Ministry for Primary Industries
Manatū Ahu Matua

24 March 2016

Project Officer Proposal P1024
Food Standards Australia New Zealand
PO Box 10559
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WELLINGTON 6036

FS350-118-1024

Dear Sir/Madam

Proposal P1024 – Revision of the Regulation of Nutritive Substances and Novel Foods – Call for Submissions

Thank you for the opportunity to comment on this proposal. The Ministry for Primary Industries (MPI) has the following comments to make.

General comments

MPI supports the need for a review of the regulation of nutritive substances (NS) and novel foods and ingredients (NF) and acknowledges that this is a complex issue. We have carefully considered whether a risk-based approach for potentially high-risk foods such as NS and NF is consistent with the requirements for making variations to the Code (other than for Standard 1.2.7, and MRL's for Australia). These requirements include FSANZ risk assessments, undertaking consultation and drafting new requirements if warranted. Options 1 and 2 maintain that consistency. However, the graduated risk-based approach involving an industry self-assessment pathway under option 3 may be inconsistent and may lack rigour without further development or modification. It is important to ensure that the regulatory approach ensures confidence in the safety of foods both for the domestic market and also for export, while not unnecessarily constraining innovation or placing an undue burden on regulators.

We support further development of option 3 or a modified option 3. We consider that a more robust option 3 can be developed, with provision for FSANZ to have a direct role in centralised safety assessment advice. We also suggest consideration of a modified option 3 that includes definitional changes, adoption of the eligible food criteria (EFC) and pre-market assessment via the FSANZ regulatory assessment process only. Either a developed or modified option 3 have the potential to significantly improve the current regime. This submission outlines MPI's views, including our concerns with the proposed option 3.

MPI believes that it is very important to note that FSANZ has the expertise to assess the safety and suitability of NF and NS, where some jurisdictions may lack critical expertise such as toxicology. Therefore MPI supports an approach where FSANZ continues to take the scientific lead on assessment. This could be achieved, for example, by administering or supporting a centralised service that builds on the experience of the current FSANZ Advisory Committee on Novel Foods (ACNF) and the former FSANZ reference group. We

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recognise that this may require increased resources within FSANZ or consideration of funding options. Furthermore, the ability for FSANZ to provide the necessary technical advice may require a change to the FSANZ Act. In considering the costs of option 3 or a modified option 3, it is important to include the additional costs to jurisdictions, compared to the cost of a centralised service administered by FSANZ.

If option 3 was developed further, consideration could be given to methods of shortening the time assessments take. For example, there may not be a need for public consultation for all new substances (subject of course to changes to the FSANZ Act). In practice jurisdictions may be able to process most of the assessments using suitable criteria but having the option of seeking expert advice in other cases. Alternatively complex cases could be referred to a FSANZ led Committee that could report on the basis of whether an application to FSANZ for premarket approval is required (which is effectively what the current ACNF undertakes). It is important that any new process ensures consistency across all jurisdictions.

New Zealand Supplemented Food Standard.

MPI is interested in the implications and opportunities this work may have on the New Zealand Food (Supplemented Food) Standard 2016 (NZ SFS). MPI considers that Proposal P1024 has the potential to assist in more closely aligning the Code and NZ SFS. Following implementation of any new regulatory regime for NS and NF, New Zealand would likely consider conducting a further review of the NZ SFS if needed. If the SFS review resulted in the new regime applying to supplemented food, then some supplemented foods that are novel foods or contain novel ingredients may require a regulatory assessment or may no longer be sold. MPI would need to carefully consider how such products would transition into the new regulatory regime in the Code.

The NZ SFS provides an interim regulatory arrangement for supplemented food until there are appropriate provisions in the Code. While Proposal P1024 could significantly assist in aligning the Code and the NZ SFS, it is unlikely to result in the SFS being repealed because other standards in the Code (for example, Standard 1.3.2) do not apply to supplemented food.

Attachment A – Summary of questions for submitters

Refer section 3.3

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

MPI agrees that the current definitions for both NS and NF pose difficulties in interpretation due to ambiguous definitions and hence in the ability to enforce the relevant provisions in the Code. While many of the difficult interpretations have related to NS permitted under standard 2.9.1, MPI has found the definition problematic for general purpose foods as well. The problems identified by FSANZ clearly highlight the uncertain nature of the definition.

