NEW ZEALAND
FOOD&GROCERYCOUNCIL

24 March 2016

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Dear Sir/Madam

Attached are the comments that the New Zealand Food & Grocery Council wishes to present on the ***Call for submissions – Proposal P1024: Revision of the Regulation of Nutritive Substances and Novel Foods.***

Yours sincerely

[redacted]

Katherine Rich
Chief Executive

Food Standards Australia New Zealand

CALL FOR SUBMISSIONS – PROPOSAL P1024 : REVISION OF THE REGULATION OF NUTRITIVE SUBSTANCES AND NOVEL FOODS

24 March 2016

The New Zealand Food & Grocery Council (the "NZFGC") welcomes the opportunity to comment on the ***Call for submissions – Proposal P1024: Revision of the Regulation of Nutritive Substances and Novel Foods.***

New Zealand Food & Grocery Council

NZFGC represents the major manufacturers and suppliers of food, beverage and grocery products in New Zealand. This sector generates over $34 billion in the New Zealand domestic retail food, beverage and grocery products market, and over $28 billion in export revenue from exports to 185 countries – some 61% of total merchandise exports. Food and beverage manufacturing is the largest manufacturing sector in New Zealand, representing 46% of total manufacturing income and 34% of all manufacturing salaries and wages. Our members directly or indirectly employ 370,000 people – one in five of the workforce.

Overarching Comments

Options

NZFGC concurs with, and identifies further, issues and problems described in Proposal P1024 that apply to the general food supply in relation to the regulatory arrangements for nutritive substances and novel foods. This includes the issues and problems with definitions. NZFGC therefore considers Options 1 (no change) and 2 (amend the current definitions) do not present the best solution or opportunities to advance the regulatory system. Indeed, these options present the risk of the problems and issues continuing into the future, especially given the difficulties that other countries have experienced with definitions.

NZFGC therefore proposes that, with further development and refinement, the framework proposed in Option 3 should be pursued.

Scope

NZFGC is concerned that of the eight standards that refer to 'nutritive substances', five of these standards are in Part 2.9 and three of those Standards are specifically excluded from the scope of Proposal P1024.

NZFGC 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. NZFGC 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.

Graduated Risk Approach
NZFGC is strongly supportive of a graduated risk approach where the effort of all parties is focussed on the substances of highest risk to consumers. This is expected to be both cost effective and efficient by ensuring resources are applied where they are likely to benefit the consumer most. This approach largely underpins Option 3 and underscores the NZFGC support for the option. A key aspect of its operation is the recognition of the work of other overseas reputable and respected agencies.

Eligible Food Criteria
NZFGC does not support positive lists for the Eligible Food Criteria. 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. We suggest some alternatives to these approaches and see this as an area for further development.

We also raise specific concerns around the exclusions proposed for EFC2 and the limitations of EFC3 and 4. In summary, these need to be reconsidered and NZFGC would be pleased to workshop these given the opportunity.

Detailed Comments

Risk Assessment (section 3.3)
Question 1: How do the current novel food and nutritive substance definitions affect your organisation, either as a food business or a food enforcement agency?
Response: The genesis of at least half of Proposal P1024, that concerning the definition of 'nutritive substance', emerged from issues identified by the Supreme Court of New South Wales in 2009 with terms within the definition that were ambiguous, noting that these terms made interpretation very difficult.

These terms have been carried through (as they should) to the new definition of 'used as a nutritive substance' in the Revised Food Standards Code. Both these and terms used in the definition of 'novel food' are subject to uncertainty, ambiguity and difficulty of interpretation.

For NZFGC 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.

The lack of clarity inhibits the use of innovative substances because the regulatory application process carries high inherent risks of either rejection of applications for new substances or prosecution (if a business makes the judgement that a substance is not novel or a nutritive substance). Equally, the lack of clarity raises incentives for less responsible or well-informed companies to try to 'get away with' non-compliant substances – creating an uneven playing field.

