Comments from the Victorian Departments of Health & Human Services and Economic Development, Jobs, Transport & Resources

Due date of submission – 24 March 2016

The Victorian Departments of Health & Human Services and Economic Development, Jobs, Transport & Resources (the departments) welcome the opportunity to provide comments on Proposal P1024 – Revision of the regulation of nutritive substances and novel foods (the proposal).

This submission provides general comments with responses to the specific questions for submitters provided in Attachment 1.

General comments

Victoria has been a strong supporter of the revision of the regulation of nutritive substances and novel foods and has contributed to all Food Standards Australia New Zealand (FSANZ) consultations on this issue.

We support the development of an alternative framework and acknowledge FSANZ's commitment to working collaboratively with industry and jurisdictions to develop provisions that protect public health and safety while being objective, enforceable and proportionate to risk.

At the 30 November 2015 FSANZ workshop on P1024, Victoria stated that it would not support an approach that relied on regulators within the jurisdictions to assess information held for eligible foods or dossiers demonstrating that foods meet gateway tests for non-eligible foods. In Victoria, that responsibility would fall to the 79 local government authorities. Neither local government nor the Department of Health and Human Services has the expertise to perform such a role, and it is thought that this would be the situation for other jurisdictions. Experience to date with the introduction of industry self-assessment for general level health claims supports this position.

Victoria advocates an alternative approach to the proposed framework. Our alternative approach would replace a full industry self-assessment of Eligible Food Criteria (EFC) with a modified, truncated FSANZ application process that would enable the rapid centralised assessment of information provided by a food business. Our approach is outlined below.

Key issues

An overarching framework

A number of standards within the Food Standards Code require a pre-market risk assessment (including dietary exposure assessment as required) to be conducted before substances can be used as, or added to, foods. This applies for nutritive substances and novel foods, as well as certain other foods or substances added to, or used in, the production of food. They include vitamins and minerals; food additives; processing aids; irradiated foods; and genetically modified (GM) foods (acknowledging that there are also additional requirements for certain substances such as technological justification, and some applicable policy guidelines).

Developing a framework that considers processes for permitting nutritive substances and novel foods in isolation of other foods requiring pre-market risk assessment presents a risk that inconsistencies may develop.

The departments suggest that consideration be given to developing an overarching framework for all foods currently subject to pre-market risk assessment through the FSANZ application process. The framework presented in the proposal (p23) forms a basis for this overarching response. Vitamins and minerals, food additives, processing aids, irradiated foods and GM foods would continue to fall into the FSANZ pre-market approval stream until it is deemed that further consideration of these is required. A gateway test would be created to specifically direct these foods straight to the current FSANZ application process at this time. Consideration could be given to providing fast tracking for the first application information elements required for foods additives under certain circumstances.

An advantage of an overarching framework would be the ability to provide consistent alignment with applicable information requirements set out in the FSANZ Application Handbook and with any relevant policy guidelines or standards in the Food Standards Code (the Code) including, for example, Standard 1.2.7.

The departments advocate for a phased approach to the implementation of any alternative framework. It is envisaged that there could be some consolidation of the information requirement elements in the Application Handbook such that a food business could be exempted from provision of certain elements (FSANZ would only be required to assess the veracity of a business's assertions. No call for public submissions would be required for the assessment of these elements) if that business can demonstrate that information has already been assessed ('recently') by another trusted international agency (JECFA for example).

In support of a centralised approach

For this framework to function successfully, there must be national consistency in the assessment of information and dossiers. This can only occur if the approach is centralised.

The assessment needs to be conducted by someone with the appropriate technical knowledge and tools and understanding of the food regulatory system. This should remain FSANZ's responsibility; FSANZ alone has the expertise and tools to perform the appropriate assessments. We note that the European Commission recently moved away from having individual member states assess novel foods dossiers to a centralised system.

The concept of industry self-assessment was not contemplated when the FSANZ Act was developed and a functioning framework that allows industry self-assessment does not exist. To address this, one option could be to amend the FSANZ Act and the Application Handbook to accommodate an alternative framework, enabling FSANZ to assess the veracity of eligible food criteria conformance and to assess dossiers. Pursuing this option could be time consuming and complex.

Another option is to introduce a tiered application process broken down into the key information criteria (see below) and to create a fast-track for foods requiring minimal scrutiny by FSANZ (for example, certain foods meeting EFC 1 and 2). This option could be developed within the current application process. An approach to how this work is outlined below.

Key information criteria

Information required to support an application would be based on the current requirements set out in the FSANZ Application Handbook. The requirements for novel foods (3.5.2) and nutritive substances are similar (3.3.3), only varying according to the intended use.

