28 July 2017

Food Standards Australia New Zealand
PO Box 5423
Kingston ACT 2604
Australia

By Email
standards.management@foodstandards.gov.au

Dear Sir / Madam,

Re. Proposal P1024 - Revision of the Regulation of Nutritive Substances & Novel Foods

The Australian Beverages Council (ABCL) is the peak body representing the collective interests of the non-alcoholic refreshment beverages industry. Our membership is comprised of multi-national companies, small and medium business, making up over 95% of the non-alcoholic beverage industry's production volume in Australia. A full list of our Members can be viewed at https://www.australianbeverages.org/about-us/member-directory .

It is understood that following the first call for submissions, FSANZ are now seeking stakeholder views in regards to regulating of nutritive substances and novel foods in the Australia New Zealand Food Standards Code (FSC) on a possible new modified framework, exclusive permission provision and approach to grandfathering.

Overarching Comments

The ABCL, acting on behalf of the non-alcoholic refreshment beverages industry in Australia supports the review of the regulation of nutritive substances and novel foods. We appreciate FSANZ recognising the need to remove ambiguity and reduce the regulatory burden that currently prevents innovation, while still protecting public health and safety through the use of a graduated risk approach.

Australian Beverages Council Ltd
2/2 Allen Street, Waterloo NSW 2017 • Tel: +61 2 9698 1122
Email: info@ausbev.org • www.australianbeverages.org

Framework

The ABCL supports the concept of an 'eligible food criteria' (or EFC) as a method of reducing the regulatory burden on low risk products. We note FSANZ intends to further develop the EFC, however this will not be addressed in this call for submissions.

We also support providing a "cut-off date" for the foods required to go through the new framework. This will reduce ambiguity and align with countries with similar regulatory approaches.

The FSANZ proposal to consider permitted novel foods listed in Schedule 25 of the FSC as no longer 'novel', under the modified framework is supported by the ABCL. We would also encourage a mechanism to remove novel food permissions from the FSC after a certain period of time.

The ABCL supports the removal of the definition of '*used as a nutritive substance*' from the FSC. We agree that the term is ambiguous, and potentially overlaps with the novel foods definition.

We also support the FSANZ assessment process being streamlined by amendments to the Handbook's data requirements.

Exclusive Permissions

The ABCL strongly feels that exclusive permission provision is required. Our Members have expressed the need to gain a return on the significant investment required for approval for these foods. No other method is considered satisfactory to provide sufficient legal protection in the Australian market.

Transition Arrangements

The ABCL supports the concept of exempting foods currently marketed from the requirements of the new framework ('grandfathering').

We also support the view that fermentative and flavour producing food culture microorganisms are inherently safe and have a history of safe use. Therefore, grandfathering of these products is appropriate.

Subsequent Consultation

We understand that this call for submissions does not address EFC or the consideration of overseas approvals. ABCL would like to highlight that the successful regulation of products related to this proposal relies heavily on the EFC. We believe further consultation regarding the creation of EFC is required. The ABCL would like to express its wish to work closely with FSANZ on the development of the EFC to ensure FSANZ is aware of the implications the EFC may have on our Members and ensure the best outcome for industry and the public.

The ABCL would also like to highlight its strong support of FSANZ consideration of overseas approvals. This would allow for greater innovation and a fairer playing field for Australia through the reduction in duplication for global food manufacturers.

The ABCL looks forward to providing more detail regarding these two issues to FSANZ in the future.

The ABCL responses to the questions FSANZ raised in this call for submissions can be found on the following page.

We thank FSANZ for the opportunity to provide this submission in support of the *Proposal P1024 - Revision of the Regulation of Nutritive Substances & Novel Foods*. If you wish to discuss any aspects of this correspondence contact me on [redacted]

Yours sincerely,

[redacted]

Melanie Pauga
[redacted]

Submission Question – Proposal P1024

Existing Permissions for Novel Foods

Issue	Submitter comments
Question: Will the removal of permissions from Schedule 25 create problems relating to requirements for specifications for these foods?	
No problems foreseen.	The ABCL does not foresee any potential negative effects stemming from the removal of novel foods listed Schedule 25 that do not have any conditions of use. We believe that FSANZ would still need to provide a record that these foods have been assessed to prevent potential duplication of work. We also support retaining the identity and purity specifications of these foods. The ABCL are supportive of novel foods becoming "traditional" after a history of safe use has been established in ANZ. We believe that 5 to 10 years is an appropriate period. It is noted that 10 years allows for a generation to consume the product. The length of time to show a safe history of use would depend on the rate of consumption of the product. For instance, the period to show a history of safe use will be significantly longer if only one food contains a novel food versus multiple food categories.
Question: Which of the novel foods listed in Schedule 25 are used only in foods regulated by specific Part 2.9 standards?	
Possibly Sports Drinks in Standard 2.9.4.	The ABCL understands that some of the novel foods listed in Schedule 25 are found in Sports Drinks governed under Standard 2.9.4.
Question: Are there other issues associated with removing permissions from Schedule 25? Please elaborate.	
No issues.	The ABCL does not see any other issues associated with removing of novel foods listed Schedule 25 without any conditions of use and allowing these foods to be considered "traditional".