An example of this is that consumers are increasingly demanding 'natural' foods but the definition of 'used as a nutritive substance' requires such substances to be 'extracted, refined or synthesised'. Nutritive substances therefore present as not meeting consumer views of 'natural'.

Question 2: Do you believe there are problems with the current definitions in addition to those outlined in the assessment summary? If so, describe the problems.
Response: The problems outlined in the consultation paper are that:

- the terms used are not defined in the Code creating uncertainty about whether specific permissions are required for certain substances before they can be used in food and allowing for very different interpretations
- substances that are specifically referred to/have specific permissions (eg vitamins or minerals) are not the issue but rather the substances that do not fit these categories
- substances that are not specifically identified in the Code may not be nutritive substances
- the exact nature of nutritive substances in the future cannot be predicted so the current definition attempts to provide flexibility to accommodate future developments through the use of terms like 'normally consumed as food' but at the cost of clarity.

These are all problems experienced by the application of the regulatory regimes for both nutritive substances and novel foods for general food products.

In addition, the novel foods definition refers to 'traditional use'. This creates problems with the rapidly changing ethnic population in Australia and New Zealand. More than 200 ethnic groups are recorded as living in New Zealand and Auckland is considered more diverse than London or Sydney, with 40 per cent of its population made up of different ethnicities (born overseas)[1]. Asian communities, in particular, have almost doubled since 2001, when 6.6 per cent of the New Zealand population was Asian and in 2013 were 12 per cent of the population (approx. 472,000 people)[2]. The proportion of Asians in Auckland in 2001 was 14.6 per cent, by 2006 the proportion was 18.9 per cent Asian and in 2013 nearly a quarter (23 per cent) identified as Asian[3]. Traditional foods for the population may have a history of safe human consumption for the ethnic groups in Australia and New Zealand.

We also note that the New Zealand Ministry of Health (for Natural Health Products) has proposed a period of 75 years for a substance to be considered "traditional" based on Australian arrangements (such as therapeutic goods). We dispute this criteria on the basis that with longevity and advances in medicine and health, 75 years is not even one generation. Taking 'years' as an indicator of 'traditional' is a fraught approach and one with which we do not agree.

Question 3: 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.
Response: Definitional overlap is also identified as problematic because enquiries have been made to the Advisory Committee on Novel Foods (the Advisory Committee) that may be considered 'in the context of either definition'. We do not think the data requirements to be evidence of this simply because the data requirements for other specific substances cover similar requirements and yet they are not considered as reflecting definitional overlap. NZFGC therefore considers a single definition or approach to 'new food' would be an efficient approach.

The Call for Submissions suggests (p10) that the existence of the Advisory Committee on Novel Foods is an acknowledgement that the definitions of non-traditional food and novel food

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[1] http://www.stats.govt.nz/Census/2013-census/profile-and-summary-reports/quickstats-about-a-place.aspx?request_value=13170&tabname=Culturaldiversity
[2] http://www.stats.govt.nz/Census/2013-census/profile-and-summary-reports/infographic-culture-identity.aspx
[3] http://www.stats.govt.nz/Census/2013-census/profile-and-summary-reports/quickstats-about-a-place.aspx?request_value=13170&tabname=Culturaldiversity

rely on uncertain concepts. The Advisory Committee comprises regulatory agency representatives only and as such is a committee that reflects the regulators view of novel foods not the science or the likelihood of 'traditional' (otherwise there would be ethnic and scientific experts advising on applications). However, we agree the concepts are uncertain to the extent that they can be interpreted differently.

Options

Option 1 Status Quo (section 4.2.1)

Question 4: Are there elements of the status quo that you support maintaining in the Code? If so, please provide details and reasons for your support.
Response: To the extent that the status quo reflects pre-market assessment for nutritive substances and novel foods through independent risk analysis by FSANZ, this is an element that NZFGC supports retaining for specific high risk substances and in Option 3, the framework provides for this in the Pre-market Approval Pathway.

