGC raises this concern as there have been examples in the past consideration of novel foods where product claims have been taken into consideration, even against the objections of the applicant. Novel foods regulation was, in the absence of Standard 1.2.7, perceived as being a mechanism by which regulators might prevent unwanted claims from being made. Again, such an approach is now unwarranted and confusing, and would foster a confusing overlap in the regulation of novel foods and health claims.

Recommendation : That novel food assessment be independent of potential product claims.

2.7 Information management

Based on the proposed requirements of this consultation, ingredient suppliers will have increased responsibility in ensuring they provide the required detail on ingredients/foods as requested by manufacturers. The AFGC will explore updating its Product Information Form (PIF) to accommodate information requirements for substantiation of novel food assessment.

2.8 Food matrix management

The treatment of novel foods or novel ingredients that are safe to consume within limits, rather than *ad libitem*, is a detail that will require further work by FSANZ in the development of this Proposal.

The AFGC is concerned that FSANZ manages dietary exposure on a 'first come, first served' basis that prejudices subsequent potential uses, either by consuming the entirety of available exposure or

by driving conservative dietary exposure assessments based upon atypically high consumption levels. This issue is not constrained to novel foods, but does affect existing approvals for novel ingredients such as plant sterols.

In the context of this Proposal, it is unclear how an application to extend the use of sterols into new (but not novel) food matrices should be progressed. Would such an application need to deal only with dietary exposure, or would it be necessary to re-establish the safety of sterols in general?

3. AFGC Response – Questions for Submitters

3.1 Risk Assessment

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

The AFGC considers that the existing definitions create -

- Uncertainty as to whether a substance is novel and therefore whether approval is required, requiring costly specialist advice and delays in time to market;
- An uneven playing field as difference in interpretation may result in one company bringing a product to market that another company may consider to be captured by the current definitions and therefore requiring pre-market approval;
- Lost opportunity for sales of products available in other markets due to uncertainty and hurdles to market;
- Lost opportunity for consumers to experience new products; and
- Loss of investment in ANZ markets and operations.

For AFGC member companies, the definitions therefore present serious impediments to developments in the food supply and are a significant limiting factor on innovation and development of food products.

While the AFGC recognises that the Advisory Committee on Novel Foods (ACNF) process mitigates these concerns to a small degree, there are costs and risks in engaging in the ACNF process that prevent the ACNF from having a greater impact.

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

The Call for Submissions document highlights the concerns of regulators that the existing definition does not provide clarity as to whether a food is or is not novel, but in the AFGC's view this goes further. A failure to be clear as to the intended scope of operation may render a regulation void for uncertainty. The current definition uses the phrase 'requires an assessment' which suggests a subjective test (requires according to whom?) that raises a significant potential of being held void if challenged.

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.

Advisory Committee on Novel Foods (ACNF)

The AFGC notes that the ACNF 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. Whilst 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. Feedback from ACNF does not provide details on why a material has been assessed as requiring an assessment of public health and safety considerations. Therefore, it is difficult for manufacturers to learn how to assess whether a material may be regarded as novel or not – the current process is not very transparent.

The AFGC does not support retention of the ACNF going forward.

Application process

The current application process is onerous and costly, especially if the company elects to proceed with a paid application.

The existing Standard impedes innovation by discouraging, through cost, delay and uncertainty, the introduction of new foods into the ANZ market, and as a result has a negative impact upon investment decisions.

Example:

Bovine milk basic protein fraction being deemed not novel, but a nutritive substance in Australia, so this market could not use it. However, this ingredient has GRAS status in the USA and FOSHU in Japan. Products have been in market with health claims in Japan and USA with it.

Products could not be marketed in ANZ and the opportunity for innovation was lost.

3.2 Risk Management

Pre-market approach

The AFGC supports a pre-market assessment approach to the regulation of nutritive substances and novel foods to determine the safety and required mitigation measures to ensure the safety of new foods and ingredients entering the market. However, the secondary considerations identified by FSANZ are important to industry for ensuring a clear path to market for new and innovative foods – that is, options should:

1. be proportionate to the varying levels of risk of new foods entering the market;
2. be objective, clearly understood and enforceable; and
3. should provide industry with the opportunity to access the market quickly and without undue regulatory burden.