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

FSANZ has summarised the issue well. MPI has no further information to add.

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.

FSANZ has summarised the issue well. MPI has no further information to add.

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

MPI supports the need to regulate the use of NF and NS that may pose a risk to public health and safety subject to appropriate safety assessments.

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

MPI supports amending the definitions of 'novel food' and 'used as a nutritive substance' in the Code under option 3. We agree with FSANZ's reasons for amending the definitions and we would be happy to work with FSANZ if improved definition(s) are an outcome of this consultation. We do not consider option 3 can be easily progressed without further clarification of the definitions, given a definition(s) would scope the new framework for NF and NS.

We recognise that there are difficulties in developing definitions; however these should not be insurmountable. MPI supports re-defining terms like 'history of human consumption' through a cut-off date (see comments on section 7.1). MPI also supports, in principle, the combination of NF and NS into one definition.

MPI appreciates that a definition alone may be not be enough, and suggests that the definitions be supported by criteria (such as the proposed EFC), setting further maximum levels of natural toxicants (or adverse effects of toxicants) as per Standard 1.4.1, expanding the prohibition and/or restriction of plants and fungi in Standard 1.4.4 and possibly extending prohibitions and restrictions to other sources such as animals, insects, calcified material etc.

If option 3 was not pursued further, MPI may support a modified option 3 that includes amending the definitions, applying the EFC and FSANZ application process, but does not include the industry self-assessment pathway.

MPI does not support the further development of option 2, as MPI believes that new definitions alone will not achieve secondary objectives such as a framework of proportionate risk and opportunities for industry to access the market quickly and without undue regulatory burden.

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

We support the concept of EFC, as this helps define a particular set of NF and NS that FSANZ has assessed, as part of Proposal P1024, as known or evidenced to be low risk. This would be a significant improvement on the current regime.

More limits and/or restrictions to support the EFC may need to be inserted into other Standards such as Standard 1.4.1 - and Standard 1.4.4. refer to comments in section 4.2.2

Specific comments:

Microorganisms
We support an approach that is consistent with that used by EFSA for *Establishing Microbiological Safety of Eligible Foods*. We agree that it is important to specify that microorganisms must be cultured to maintain genetic stability in order to be considered eligible foods. This will assist in ensuring that a microorganism listed as an eligible food maintains the characteristics that were assessed by EFSA in arriving at a qualified presumption of safety.

We suggest a modification to the following wording under section 3.1.1 (4th paragraph) of supporting document 2: "*The principle of being identifiable is interlinked with the ability to demonstrate that the microorganism being assessed can be stably maintained through repeated culture and maintains genomic and phenotypic stability in the food matrix, the host and the environment*. MPIs comment is that this should be modified to stress that genetic stability should be maintained in a whole range of environmental conditions to which the food might be exposed to.

Extracts; Substances derived from food
MPI considers that further clarification needs to be made for Criterion 3 and 4 and how these two criteria intersect with Criterion 2. An NF or NS is subject to Criterion 2 in order to be eligible for Criteria 3 and 4. Under the proposed EFC concept, a food is considered eligible if it meets any one of the four Criterion. It needs to be clear how Criterion 2 differs from 3 and 4 such that an extract or a substance (as described currently in the proposal) that is intended to be subject to Criterion 3 or 4 does not meet Criterion 2.

Exclusions from EFC
MPI supports further work on additional clarification to Exclusion 1. In developing further detail for Exclusion 1, it is important to keep in mind that the food-medicine interface in Australia differs to that in New Zealand due to the different legislative regimes. At the time of writing this submission, the Natural Health Products Bill is yet to be passed and this Bill further differentiates the food-medicine interface in both countries. Despite this, the Food Act 2014 is clear in excluding medicines, psychoactive substances, and controlled drugs from the definition of food (as per section 9 of the Food Act 2014). Should the Natural Health Products Bill be passed, the definition of food will be amended in the Act to exclude natural health products as well.