An Advisory or Expert Committee that might advise on the evidence from a scientific and ethnic perspective rather than or in addition to a regulatory perspective (as does the current Advisory Committee) would be valuable. Industry has found the advice from the regulatory perspective helpful in providing a view on whether a substance might be considered novel or nutritive and there may well be ongoing value in a regulatory advisory committee. However, an expert panel might be better placed to advise FSANZ (and industry) on the scientific evidence and other aspects of application of the future regulatory system.

Novel and new foods generally have a lengthy lead-in period and serious investment in order to bring foods to market. We would also like to see exclusivity provisions for the Pre-market Approval Pathway extended to 3 years to enable better return for investment in innovation. A faster moving 'free rider' could otherwise take advantage of a pre-approval more rapidly than a larger business, and such activity can limit the return on investment.

Question 5: Can you identify any problems with the status quo in addition to those highlighted in this report? If so, please provide details.
Response: The problems with the status quo identified in the report are legal clarity, uncertainty and enforcement issues.

An additional problem relates to the absence of any mutual recognition or integration of pre-market assessments conducted by reputable agencies overseas. Companies working in the global context are particularly frustrated by the duplication, cost and time to repeat work already conducted expertly elsewhere. For some products, such as infant formula products, there is also the issue of limiting the population base for novel foods to 'Australia and New Zealand'. We understand INC states in its submission that 'infants' are considered reasonably homogeneous worldwide and as a result, the population for infant formula products should be expanded to reflect the global community of infants 0-12 months.

We also consider that policy guidelines should generally support a mutual recognition approach and certainly not present as a barrier to FSANZ undertaking such an approach. We are intending to raise this through the appropriate channels.

Option 2 Amend the current definition (section 4.2.2)

Question 6: 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.
Response: As noted above, NZFGC considers definitions, irrespective of amendment will not offer solutions to the regulatory issues and problems we face. We have pointed to the same experience overseas with using definitions as a basis.

We also note at the outset that the term 'nutritive substance' appears in eight standards in the Code. Three standards are outside Part 2.9: Standard 1.1.1 The Structure of the Code and general provisions (where the term is used together with novel foods), Standard 1.1.2 Definitions used throughout the Code (again the term novel food also appears) and Standard 1.3.2 Vitamins and minerals where 'nutritive substances' appears in three clauses. Of the five standards that use the term 'nutritive substances' in Part 2.9 Special Purpose Foods, three of those Standards are excluded from the scope of the Proposal (Standards 2.9.1, 2.9.2 and 2.9.5).

While the 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. NZFGC therefore recommends the scope of Proposal P1028 be expanded to include all relevant Standards.

An expansion of scope would also result in meaningful and informed consideration of applying the same framework for the future regulation of new substances (currently nutritive substances and novel foods), with appropriate amendments to address special requirements, to the Food Standards Code as a whole.

Option 3 Develop an Alternative Framework (section 4.2.3)

NZFGC notes that the alternative framework proposed by FSANZ takes a proportionate approach to risk that reflects 4 main elements:

- identifying foods that do not require regulatory approval before market entry – the Eligible Food Pathway
- pre-market assessment either by industry (self-assessment) – the Pre-market Assessment by Notification Pathway
- pre-market assessment by FSANZ – the Pre-market Approval Pathway
- description of data and documentation requirements for assessment/approval.

NZFGC considers a proportionate approach to risk to be a more efficient approach to managing the market entry of new food substances than definitions and therefore supports Option 3 noting further development needs to be undertaken in a range of areas.

NZFGC 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.

In particular, infant formula products regulated under Standard 2.9.1 and infant foods regulated under Standard 2.9.2 are out of scope for this proposal. It is not clear why this is the case or how it has been justified especially in relation to infant foods where no parallel proposal (as for infant formula products) is underway. It is also concerning that in both cases, there is the risk that if Proposal P1024 proceeds, the regulation of nutritive substances and novel foods for infant formula products and infant foods will effectively default to the current arrangements. This consigns them and the most vulnerable population groups to a system that is clearly able to be improved and that is less than best practice.

As it is likely that to take at least 3 years to finalise Proposal P1028 and at least that long prepare and process another proposal to cover infant foods, we are concerned that this will delay innovation in these most important food categories and potentially continue to leave infant formula products and infant foods open to the safety concerns that catalysed this Proposal P1024.