International regulation

The AFGC supports compatibility with international approaches to the regulation of novel foods as a consideration in formulating an amended approach – many companies based in Australia and New Zealand rely on innovation developed by global parent companies or suppliers for markets other than ANZ. Incompatibility with the regulations of international jurisdictions often sees Australian and New Zealand consumers missing out.

Example:

Company X is currently looking at a food which is produced in US for the US market. There is an ingredient which they believe is not allowed in Australia based on previous advice from the ACNF. Their options would be to not proceed with this food; or to ask their US business to reformulate the food specifically to meet the Australian requirements. Due to the low volumes required for Australia compared to US, it is unlikely that they would agree to reformulate entirely or to have a specific formulation for the Australian product due to increased costs/complexity. The likely final result is that within current food regulations that Company X will not be able to launch the food in Australia. However, if the raw material is an approved food in the US, and this is acknowledged in the new regulations, then it should make the process much easier to "lift and launch".

Example:

Consider olive leaf extract as viable source of hydroxytyrosol.

In the EU olive leaf is listed by EFSA as a source of this active compound to support a health claim, but regarded as a novel ingredient here. The following wording reflects the conclusion from EFSA of the scientific evidence:

"Consumption of olive oil polyphenols contributes to the protection of blood lipids from oxidative damage".

Olive polyphenols derived from olive leaf are amongst the olive plant sources listed of the specific polyphenol (hydroxytyrosol) required to substantiate the claim. In order to bear the claim, 5 mg of hydroxytyrosol and its derivatives (e.g. oleuropein complex and tyrosol) in olive oil should be consumed daily. *(Commission Regulation (EU) 432/2012 of 16/05/2012)*

3.2.1 Option 1

The AFGC does not support option 1. The current approach to mandatory premarket clearance is anti-innovation and unnecessarily restrictive.

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

Consideration needs to given as to the mechanism for continuing current novel food permissions. It may be that such foods now have a history of consumption sufficient to characterise them as no longer being novel. The only issue that arises is whether it remains scientifically justified to retain the labelling obligations in relation to phytosterols.

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

No, the FSANZ assessment of the current process is comprehensive and recognises the limitations for all stakeholders.

3.2.2 Option 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.

Yes, the AFGC supports amending the definition of 'novel food' and the removal from the Code of the definition and concept of 'nutritive substance'. However, while Proposal P1024 might consider whether the term 'used as a nutritive substance' is redundant, this consideration cannot be undertaken if Standards that the term is used in are excluded from the scope of the Proposal. AFGC therefore recommends the scope of Proposal P1028 be expanded to include all relevant Standards.

A definition of novel food relating to the absence of a history of consumption in Australia and New Zealand as at a set date would remove the uncertainty that lies at the heart of the current definition, and render it objective. Consideration could be given to definition which captures both novel foods and nutritive substances – ie "new substances".

That said, such a definition is far broader than the existing one, and the AFGC's support is conditional on there being a sufficient 'free' path to market such that there is no disadvantage.

However, the issues relating to novel food regulation go beyond mere definition, and it is the broader reform in Option 3 which the AFGC supports.

3.2.3 Option 3 – Develop an alternative framework

The AFGC supports the proposal for an alternative framework and provides the following comments in relation to specific aspects of this framework.

The AFGC is of the view that, with appropriate differentiation, the framework proposed in Option 3 should be applied to all the Standards in Part 2.9. Applying the same framework for the future regulation of new substances (currently nutritive substances and novel foods) but adjusting elements of that framework to address the specific considerations necessary for the population groups and conditions covered by the standards in Part 2.9 ensures consistency of approach across the Food Standards Code.