The Food Act 2014 attempts to mitigate the potential risk of other pharmacological effects (i.e. not therapeutic effects as these terms are used in section 2.5.1 of SD3) by excluding any psychoactive substances (within the meaning of Psychoactive Substances Act 2013). As this provision is already in the Food Act 2014, this means that in New Zealand, MPI is able to enforce this for applicable novel foods should it be necessary. Any further detail to Exclusion 1 needs to be developed with this in mind and must not contradict the Food Act 2014 in general. MPI is happy to work with FSANZ to ensure that Exclusion 1 strengthens and is consistent with the restrictions and prohibitions that are already in place under New Zealand legislation.

With regards to Exclusion 2, FSANZ has summarised the issue well. MPI has no further comments to add.

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

The type of information that food businesses need to hold should be from trusted sources that are able to be accessed by a small business within reasonable means. This information should also not be limited to one type of information only (e.g. peer reviewed journals only). Food businesses should be expected to hold or have access to information sourced from: peer reviewed journals, their own clinical studies, toxicology study reports, or evidence that the eligible food is not considered a NF by an overseas competent authority (e.g. not considered a NF in the EU, USA or Canada).

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

MPI agrees with the exclusions to the EFC that FSANZ is proposing and has no further information to add.

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.

As discussed in SD3, there are two aspects of pharmacological effects, one being therapeutic effects and the other being other effects such as drug-like/hallucinogenic effects. For the latter, the exclusion of any psychoactive substances (within the meaning of the Psychoactive Substances Act 2013) demonstrates that New Zealand considers there is a 'reasonable potential' for a food to have undesired pharmacological effects. In this case, the Food Act 2014 uses the meaning of psychoactive substances as per the Psychoactive Substances Act 2013 as a proxy to determine 'reasonable potential'.

Therapeutic effects are harder to quantify and may require that the levels permitted in food relate to levels set by Medsafe or the TGA to restrict their use as active ingredients in medicines or complementary medicines.

Refer section 4.2.3.3

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

MPI supports further investigation of an alternative approach.

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.

MPI supports further work on option 3, particularly around the framework for industry pre-market self-assessments However, as already noted, MPI is concerned that the proposed framework for option 3 may not be viable, unless FSANZ is able to assist jurisdictions with centralised technical advice, or FSANZ provides such a service under a new model (requiring changes to the FSANZ Act and the funding model, as noted earlier in this submission).

Under the proposed pre-market self-assessment notification process, the consultation document sets out that a food business would submit its safety dossier to the food regulators/authorities (pre-market). MPI considers the food

regulators/authorities in this context to be the food regulators/authorities in each jurisdiction. The dossier would then be published on the website of the food regulators/authorities.

Due to the restrictions in the FSANZ Act, it would appear that FSANZ may not be able to be considered the authority, although it has the expertise to assess dossiers. Changes to the FSANZ Act should be considered, if supported by jurisdictions and food businesses, to enable a regime that allows FSANZ to profile industry self-assessments within a specified time period before an NF or NS is permitted to be sold on the market and the corresponding dossier published.

We do not support individual jurisdictions being responsible for dossiers because:

- jurisdictions would in effect be required to assess dossiers, due to the legal issues that may surface if an assessment is not conducted;
- some jurisdictions may not have the resources nor the expertise to make assessments;
- publication of a dossier on the website of a jurisdiction's enforcement agency could be viewed as an endorsement of the safety of the NF or NS, whether or not that enforcement agency has adequately assessed the dossier;
- inconsistencies could arise if one jurisdiction differed in its opinion to another.

Expert Committee

Under the proposed option 3, we suggest consideration of dossiers being submitted to a centralised advisory committee. There are a number of options for this, including FSANZ (solely), a combination of experts from FSANZ and representatives from jurisdictions (similar to the way the current ACNF is set up), or a jurisdictional body such as ISFR that can seek assistance from an expert group. Any advisory committee/jurisdictional body set up under a new regime should be permitted a specified period of time (for example 30 days) to assess the evidence, after which the dossiers must be publicised by the committee/body and the product should be able to be sold on the market.