As stated above, the Eligible Food Criteria and Pre-Market Assessment by Notification Pathways provide for speed to market for industry and consumers, and promotes innovation without excessive regulatory burden. These are features that are of at least equal relevance to the products covered by the standards in Part 2.9. More work will be needed to map differentiating factors for specialist products within the Pathways but the overall framework should apply.

NZFGC is strongly of the view is that the scope of Proposal P1024 be revisited as soon as possible and Infant Formula Products and Food for Infants be included. We support the framework proposed for Option 3 for general foods be also applied to the products regulated under Part 2.9.

In relation to removing duplication by FSANZ of both its own and overseas assessments, a useful example to consider is how sterols will be managed from a regulatory perspective going forward. Sterols are the only novel foods that are permitted on a specific food matrix basis, which means applications would be required for any new food matrix to be permitted to have added plant sterols. As FSANZ has undertaken many previous risk assessments on the safety and efficacy of plant sterols, and risk assessments have also been done by other international regulators, sterols would be a useful case study to consider how a risk based approach can be used to optimise the use of existing work and minimise the requirement for FSANZ to undertake additional repetitive risk assessment.

Identifying foods that do not require regulatory approval (section 4.2.3.1)
Question 7: Are the EFC appropriate for identifying foods that do not need regulatory approval?
Response:

> ***EFC1*** *Microorganisms are eligible if they are listed in the Standard (in the Code) and are cultured to maintain genetic stability.*

FSANZ proposes the development of a list of eligible micro-organisms. New micro-organisms not on the list would "need to undergo a form of pre-market assessment"[4] before they could be marketed.

NZFGC does not support this EFC. Other than the fact that few enquiries have been made to the Advisory Committee 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.

We wonder how the list would be updated to reflect developments and assessments overseas to ensure currency and maximise efficiency (not repeating the work undertaken elsewhere). We also see the only form of pre-market assessment for micro-organisms to be "a full risk assessment is completed by FSANZ to determine their safety"[5]. Such a system is fraught with delays, high resourcing and patchy coverage at the best of times.

If micro-organisms were subject to industry safety assessment, this would require companies making notifications to hold a full assessment documentation on the micro-organism. There is no way of ensuring a list of approved microorganisms either notified or approved is maintained.

We also question the limitations placed on extracts and substances when added back to foods and where there has been no specific risk identified.

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[4] p4 SD3
[5] p3 SD2

The list approach is an archaic mechanism where examples abound of regulation lagging and industry innovation being constrained. It is also not consistent with the overall graduated risk approach and the resourcing available within FSANZ to constantly update a positive list.

There are significant implications for dairy products and alcoholic beverages where microorganisms are integral to the production process for cheese and yoghurt as well as alcoholic fermentation and lactic acid conversion. Such microorganisms are not regulated below the level of general permissions anywhere globally. For example, we understand that Fonterra has reviewed the EFSA QPS list and several commonly used starters are absent from the list. Examples of missing microorganisms include:

- Staphylococcus (most white mould and other specialty cheeses, salami and other)
  - S. carnosus
  - S. xylosis
- Penicillium (white mould cheese)
- Geotricum (white mould cheese)
- Macrococcus
- Streptococcus salivarius
- Micrococcus
- Enterococcus (lots of salami and other foods).

Most alcoholic beverage producers use cultured yeast strains for alcoholic fermentation (largely but not always of Saccharomyces cerevisiae). But new strains are being developed all the time and so-called "wild" yeasts are popular also. As well, it would be almost impossible to rule out the presence of some element of a local yeast population playing a role in the fermentation process for wine even where cultured yeasts are used. Would a producer need to test to see which specific yeast strains were part of every final product? Artisanal style products would likely cease to exist, an area of development, consumer demand and potential export success (see the latest reports of exports of New Zealand artisan beers to China in this regard).