Current requirements in Common (summarised):

A – Technical information on the food including:

1. Characterisation of the food – The chemical and physical nature of the food including the specific name/description of the food and, in the case of certain etracts and substances, the identification of the chemical compounds or entities. The name the food will be marketed under.
2. Source and means of processing or production.
3. Purpose of use or addition (including to what foods and in what quantities as appropriate).

B – Safety

C – Dietary Exposure.

Proposed tiered approach

Fast-track Assessment of EFC by FSANZ based on information provided on A and B

The specific nature of the minimally processed food (which would generally retain the essential characteristics of the whole food), extract or substance would enable FSANZ to assess whether claims made about a safe history of use could be substantiated or whether recognised international agencies had already assessed the safety of that specific product.

Requirement B would be satisfied by provision of information on the risk assessment of the same specific product by, for example, the Joint Expert Committee on Food Additives (JECFA). If the product had been determined to be generally regarded as safe (GRAS) by JECFA, no dietary exposure assessment would be required. If JECFA had set an Acceptable Daily Intake (ADI) or similar, then dietary exposure assessment would be required to be undertaken by FSANZ. We could also consider GRAS notifications received by the USFDA, which have been deemed to be reasonable, and decisions from other suitable authorities. To support our exporting industries FSANZ should also consider taking into account decisions from reputable authorities of our major trading partners, e.g. Japan.

The fast-tracked assessment could be carried out by a group similar to the FSANZ Advisory Committee on Novel Foods (ACNF) comprising FSANZ officers. The ACNF currently meets as required and this can be as often as monthly. A two month turnaround (or less), on assessments where dietary exposure data is not required, should be achievable. No call for public submissions would be required.

The purpose of use or addition would be provided by the business but may also be able to be inferred from the information on the characterisation of the food. This purpose may be used to determine whether additional information elements would be required to be assessed to progress an application. For example, if the product was deemed to be a food additive then requirements A and B might have been satisfied but the other Application Handbook requirements for food additives may need to be assessed (for example, technological justification or dietary exposure). We suggest that gateway tests be used to determine when products can go to market following assessment of requirements A and B **or** specify:

- other assessments that may be required;
- other standards would need to be complied with; or
- if there is an applicable policy guideline that FSANZ should have regard to.

For example, if an eligible food was to be used for nutritional purposes there may be other requirements currently in the Application Handbook (which would be moved into the proposed tiered approach) or in Standard 1.2.7 that may need to be addressed.

New foods that are approved, and that do not fall under other standards, would be listed in a schedule in the Code. The schedule would have a section for foods with restrictions on their use. This would provide regulatory certainty for both industry and regulators.

ATTACHMENT 1

Questions for submitters (in the order set out in Attachment A to the proposal)

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?

Victoria has already provided FSANZ with information on the difficulties with the enforcement of the current standards or with reliance on the general *Food Act 1984* provisions regarding the sale of safe and suitable food. Opinions provided by the advisory committee on novel foods have recently been challenged by some food businesses as having no legal status.

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 main issue is created by terms used in the definitions that also require definition to provide certainty. We do not consider that continuing down this path would resolve current and potential problems.

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

The creation of categories of foods or substances for a particular regulatory purpose based on definitions, or undefined terms in some cases, can cause more problems than it solves. A broader approach to determining whether or not a product should undergo a pre-market risk assessment is required. In some cases it will be the purpose of the use or addition of a food that will determine what information is needed to grant approval, rather than an initial categorisation of that food.

We also have some concerns that there is a lack of awareness on the part of some business sectors of the current provisions, including the requirement for a food business to seek approval before using or selling a novel food or nutritive substance. Online sales and imported products, particularly 'supplementary' foods, create problems for enforcement agencies. Progression of P1024 should provide a trigger to remind food businesses of the restrictions and requirements regarding the introduction of new foods to the market.

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.

No.

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

Refer section 4.2.2

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

No.

Refer section 4.2.3.1

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

The departments support the proposed role of EFC in the alternative approach. However, there are a number of issues that will need to be addressed to ensure legal clarity:

- There still needs to be a centralised decision making and this should include a 'pared back' rapid assessment process, particularly for EFC 1 and 2 products.

- Some terms that are used in the EFC are suitable for a discussion paper but may cause problems if moved into a requirement in the Code. Defining some of these terms may result in the same type of problems that have been created by the current definitions of novel food and nutritive substance.

  For example, 'physically fractionated' forms part of the description of EFC 2. The Macquarie dictionary defines fractionated as, 'to separate (a mixture) into its components, or into portions having different properties, as by distillation, crystallisation, chromatography, or the like'. These processes can be used to selectively isolate and purify substances. This does not appear to be what is intended to cover products such as cereal flours. The application of more than one of the processes currently listed in EFC 2 could also have this effect.