Identifying foods that do not require regulatory approval

Eligible Food Criteria (EFC)

The AFGC supports the concept of allowing a 'free' path to market, but finds the terminology of 'eligible food' unhelpful and confusing in this context. All novel foods are potentially eligible to get market access. The AFGC considers a content-neutral nomenclature would clarify the operation of Option 3, such that a 'novel food' might be said to be –

- **'Exempted"** if it meets certain criteria, the consequence being that no further action is needed before the product is allowed to market as a food or ingredient;
- **"Reported"** if it is not exempted, and meets certain other criteria, the consequence being that a self-assessment analysis and process is required before the product is allowed to market as a food or ingredient; or
- **"Assessed"** if it is not exempted or reported (self-assessed), the consequence being that a regulatory analysis and process is required before the product is allowed to market as a food or ingredient;

This makes it clear that all are types of novel food, and that there is a cascade of regulatory intervention governed by appropriate (risk-focussed) criteria. This allows the debate to shift to the two critical questions: what are the criteria for determining exempted, assessed and reported; and what exactly is the nature and content of the self-assessment.

The AFGC has prepared a flow chart provided below to illustrate the simplified proposed path to market.

Figure 1: AFGC Proposed Path to market

FOOD OR SUBSTANCE

PRE-MARKET

IS THE FOOD NOVEL [according to the new definition]?

YES	NO
Proceed to Gate 1	Can be sold, no approval required

GATE 1: Exemption

Does the food or substance have approval from a comparable overseas economy/jurisdiction as an ad libitum food?

NO	YES
Proceed to Gate 2	Can be sold, data to be held by company.

GATE 2: Reported

Does the food or substance have approval from a comparable overseas economy/jurisdiction with some restrictions?

NO	YES
Proceed to Gate 3	Can be sold, safety assessment data to be held by company. Data reported to FSANZ

GATE 3: Assessed

Company to prepare an application for approval of a novel food according to the requirements of the FSANZ Application Handbook.

POST-MARKET

Post market monitoring by jurisdictions

Based on the simplified process proposed by the AFGC, the EFC becomes redundant. The AFGC do not support the proposed EFC and our comments are set out below.

EFC 1 - Microorganisms

The AFGC does not support the establishment/use of lists – they can never fully cover all possibilities and will therefore require ongoing monitoring and updating and will generally lag, creating impediments to innovation. With respect to the development of a list of eligible microorganisms - other than the fact that few enquiries have been made to the ACNF about micro-organisms, there doesn't seem to be any other rationale for requiring all new micro-organisms to undergo pre-market assessment. Micro-organisms are widely used in the food and beverage sector, the population of micro-organisms is dynamic and diverse. To constrain use by a positive list is neither efficient nor practical.

EFC 2 – Food classes & eligible processes

The AFGC does not support the establishment/use of lists for the reasons stated above.

FSANZ proposes that animal and crop commodities ('primary foods') excluding fungi, algae and seaweeds be permitted to be sold without pre-market assessment provided they are not prohibited under Standard 1.4.4. Japan, China, South Korea and other Asian countries have a long history of edible seaweed consumption that continues to the present day and the AFGC question the rationale for forcing seaweed into a costly and burdensome regulatory application process.

The assessment of a food/substance as safe will include assessment of the process undergone to produce it, this should not be used as a means to determine eligibility.

EFC 3

The concept of only being eligible 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 is a road block – these substances will generally be added at higher levels to achieve a function in the food. This hurdle will have the effect of consigning almost all substances from EFC3 to pre-market assessment since few companies would invest in extraction if the substance extracted was limited to return in the processed food at the same level. There is limited value in developing new extracts and processes if use of the extracts and processes are 'status quo'.

Plant sterols are the most obvious example of this, the naturally occurring levels are negligible and one of the reasons the end product costs so much is due to how concentrated the sterols need to be.

EFC 4

Similar to EFC 3 – the requirement that substances obtained from animal or plant commodities are eligible only if they are added back to the same food class at the same concentration as the range in the relevant food class is also a road block. These 2 requirements will mean that most substances will not be eligible, creating a more restrictive system than currently exists.

Exclusions to the EFC

The AFGC does not support exclusions to the EFC.

Questions:

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

The AFGC does not support the concept of EFC for the reasons provided in the previous section.