NZFGC suggests that as an alternative, FSANZ amend this criteria so that it instead allows for the use of microorganisms that meet a set of criteria where presence on the EFSA QPS list is only one way that eligibility could be established. These criteria might include:

- presence on similar lists published by other reputable Food Safety Authorities
- being recognised in lists published by reputable scientific journals as having a long history of safe use (e.g. Journal of Food Microbiology's "Food fermentations: Microorganisms with technological beneficial use"[6]
- allowing the use of "harmless" microorganisms as is provided for by Codex in the General Cheese Standard.

EFC2 *Animal food commodities and plant commodities that are described in the list of food classes, except for plants listed in Schedule 1 of Standard 1.4.4.*

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. In light of the population of Auckland being

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6 Bourdichon, F., et al., Food fermentations: Microorganisms with technological beneficial use, Int. J. Food Microbiol. (2012), doi:10.1016/j.ijfoodmicro.2011.12.030

almost a quarter Asian, we question the rationale for forcing seaweed into a costly and burdensome regulatory application process. We note that sushi is wrapped in sheets of nori, the big-leafed kelp kombu is a key ingredient in dashi broth and bright green wakame often features in salads and soups.

It makes no sense to exclude enzymatic processing, where food would be automatically excluded from EFC2 if an enzyme is added but that if a micro-organism was added to produce the enzyme, this would be eligible. We understand that had this proposal been in place all whey protein ingredients would have required FSANZ pre-market assessment including many of the proprietary enzymes developed in New Zealand. Again we suggest that a Codex style approach (e.g. General Cheese Standard) be employed that would allow the use of "safe and suitable" enzymes.

Also since an exclusion is proposed for substances 'having a pharmacological effect', then the risk would be captured.

It is worth noting that even under the Eligible Food Pathway, companies will still have to undertake a safety assessment. If there is no available information on the safety of the micro-organism or enzyme to meet the requirement set out in SD2, a full pre-market safety assessment would be required. The EFCs do not need to eliminate all of the potentially medium to high risk micro-organisms and enzymes but rather to ensure the gateway opens for the lower risk substances.

> ***EFC3*** *Animal and plant commodities that have been enzymatically modified, physically fractionated, fermented (using microorganisms that meet criterion 1), and/or physically processed (including chopping, cutting, peeling, grinding, squeezing, pressing, steeping, infusion, distillation, filtering and dehydration) subject to criteria 4 and 5.*

The proposal is that extracts are eligible if they are prepared from foods described in EFC2 so long as the extract, when added to a processed food, does not exceed the level naturally occurring in the source commodity or substance. This EFC 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. It does not appear to be a graduated risk approach but simply reverts to the status quo. This basically makes EFC3 largely redundant insofar as it reflects no change in the addition to foods, above the original concentration. There is limited value in developing new extracts and processes if use of the extracts and processes are 'status quo'.

A concern for many manufacturers is that innovation can emerge from efforts to mimic other substances and food products as closely as possible. The source commodity of a substance is not therefore the benchmark but could be a target food or substance.

> ***EFC4*** *Extracts are eligible if they are prepared from foods described in criteria 2 and 3 when added to processed foods where the total concentration of the naturally occurring and added components in the extract is no higher than that present as if the source commodity or a product described in criterion 3 were used as an ingredient.*

This proposes 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. As with EFC3, it does not appear to be a graduated risk approach but simply reverts to the status quo.

EFC3 and 4 are much narrower than the Policy Guideline envisages and reflects a strongly risk averse approach. It is anti-innovation insofar as if a substance is safe to use, then it is safe to use in a plant or animal commodity. If consumers don't expect it, then that is a classification issue for the final product rather than a reason to exclude it from eligibility.

Question 8: 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.
Response: NZFGC is not aware of substances that may meet the EFC that should otherwise be subject to pre-market assessment.

Question 9: Are there foods that would not meet the EFC, but you consider should be eligible? If so, please describe the properties of these foods.
Response: NZFGC identifies some micro-organisms, seaweed, fungi and algae since those of high risk would be captured by exclusions. The broad exclusion of algae including seaweed is not effectively justified and needs to be. The same applies to fungi. Fungi that contain toxins at levels of concern to human consumption should be listed in Standard 1.4.1 making this exclusion unnecessary.