  The intent of EFC 2 appears to be to permit minimally processed products of animal food commodities and plant commodities. These products should generally maintain the essential characteristics of the whole food. Where the essential characteristics are not retained, as is the case with cereal flours, the specific process rather than a general term should be used.

  Fermentation (listed under EFC 2) will change the essential composition of a food and may also produce substances that will need to be assessed and possibly regulated in much the same way that methanol is limited in alcoholic beverages.

  EFC 3 and 4 are essentially products of the foods from EFC 2. The establishment of appropriate gateway tests will be critical in determining what assessments may be required for certain extracts and substances and what other standards those considerations may involve (see comments on implementation and enforcement and a tiered approach). This is where the purpose of the food and the level of specificity about the chemical and physical characterisation of the food will be critical. This will assist in determining, for example, whether the food is a processing aid or a food additive (see further comments below), whether it will be used to make a claim under Standard 1.2.7, or whether that same food has been the subject of a risk assessment by a respected international food agency.

  Note: The proposal states that reference to a 'substance' means a single chemical entity which is inconsistent with the Food Act definition: ***substance*** *includes a mixture or compound* (sec 4 (1)). EFC 4 would need to be modified to address this definition.

- There will need to be clear definitions provided for exclusions to the EFC. For example, what constitutes 'pharmacological properties' and clarity provided around verifying eligible foods; who determines there is no potential for adverse effects in non-target populations; or what a segment of the market prone to misuse means. Under the proposed tiered approach, FSANZ would be assessing applications for

eligible foods, which would provide consistency in the interpretation of these terms. However, they will still need to be defined or supported by guidance.

- The EFC need to operate alongside the food additives standard. Use of the term 'extracts' under EFC 3 raises the broader issue of being able to differentiate between a food with an intrinsic technological function (for example, lemon juice used as an acidulant), which could therefore meet an EFC, and the selectively extracted active component (for example, citric acid), which would be considered to be a food additive.

  For example, the EU uses the term 'colouring food' which is pertinent to this matter. Beetroot juice, or even beetroot juice powder, maintains the essential characteristics of the whole food. It can be added to other foods to colour them but it is not a food additive. If the active colourant was selectively extracted and refined, it would be regarded as a food additive.

  Consideration will need to be given to establishing an approach to determining what level of 'extraction' moves a product from a food with technological properties (or even specific nutritional benefits) to a food additive, processing aid etc.

  The definition of used as a food additive under Standard 1.1.2 – 11 of the revised Code includes:

  (b) any substance that is:

  (i) a *non-traditional food and

  (ii) has been concentrated, refined, or synthesised, to perform 1 or more of the technological purposes listed in Schedule 14.

  The use of the terms 'concentrated, 'refined' or 'synthesised', has the potential to cause confusion or conflict with EFC unless the issue of the level of concentration, refinement or extraction can be addressed to determine when an extract under EFC 3, for example, becomes a food additive.

  The determination will be assisted by a requirement to provide information to adequately characterise an extract or substance and declare its purpose. See Application handbook B 1 information on the type of novel food 2 purpose.

  The alternative framework should be able to be used in future to assess food additives (especially those with certain GRAS status). However, there would still be the need to differentiate between eligible foods with a technological property and a food additive. Food additives would have to be assessed for technological justification, and be subject to specific labelling requirements. Non GRAS food additives would have to undergo dietary exposure assessment.

  This further highlights the fact that the EFC essentially deal with the safety of the food. Other elements would still require assessment depending on the intended purpose of the EF.

  The use of 'non-traditional food' as part of the definition of 'used as a food additive' would also need to be addressed if the novel food standard was removed from the Code.

- Any decisions made or definitions developed should not impede or pre-determine any future consideration of food additives or processing aids within the new framework.

- Under the proposed framework, businesses contemplating marketing foods previously falling within the definition of nutritive substance should be subject to the

same level of information requirements as currently set out in the FSANZ Application Handbook both for nutritive substances and for 1.2.7 claims.

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.

See comments above regarding fermented foods. Supporting Document 3 also gives the example of Beta-glucan and the situations in which it could be considered an eligible food, however Beta-glucan is typically added to foods to help control blood cholesterol and blood glucose levels, which could be considered to be a pharmacological effect.

In addition to a centralised rapid assessment of the veracity of eligible food claims, there may be products meeting EFC 3 and 4 which are added to target foods or the same food class so that a dietary exposure assessment may be required.

Where it is clear from the stated purpose of the food and the characterisation of the food (meeting the EFC) that it may fall under the food additive standard or standard 1.2.7, then additional application information requirements would be triggered if use was to be progressed.