The AFGC suggest a name change to “exempted food” in line with AFGC proposed terminology.

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.

The AFGC does not support the concept of EFC.

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

As indicated above, the AFGC considers that foods which have received approval for sale as a food (as distinct, for example, as a supplement of additive) under the laws of a comparable economy should qualify for this path to market.

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

The AFGC does not believe substances meeting the EFC should be subject to full safety documentation requirements but that information or documentation setting out the basis of a substance meeting the exempted pathway could be held. This would need to be a simple, clear and achievable process for companies to compile and potentially provided by a supplier. For example, the AFGC Product Information Form (PIF) could be amended to include some specific questions in relation to data supporting the safety of exempted foods. Other sources of information could include:

- Safety assessments conducted by overseas governments
- Peer reviewed safety assessment
- JECFA and FCC monographs

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

The AFGC does not support the concept of EFC.

The AFGC does not support the proposal for exclusions to the EFC. The EFC should be sufficiently robust to identify any types of foods that require further assessment including the types of foods that the ACNF has consistently identified as requiring pre-market assessment.

Exemptions are an admission that the criteria are not sufficiently robust and the aim should be to ensure that the criteria is able to direct these products down the pre-market assessment route.

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.

The AFGC consider this term to be problematic particularly in the case of extracts and substances that will provide more concentrated sources of bioactives, such as lycopene, polyphenols etc. One of the examples provided in SD3 for a material likely to meet Eligible Food Criterion 3 was cranberry extract. It could be argued that this material would have the potential to have pharmacological effects.

Pathways for market entry of foods not meeting the EFC

Industry Self-Assessment

The AFGC supports the industry self-assessment (assessed) pathway as an option for some foods that do not meet the EFC (exempted). As noted by FSANZ, industry already has an obligation to provide safe food and the self-assessment pathway builds on the current obligation. In the case of novel foods, industry currently does a level of self-assessment to determine whether a food is novel and therefore requires approval via the current application process.

The level of expertise required to develop the potential dossier requirements would be similar to that required for a nutritive substance or novel food application currently. Could you build to say also similar to that of the self-substantiated health claims?

The AFGC does not support publication of the full safety assessment dossier (discussed under the following section).

Industry Self-Assessment Gateway tests (CFS, Attachment c)

The AFGC supports the development of a "gateway" test to determine if foods not meeting the EFC can be managed by an industry self-assessment.

FSANZ suggests that the where the food has been approved by an international food regulatory agency, 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. The AFGC consider the overseas approval to be sufficient for exempt eligibility and do not support additional requirements specific to the Australian and New Zealand markets (assessed). This creates an additional and unnecessary burden for industry.

The AFGC does not support the FSANZ suggestion for "carve outs" – this over complicates the pathway to market without any clear justification for doing so. It is difficult to envisage the circumstances where a food eligible for the first path to market would pose such a risk to safety that it requires regulatory pre-market assessment, but such case might best be considered as special cases rather than seeking to develop complicated processes under novel foods regulation. For example, a plant extract of concern might be better considered under the standard for prohibited botanicals rather than under novel foods.

Data and dossier requirements

Record Keeping Requirements

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. FSANZ have made reference in the call for submissions document that, in the case of food retailers / caterers food control plans would need to verify the information is held by the manufacturer / supplier of the eligible food. The AFGC support the requirement to hold this verification information however it may not necessarily be held in a food control plan. Companies have many different forms of documentation and systems for managing this information either locally or globally - it should up to the Company how this information is managed.

Recommendation: It is possible that the AFGC Product Information Forum (PIF) could be modified to hold some of this information for eligible foods.

Content

The AFGC supports the provision of data and assessment requirements in the Code with supporting guidance material similar to the current situation with self-substantiated general level health claims.

The AFGC highlights again the current and ongoing obligation of businesses to provide safe food and see the self-assessment of novel foods and nutritive substances as no different.

Assessment of self-assessment dossiers

FSANZ has proposed that industry self-assessment dossiers may undergo a preliminary assessment by food enforcement agencies prior to publication.