Question 10: What type of information should be held by food businesses to support the safety of eligible foods? Please describe the type of information and why this information would support safety.
Response: Compliance with the EFC is needed by enforcement agencies which would necessarily cover the safety of eligible foods. NZFGC 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 Eligible Food Criteria 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. Such information should be available to regulators only, not in the public arena.

NZFGC would oppose the extension of this arrangement to retailers since many retailers are also competitors (with home brands) thus resulting in a dilution of investment and innovation. Retailers would not, any many cases, necessarily be aware of substances in complex foods.

For manufacturers, should documentation for ingredient substances sit with ingredient suppliers? There are significant issues of intellectual property and the extension of the requirements across international borders if ingredient/substance suppliers are to hold documentation.

The issue goes further if complex foods are imported. Where is the documentation to be held then and if not applied to imported food, is this creating an uneven playing field?

Question 11: Are the exclusions to the EFC appropriate in identifying foods that should be subject to pre-market assessment, despite otherwise meeting the EFC?
Response: The first exclusion in the Call for Submissions is described as ‘foods with characteristics that will always require pre-market safety assessment eg pharmacological properties’. SD3 describes this further and identifies the problem with defining ‘pharmacological’. If ‘pharmacological properties’ are intended to mean ‘therapeutic properties’ then NZFGC suggests that the only foods that would be affected are those that are within the scope of Standard 2.9.5 since all other uses of substances are for processing or dietary purposes. It is also the case that ‘pharmacological properties’ is in part defined by the context and the sector involved. Most vitamins and minerals might be considered to have ‘pharmacological properties’ but in the context of the general food supply, they are micronutrients for growth.

NZFGC could envisage support for the pre-market safety assessment of substances with pharmacological properties so long as ‘pharmacological property’ and all other terms used to describe characteristics were clearly defined. We note that FSANZ has recognised this as a particular issue (SD3) and that “there does not appear to be an internationally recognised

consistent definition of 'pharmacological' in the literature"[7]. We agree that a term such as 'biologically active substance' is too broad.

NZFGC is also concerned about what other characteristics of foods might be applied in the future to exclude a substance from being an eligible food. We assume this would require an amendment to the Code and therefore be the subject of full consultation.

Two further exclusions are described as the potential for adverse effects for a non-target population sub-group and foods in a market segment prone to misuse by suppliers. These exclusions are too broad and open to variable interpretation by different regulators depending on their risk appetite. The term 'potential for adverse effects' could apply to many common substances. These exclusions would also have the potential to create uncertainty at the least and be excessively narrowing at worst.

Question 12: 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.
Response: NZFGC notes that the New Zealand Medicines Act 1981 considers a medicine to be substance, inter alia, that "achieves, is likely to achieve, its principal intended action in or on the human body by pharmacological, immunological, or metabolic means"[8] and agrees that the prospect of traversing the food-medicine interface from time to time is a reality. No definition of 'pharmacological' is included in the Medicines Act 1981.

NZFGC agrees that if this exclusion is to apply, then 'reasonable potential' to have effects beyond nourishment and maintenance of life needs to be defined to the extent possible and note the particular challenges involved in doing so.

Data and documentation requirements (section 4.2.3.3)
Question 13: Do you regard the investigation of an alternative approach to regulating nutritive substances and novel foods in the Code as a viable option?
Response: NZFGC considers the investigation of the alternative approach reflected in Option 3 to regulating nutritive substances and novel foods in the Code as a viable option.

NZFGC further believes that the approach encompassing "gateway tests to determine an appropriate assessment pathway"[9] should be considered for application to the standards in Part 2.9.

NZFGC considers "gateway tests to determine an appropriate assessment pathway" should be developed further in light of the industry's experience with the preparation of assessment data and documentation under the Standard 1.2.7. As in those case, confidentiality is a major issue which is described below.