Enforcement issues

We have concerns about the lack of legal certainty when opinions differ between industry and jurisdictions on the safety of an NS or NF. In the way the self-assessment pathway is currently represented in this proposal, it appears that a business can begin to sell an NF or NS following the notification of their dossier to the food regulators/authorities. This would mean that should the food regulators/authorities assess the dossier and disagree with the business' assessment or consider that the dossier does not meet assessment requirements, the NF or NS is already being sold. This could result in retrospective enforcement as the business would not know until after sale of their NF or NS that the food regulators/authorities have disagreed with the business' assessment.

MPI notes that it may also be hard to prove that the manufacturer has not complied with the dossier/assessment requirements. Despite the possibility that food authorities may disagree with self-assessment they may have difficulty to find evidence of non-compliance with the self-assessment process.

Option 3 contains the Gateway tests, and we appreciate that the detail of this is still to be developed. At this stage we are not sure whether criteria can be developed that clearly determine whether industry can self-assess their dossier or not. We are also uncertain as to whether requirements can be drafted that ensure consistent opinion on a dossier. Any lack of clarity could result in industry ignoring the opinion of the advisory committee or jurisdictional body. The scenario as described under section 3.1 of the consultation document could develop, whereby effective enforcement

action for unsafe food becomes difficult because the onus of proof is on the enforcement agency to establish, beyond reasonable doubt, that the NF or NS poses an obvious and irrefutable safety concern. We therefore, suggest that changes to the FSANZ Act 1991 be explored as a means of providing legal certainty for enforcement agencies.

We have considered an option that includes jurisdictions being able to request that a business makes an application to FSANZ for approval, if they consider there is uncertainty around the safety of a NF or NS. However, we are concerned this mechanism might result in jurisdictions using it as a default mechanism. This would defeat the purpose of industry safety assessments.

Finally we would like clarification on whether a food business has the ability to opt for the application process, even if they are eligible to undertake a pre-market self-assessment. We think that this is provided for in Figure 1, but seek confirmation of this from FSANZ. MPI questions what would happen where a business opts to go through the application process (even though their NF or NS meets the criteria for the self-assessment pathway) to have their application rejected following assessment by FSANZ, while another business goes through the self-assessment pathway with the same NF or NS and considers it eligible to go to market.

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

As already identified in the consultation document, consumers and industry would benefit from a low cost, faster path to market, provided the food regulators/authorities are able to assess dossiers without undue delay. Unlike Applications submitted to FSANZ, no consultation is required. This, however, relies on the food regulators/authorities having the resources and expertise to assess dossiers, and a willingness to publish the dossiers on a collective website. If the regulators/authorities faced resourcing issues or did not have the required expertise, it could be more expedient for the food business to submit an application to FSANZ.

Confidentiality throughout the regulators/authorities assessment phase and possibly for a period following notification would provide a substantial commercial benefit for industry.

Regulatory certainty would result if the assessment by the regulators/authorities have a legal status. If, however, the regulators/authorities could only provide an opinion, then other options need to be explored.

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.

Expert Committee

Suitable guidance and criteria could be developed to achieve an appropriate level of assessment. However, as noted earlier in this submission, option 3 does not appear to provide enough regulatory oversight, as jurisdictions, whether individually or as a collective, are unlikely to have the resources or expertise to fully assess dossiers prior to publication online. Therefore, support from a centralised expert committee should be considered. An expert committee could be of value to both businesses seeking confirmation of their safety assessments and jurisdictions seeking recommendations prior to publication of a dossier. However, if as stated in section 3.1, there would still be limits on the ability to determine compliance with the standard, given “the onus of proof is to establish, beyond reasonable doubt, that the food/substance poses an obvious and irrefutable safety concern” then other approaches need to be considered.

MPI supports the notification and publication of dossiers for transparency, public accountability and a level of assurance for public health and consumers that food being supplied for sale is safe. Consumers would have more confidence in the safety of new foods that are industry self-assessed if those assessments were validated by a relevant Authority such as FSANZ.

Release of confidential information
Consumers would have more confidence if the full dossier for a NF or NS is published (as per the current proposal). MPI is aware that industry is concerned about having to release confidential information/and or intellectual property by publishing the dossier. If FSANZ allows for some form of data protection with regards to the information published on the dossier, MPI can support this, provided there is enough information published to demonstrate that the dossier was assessed objectively by the self-assessor (i.e. the business) and by the food regulators/authorities.