The AFGC understand that an informal version of this process is currently happening with some jurisdictions in relation to dossiers for general level health claims. This does place a burden on the jurisdictions in both time, expertise and resources and may slow down the process for companies in jurisdictions such as NSW and Victoria where a lot of food companies are based.

Publication

The AFGC does not support the proposal to publish submitted safety assessment dossiers online. Companies will not take up this opportunity for self-assessment if confidential proprietary information is to be publically available. Companies invest many millions of dollars in research and development and cannot afford to compromise their investment by making this information publically available for their competitors to benefit from.

In addition, the AFGC questions the ability of consumers to understand the material presented in a safety dossier. Publication may actually have the opposite effect of causing concern in consumers due to the complex nature of safety assessments involving toxicology principles and modelling.

Implementation and compliance

The AFGC understands that assessment and monitoring of compliance to the self-assessment pathway will rest with the jurisdictions much as it does now with self-assessment of general level health claims. While non-compliance, that is, lack of a safety assessment or dossier will be easy to assess, the compliance of dossiers will require another level of expertise which may not currently

reside within the jurisdictions. This may impose an additional burden on industry if companies have to spend time liaising with jurisdictions on dossiers.

There also needs to be a clear process that the jurisdictions will use to review the dossiers, eg: check against the industry guide for developing such dossiers. Industry needs to be aware of how the dossiers will be assessed if a different assessment tool is to be used. Jurisdictions can take the learnings from having to 'calibrate and align' with health claims and apply this to assessment of novel foods going forward.

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.

Yes, the AFGC supports this option as viable and has presented an alternative framework to the EFC for consideration.

The AFGC does not support the requirement for publication of self-assessment dossiers.

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

The AFGC has presented an alternative to the EFC and is willing to work with FSANZ on further development of this alternative.

The AFGC provides the following examples:

- marine algae
- new strains of an existing microbe
- some ingredients for infant foods and infant formula products
- extracts used in quantities greater than those proposed be permitted under the EFC
- substances added to other classes of food
- substances such as beta-glucan.

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

Benefits:

- Time to market reduced over current application process where the dossier is prepared and then a delay while the application sits on the waiting list (if not a paid application) and is then assessed by FSANZ – flagging to competitors what the company is planning and providing no exclusivity. Self-assessment would remove the waiting list delay which can be in excess of 12 months not flag a company's intentions to the market.

- Less development time for product manufacturers if novel food suppliers already have dossier prepared. It reduces uncertainty that can arise with new raw materials during product development.

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.

The AFGC supports notification of the findings of self-assessment dossiers but does not support publication of the dossier as previously discussed.

Additional questions (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?

The Macquarie Dictionary (3rd ed) includes the following definitions that may assist –

> "Nutriment" – any matter that, taken into a living organism, serves to sustain it in its existence, promoting growth, replacing loss and providing energy.
>
> "Medicine" – 1. any substance or substances used in treating disease; a medicament; a remedy 2. The art or science of restoring or preserving health or due physical condition, as by means of drugs …"
>
> "Drug" – a chemical substance given with the intention of preventing or curing disease or otherwise enhancing the physical or mental welfare of humans or animals".

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).

In strict legal terms, the only rationale in Australian and New Zealand for declaring substances to be no longer novel is when the use of the food is subject to labelling or usage restrictions that are no longer considered to be necessary.

In more practical terms, there is a difference between a food regulated as being novel and a food generally available for free sale when it comes to seeking market entry or approvals in additional markets. For this reason it would be appropriate to make provision for foods to be no longer considered novel after an appropriate period (say 5 or 10 years) if they have achieved a history of consumption in the ANZ market and no unanticipated issues have emerged.

FSANZ Assessment of applications

The AFGC supports the options of pre-market self-assessment and pre-market approval by FSANZ subject to further discussion on the criteria for the latter. This is similar to the structure for general level health claims and high level health claims in place at present.

3.3 Draft Framework – other considerations

Impact of the draft framework on current standards

FSANZ propose that existing permissions for novel foods would be maintained in a revised standard or in commodity based standards in Chapter 2 of the Code (phytosterols 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.