Question 14: 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.
Response: NZFGC considers Option 3 is a viable option. The foregoing suggests that the EFC are critical elements for the Option together with gateway tests. NZFGC considers that the extent to which the Option applies to Standards in Part 2.9 can be accommodated through tailoring the EFC and gateway tests to address the particular needs of those Standards, the

[7] p17 SD3
[8] Section 3(1)(a)(ii) Medicines Act 1981
[9] p20 CFS

products they cover, the Policy Guidelines specific to them and the population groups they target.

Question 15: Do you have suggestions for the type of foods that would not meet the EFC, but may be suitable for industry self-assessment?
Response: NZFGC 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.

Question 16: Please provide details of how a self-assessment pathway may or may not provide benefits to industry.
Response: NZFGC suggests that substances suitable for industry notification under the Pre-Market Assessment by Notification Pathway include those that have been subject to pre-market assessment by overseas reputable or recognised authorities such as Codex (through member contributions and assessments by other international agencies such as JECFA), EU and USFDA (GRAS substances). See also the response to Question 7.

Concerns exist around the potential inconsistency in implementation leading to uneven playing field, application to imported food, the reputational risk from challenges to documentation from a non-scientific standpoint and loss of confidentiality. For example, one company may assess a substance as eligible and proceed to use it, while another company might assess the same substance under the Pre-Market Assessment by Notification Pathway. If the case for eligibility is proven, the company undertaking self-assessment has wasted its investment.

Documentation complexity needs to be graduated with risk. It is also unclear how challenges will be resolved / denied and how the potential loss of public confidence during this process could be managed.

Question 17: 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.
Response: NZFGC considers the publication of safety assessment documentation to be problematic in relation to the ownership of intellectual property, where the documentation might be held, commerciality of developments and protection of research investment.

Notification is not an issue depending on the extent of any additional information that may be required. In general, documentation held within Australia or New Zealand could be available as “commercial-in-confidence” to the relevant regulator but as noted in response to Question 10, documentation not held in the region presents difficulties that would need to be addressed. Even for substances proposed by industry with industry generated data that had been subject to pre-market approval by another recognised agency, confidentiality would be an issue.

Where a substance had no pre-approval elsewhere in the world, NZFGC considers that new, higher risk substances should be subject to an application for the Pre-Market Approval Pathway.

It is important to consider that this approach may not give rise to an increase in confidence. The potential publication of documentation opens up opportunity for consumers, public health advocates, and advocacy interests to challenge company positions from an idealistic or non-scientific position. This could lead to reputational loss, particularly if media is involved. If

this results in companies being less likely to use the Pre-Market Assessment by Notification Pathway, then the advantage of this graduated risk approach is hugely diminished. Documentation should be limited in availability to enforcement agencies.

Draft Framework – Other Considerations

Impact of the Draft Framework on current standards (section 4.3.1)

Question 18: 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.

Response: NZFGC cannot identify downsides to the application of the Option 3 framework to the regulation of novel foods and nutritive substances at this early stage in development other than those identified in response to the questions above.

We will be looking for the next level of detail to take discussion further. We might expect, for example, that particular controls around notifications might be developed in order to better control the removal of poor or non-existent assessments that might otherwise bring disrepute to the companies working at a high level of compliance. We might also expect some draft guidance documents to be developed to better delineate expectations and ensure minimum effective regulation is maintained as the gold standard.

Other Matters

Exclusive permission for brand and class of food (section 6.2)

Question 19: Do you support retaining the provision to grant exclusive permission in the Code for foods approved by FSANZ? Please provide reasons for your view.

Response: NZFGC supports retaining and extending the provision to grant exclusive permission in the Food Standards Code for foods approved by FSANZ but also for exclusivity to apply to notification of industry self-assessed substances. There may be some exceptions to this for Part 2.9 application but investment to bring new substances to market for the general food supply should benefit the investor and not be subject to free-riders at least for a specified period of time.

More development on the management of parallel/concurrent applications and assessments is required possibly with allowance for two or more companies to have the same permission for the same class of substances. There is also the issue of unintended consequences particularly with industry self-assessment such as the potential to “block” a competitor by preparing a notification (or making an application for approval) when no intent/capacity to use the substance exists.