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

Not at this time.

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.

It would not be sufficient for food businesses to simply hold information. The experience provided by the self-substantiation of health claims demonstrates there needs to be a centralised body that verifies the safety of a proposed eligible food. The type of information provided to FSANZ for assessment should mirror the requirements currently set out in the Application Handbook for novel foods and nutritive substances. See 'key information criteria' under the implementation and enforcement heading.

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

As previously mentioned, clarity is needed around what constitutes each exclusion. In line with comments made above, we consider that all foods should undergo a tiered pre-market assessment with some being fast-tracked based on information provided by the business.

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.

Given the issues Victoria has had with substances added to formulated supplementary sports foods we do not consider that a food business or a jurisdiction has the ability to make those judgements. Under a tiered approach a business would need to provide information characterising the food (minimally processed, extracted etc) to a degree of specificity that would enable FSANZ to make such judgements.

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?

Yes.

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?

The draft framework as presented is not a viable option. A variation of option 3 could be viable. This would require exclusion of the first proposed element of the draft framework, which would allow new foods that meet the EFC to go to market without regulatory approval. We advocate a tiered approach where FSANZ would undertake a fast-track assessment of foods meeting the EFC. This could be achieved by using the same FSANZ experts who currently serve on the advisory committee on novel foods, which meets as required, to assess applications and provide a decision. Under a new framework, these decisions would need to have legal status. FSANZ would continue to have regard to applicable policy guidelines.

What aspects of the draft framework do you think are viable or not viable? Please provide supporting statements for your view.

Industry self-assessment without centralised regulatory oversight is not viable. The interconnections with other standards must also be taken into account to ensure there is consistency and no conflict. A tiered approach (based on risk) should be considered to build in steps to ensure that areas where further assessment is required are systematically identified.

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

Not at this time.

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

N/A

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.

No. The departments do not believe publication of dossiers is either sufficient to provide regulatory oversight or necessary to ensure consumer confidence. Publication of dossiers can undermine the incentive for businesses to invest in the addition of novel or nutritive substances to foods that could be beneficial to consumers. Under the tiered approach outlined above, the departments believe that consumers can be confident that an authority with the appropriate level of expertise has assessed dossiers sufficiently to validate safety of the substance in its proposed use. Also see comments above.

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 advocate an overarching framework that would cover all foods requiring pre-market risk assessment and a tiered regulatory assessment approach proportionate to the risk, which incorporates the application of other standards.

Refer section 6.2

Note: N/A denotes an industry rather than a regulator appropriate response.

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

N/A

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?

N/A

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)?

N/A

Refer section 7.1

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

N/A

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

The Code should include a schedule of eligible foods (which would include non-eligible foods that had passed gateway tests). Current permissions could be moved to this list. The list could have two sections, one with GRAS status, the other with restrictions.

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

N/A

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.

No.

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

No.

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

N/A

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?

We have concerns that some industry sectors are not aware of the current provisions. We see this proposal (P1024) as a trigger to raise awareness. Providing an overarching framework would enable businesses to understand the whole picture regarding what foods (or food production methods) are required to undergo pre-market approval, and what processes and approval steps will apply to what products and production methods.

FSANZ, industry bodies and regulators will have a role to play in communicating any new provisions.

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

The development of a schedule in the Code to list new approved foods, and foods currently listed, will be critical in informing surveillance and enforcement activities.

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?

Given the issues Victoria has had with substances added to formulated supplementary sports foods, we do not consider that a food business or a jurisdiction has the ability to make those judgements. Under a tiered approach a business would need to provide information characterising the food (minimally processed, extracted and so on) to a degree of specificity that would enable FSANZ to make such judgements.

These terms, regardless of whether an attempt is made to define them, have the potential to create a similar problem to that which exists with the current definitions for novel foods and nutritive substances. Such terms could be used in guideline documents or in the information requirements set out in the Application Handbook, but ultimately FSANZ is best placed to make those judgements.

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).

N/A

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.

N/A

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.

N/A

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

N/A

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.

N/A

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.

Victoria currently deals with a number of enquiries, but spends more time trying to resolve issues associated with the addition of questionable substances to foods where businesses challenge requests to remove products from the market.

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

If option 3 was introduced with the regulatory oversight outlined above, we would expect that there would be greater certainty for both food businesses and regulators. The creation of a schedule of new eligible foods in the Code and the ability to legally remove products containing non-listed foods from the market would have the potential to reduce enforcement costs.

Please contact Jack Ward on 03 9096 1252 if you would like to discuss any of the matters raised in this submission. In particular the departments are preparing a detailed flow diagram to illustrate the proposed overarching framework and tiered approach that we have proposed.