The AFGC considers a more substantial response is required. As noted previously, the treatment of foods that are no longer novel should be expressly addressed, and the concept of nutritive substance should be managed through appropriate amendment of standards.

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.

See previous comments. The AFGC supports the regulation of novel foods under a graduated risk approach, the objective being to establish safety in the target foods for consumers at the usage rate. The AFGC considers the concept of nutritive substances to be flawed as it is duplicative, confusing, complex and uncertain.

3.4 Other Matters

3.4.1 The New Zealand Food (Supplemented Food) Standard 2013

The AFGC consider that every effort should be made to more closely align the Code and the New Zealand Standard. This consultation provides the opportunity to progress this goal towards the ideal outcome where the New Zealand Standard to be repealed because it is no longer required.

Recommendation:

3.4.2 Exclusive permission for brand and class of food

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

Current period of 15 months is not long enough to achieve a return on investment. If it is to be retained the period of exclusivity must be extended to 3 years.

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)?

The AFGC considers that if documentation and data sets for the Pre-Market Assessment by Notification Pathway are not public, then notification delivers some level of exclusivity and has the advantage of speed to market. The exclusivity of the Pre-Market Approval Pathway remains attractive for substances not meeting the gateway test for industry self-assessment.

3.5 Transition and Implementation

3.5.1 Transitional Period

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

The AFGC supports a cut-off date, which is a facility that has been employed both in the EU and the US. The advantage is that it objectively identifies foods that would be subject to the proposed new framework. If the standards in Part 2.9 are not included in P1024 there could be a significant regulatory gap for a significant range of products.

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

The AFGC considers grandfathering removes doubt about substances, particularly nutritive substances which might currently be in products and supports a grandfathering provision.

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

The AFGC considers the usual 12-month stock-in-trade provision should be provided as this needs further consideration depending on the implementation arrangements.

3.5.2 Implementation

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.

A six-month transition period is not sufficient time – the preparation of a self-assessment dossier or an application would take longer than this. The fact that the Standard is being developed should not be considered as an “early warning” – until the actual details are finalised companies will be reluctant to commence work and invest time and resources where the “rules” could change along the way. Companies will need certainty, including the updating of the Application Handbook in advance of committing to development of dossiers.

The AFGC consider that a minimum of 12 months’ transition period should be considered

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

As above.

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

The AFGC would be willing to assist with education and awareness of its members during the transition period. We cannot speak on behalf of other peak bodies but consider they likely would be willing to assist FSANZ and the jurisdictions as appropriate. The Food and Beverage Importers Association would be a key industry body. Bodies supporting ingredient suppliers will be key.

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?

The AFGC also suggests that raw material suppliers need to be targeted and educated as well, as a portion of the documentation requirements would fall to them to provide.

The AFGC notes that the Application handbook will need to be amended with a clear statement and guidance in relation to the treatment of novel foods.

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

The AFGC considers this to be the responsibility of the various State, Territory and New Zealand agencies, but would note that lack of enforcement in relation to the existing Standard undermines its justification and value. Compliance with standards cannot be done as a voluntary exercise without creating market distortion.

4. Assessment of Costs and Benefits (SD1)

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.

The AFGC consider member companies who have been through the application process are best placed to advise on costs in their individual submissions.

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.

The AFGC understands research, development and legal costs associated with determining whether a substance is novel or nutritive or neither are commonly incurred in this area. Legal costs of defending the decisions a manufacturer makes are also incurred.

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

Industry find the current provisions costly, involving lengthy processes to get products to market. Current provisions are generally too vague to be usable. If it is not clear whether a material is novel or not can often mean that it is simply discarded as an option.

As a result, applications for novel food approvals are limited. If pre-market assessment of all new substances was only by approval, the prospect is that substances approved overseas would not be brought to market in Australia and New Zealand. Recognition of approvals made overseas will be a key aspect of the efficiency of the system.

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.

The AFGC understands there are at times export trade and import opportunities missed because of approval lags or absence of approvals.