Question 20: 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)?

Response: NZFGC 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.

Transition and Implementation

Proposed transitional period (section 7.1)

Question 21: Do you support a cut-off date? Please provide reasons for your view.

Response: NZFGC 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.

Question 22: Do you see a need for grandfathering provisions? Please provide reasons for your view.
Response: NZFGC considers grandfathering removes doubt about substances, particularly nutritive substances which might currently be in products and supports a grandfathering provision.

Question 23: Do you see a need for a stock in trade provision? Please provide reasons for your view.
Response: NZFGC considers the usual 12 month stock-in-trade provision should be provided as this needs further consideration depending on the implementation arrangements.

Implementation (section 7.2)

Question 24: 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.
Response: NZFGC recognises that regulators are seeking to address the problems with the current regime as soon as possible. In light of this, while NZFGC concurs with the transition period proposed of 6 months, it would be important for extensive guidance and industry workshopping and training to be in place before the commencement of the transition period. There is also an issue around providing longer for products that were already in the process of application preparation since the investment in application preparation is a significant cost in its own right (outside the application fees and charges arrangements).

Question 25: Do you have any comments regarding the proposal not to allow a stock-in-trade provision during the transition period?
Response: See the response to Question 23.

Question 26: Do you have any suggestions as to which peak bodies should be involved in familiarising industry of the new provisions?
Response: NZFGC considers it is an association that is well placed to work closely and constructively with relevant agencies on implementation and familiarisation proposals including ISFR, FSANZ and other regulators.
&**Question 27:** 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?
Response: NZFGC suggests four courses might be pursued to enhance awareness:

- Workshops on the provisions to make clear expectations of documentation and decisions on pathways
- Addressing the NZFGC Health & Technical Working Group on the provisions
- Addressing the broader NZFGC membership on the arrangements at a pan industry event
- Written material for food and beverage manufacturers.

NZFGC 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. A number of these companies operating in New Zealand are also NZFGC members.

Question 28: Are there any particular comments you feel are appropriate to ensuring satisfactory post-market surveillance?
Response: A dedicated industry-regulator working group could be set up to assist with implementation. This might be separate to ISFR or operate under the ISFR umbrella. The important feature is that this be a collaborative effort with industry.

Draft Framework for Alternative approach (Attachment C)

Question 29: 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?
Response: NZFGC has no suggestions at this time.

Question 30: 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).
Response: The key reason for novel foods in the general food supply permitted in the Food Standards Code to be declared 'not novel' after a certain period of time is to not dilute the

'novel foods' lists with substances that are no longer novel. It is instructional to recognise that margarine was once a novel food. Its inclusion on a novel foods list in the 2000s would be amusing rather than helpful. There may well be exceptions to novel foods no longer being 'novel' such as for some of the standards in Part 2.9.

Qualitative assessment of costs and benefits (SD1)

Question 31: 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.

Response: Few NZFGC members have made applications. Those that have are best placed to advise costs in their individual submissions.

Question 32: 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.

Response: NZFGC 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. NZFGC members are best placed to advise costs in their individual submissions.

Question 33: How (if at all) do the current provisions influence your business's decisions regarding developing and launching new products?

Response: NZFGC members find the current provisions very constraining, costly and lengthy processes. 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. A mutual recognition arrangement for approvals made overseas will be a key aspect of the efficiency of the system.

Question 34: 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.

Response: NZFGC understands there are at times export trade and import opportunities missed because of approval lags or absence of approvals.

Question 35: (For food regulators) What types of enforcement costs does your organisation experience as a result of the current nutritive substance and novel food standards? E.g. dealing with enquiries about whether a food is novel or a nutritive substance, notifying food businesses that their food is a nutritive substance or novel food and requires pre-market assessment by FSANZ.

Response: Not Applicable.

Question 36: (For food regulators) How would (if at all would) the types of enforcement costs change if Options 2 or 3 were introduced?

Response: Not Applicable.