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

We support combining these substances, as both classes need pre-market assessment to some degree. Exclusion of food categories such as foods for special medical purposes, infant formula and infant foods mean that a combined approach should continue to be pursued.

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

MPI supports this approach, if industry continues to support the need for this. It provides a competitive advantage for the innovative business seeking approval and enables it to recoup some of the costs associated with providing dossiers for a FSANZ safety assessment. Having this exclusive permission could encourage businesses to keep innovating if they have certainty that other companies would not be able to "piggy back" off their application or poach their information when their dossier is published.

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)?

We consider that exclusive permission should be given to businesses conducting a self-assessment in the same way as businesses who are required to apply to FSANZ for a safety assessment, as considerable resources are invested in both scenarios. If our position is not supported in the final Standard, then we would support industry having the option of submitting an application to FSANZ, even if they passed the Gateway criteria for self-assessment, so that they can choose to use the application process for the benefit of the exclusive use permission.

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

As stated above, MPI supports re-defining terms like 'history of human consumption' through a cut-off date as it is the most efficient way of providing legal certainty. The consultation document has provided sufficient rationale under section 2 to justify the rationale.

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

MPI supports continued permission for substances currently identified in the Code as NF or NS.

A cut-off date that is the same as the gazettal date would allow NF and NS that are currently on the market but not a permitted NF under Schedule 25 of the Code. We do not think these foods should be grandfathered in automatically as some of them may not have had any pre-market assessment. We suggest a market scan by jurisdictions or FSANZ and an assessment of such foods by FSANZ should be considered as part of Proposal P1024. Any new foods that are assessed as being safe could then be added to the permitted list.

Consideration should also be given to the record of views of the ACNF. Some re-assessments will be required as ACNF records do not always reveal all of the details (for example, the amount of a substance that would be added to the diet).

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

If a review of the NZ SFS adopts the outcome of Proposal P1024, there could be implications for businesses supplying supplemented food, in which case, we would support a stock-in-trade provision

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

MPI supports a transition period. The period needed for the transition would depend on which option, or variation of an option, proceeds.

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

MPI considers that not allowing a stock-in-trade provision could be financially detrimental for businesses, especially if they have significant financial implications related to their stock. However, MPI would not support businesses "stocking up" to take advantage of any stock-in-trade provisions.

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

MPI considers that the industry organisations such as the New Zealand and the Australian Food and Grocery Council, NZIFST, AIFST, New Zealand Beverage Council could be involved in familiarising their members and the wider food industry of the new provisions. MPI could use its various industry forums to inform industry about any new provisions. Other jurisdictions will also have their own connections with industry.

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?

In implementing the new Food Act 2014 (which commenced on 1 March 2016), MPI utilised a variety of fora to raise awareness of the new provisions under the Act as the new approach had significant implications for anyone selling food. For example, MPI had information available on the website, trade stands at various food shows and industry conferences, articles in the NZIFST journal, and connecting with various industry organisations. We suggest that FSANZ might like to talk to MPI's Food Act implementation team at an appropriate time, should the new provisions be adopted.

Refer Attachment C

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

Please refer to our comments to the final question for section 4.2.3.1.

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).
Not applicable to MPI.

Refer SD1

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

Not applicable to MPI.

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

Not applicable to MPI.

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

Not applicable to MPI.

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

Not applicable to MPI.

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

Current costs are as described: dealing with enquiries about whether a food or ingredient is a NF or NS, notifying food businesses that their food can no longer be sold as it is or contains a NS or NF and requires pre-market assessment by FSANZ. However, it does not appear that many food businesses are fully aware of the requirements around NF as per Standard 1.5.1.

As the NZ SFS permits the addition of NF and NS in a supplemented food, enforcement costs include assessing whether or not a food is a supplemented food, and if it is not, whether or not the food is eligible to be a supplemented food.

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

MPI considers that the types of enforcement costs are likely to be the same. However, if there is greater awareness about the new provisions, there are likely to be less instances of these types of enforcement costs occurring.

Yours sincerely

[redacted]
Manager Food Science and Risk Assessment