Nutritive and Related Substances

Issue	Submitter comments
Question: Do you consider other nutritive type substances (in addition to vitamins, minerals, electrolytes and L-amino acids) should always be subject to pre-market approval by FSANZ? Please provide reasons for your view.	
No.	The ABCL does not feel that other nutritive type substances should always be subject to pre-market approval. We would support changing the term "*used as a nutritive substance*" as it is open ended and as FSANZ has mentioned is an ambiguous definition. It is

	also noted that there is currently overlap between nutritive substances and novel foods. Some substances could be considered both a nutritive substance and a novel food. As stated in the Consultation Papers, the objective for this proposal is to reduce the health risks to consumers from potentially unsafe foods in a way that is cost-effective. The ABCL supports FSANZ using a risk based approach to reviewing both nutritive type substances and novel foods. Assessment of safety of both requires similar information to determine they are safe for human consumption. The ABCL feels that the proposed modified framework could capture and appropriately assess the risk of "other potential nutritive substance" through eligible food criteria as it would for novel foods. However, as the eligible food criteria has not been defined we are not able to comment on the appropriateness of the criteria. The ABCL feels assessment of nutritive type substances would depend on factors that are also relevant in the assessment of novel foods, for example the relationship to foods currently consumed in ANZ, consumption patterns normally seen. The ABCL note that FSANZ will address the eligible food criteria in another call for submissions.

Review of Exclusive Permissions

Issue	Submitter comments
Question: Does there remain a requirement to provide exclusive permission as a condition of use in the Code?	
Yes.	The ABCL strongly feels that exclusive permission is required to ensure that industry can gain a return on the significant investment required for approval for these foods. Without providing exclusive permission there will be little incentive for industry to innovate. This will ultimately decrease the choice available to the consumer. We again highlight the need to reduce competitors 'free-riding', by marketing the same or similar products, without having made any investment in obtaining regulatory approval for the new product. How exclusive permission is handled depends on where the exclusive rights lay. This would be different for ingredient manufacturers versus final food manufacturers: 1. Ingredient suppliers who may want an exclusive right to sell the ingredient to manufacturers, and keep other ingredient suppliers out of the market. This could be dealt with similarly to food additive permissions, which are often be protected by patents and other intellectual property rights, by limiting approval, or the specification to a source of the ingredient; 2. Final food manufacturers may seek to use the ingredient and want exclusive permission to prevent competitors from copying their product. A period of market exclusivity would allow them to establish their product in the market and gain a return on the investment required to gain approval.

	The level of market exclusivity an ingredient supplier would need to recoup their investment is likely to be much longer than a food manufacturer. We would appreciate further consideration from FSANZ on this point.
Question: What costs to the community, Government and industry arise from the grant and use of exclusive permissions? Please provide data if possible.	
Cost to industry of gaining approval.	Exclusive permission provides a competitive advantage to the manufacturer who has expended considerable investment into gaining approval. This creates a competitive barrier. To ensure that exclusive permission is used appropriately and encourages further innovation the scope of use should be quite clearly defined.
Question: What direct and indirect benefits to the community, Government and industry arise from the grant and use of exclusive permissions? Please provide data if possible.	
Benefit of greater consumer choice.	As stated in the Consultation Papers, ANZ is a relatively small market and the cost presented through obtaining approval can prevent food manufacturers from bringing nutritive substances and novel foods to market. This reduces consumers choice in the market, especially for foods which potentially have a higher nutritional value, such as reduced sugar products. The allowance for greater length of exclusive permission would make the ANZ market more attractive and encourage new product innovation and development.
Question: Why should Australian and New Zealand food laws make Australian and New Zealand food regulators bear the onus and cost of protecting industry's intellectual property in products being sold commercially?	
To protect consumers while encouraging innovation.	The Food Standards Code allows for the controlled use of foods in the supply chain. This mechanism protects consumers and provides the best method of protecting innovative development that encourages local manufacturers to develop new products.
Question: Why are other existing measures (such as intellectual property laws allowing a patent or innovation patent) not adequate to protect industry's investment in developing commercial food products?	
Patents are more general and difficult to gain for foods and manufacturing practices.	Using measures such as patents tend to be more generalised and less understood. They can be very complex and challenging area of law. Often it is difficult to gain a patent for a food or a food manufacturing process.
Question: What other alternatives exist to protect industry's investment in developing commercial food products (i.e. other than reliance on the Code and Australian and New Zealand food laws)?	
Not aware of effective alternatives.	The ABCL are not aware of any other alternative effective methods for protecting industry investment in developing commercial foods products.

Question: Is the current 15-month period applied to exclusive permissions sufficient? If 15 months is not considered sufficient, please explain why this is the case and what period of time would be sufficient and why. Please provide data if possible.	
No, no less than 3 years would be appropriate.	The ABCL does not feel that 15 months is a long enough period to allow for return on investment. Considerable cost is required in order to gain approval. Often innovation of very novel product would take 3 to 5 years and the cost of development and safety can be millions of dollars. An extension of the time permitted would encourage innovation, in turn this would allow for greater variety of products and possibly providing improved nutritional benefits. Examples of this are development of sugar replacement/sweetener development. It was noted that FSANZ has expressed a need for consistency between domestic and international food standards and the desirability of an efficient and internationally competitive food industry. The ABCL support greater alignment with international standards. We note EFSA's allowance for 5 year data protection. This would support innovation from multinational companies to help alignment of timeframes for product launches. The ABCL feel that a 5 year exclusive permission would allow for a reasonable return on investment, however 3 years should be considered as a minimum.
Question: Does the innovation activity your business undertakes typically occur in Australia or New Zealand? Will this change if the period for exclusive permissions are increased and, if so, how and why? Please provide data if possible.	
Where the subject matter expert is.	Innovation activity normally occurs where the subject matter expert is based. This is unlikely not be influence by exclusive permissions.
Question: Does your business typically place new products on the market at the same time or before placing them on the market in larger overseas markets? Please provide examples or data if possible.	
Australia is often used as a test market.	Australia is often used as a test market for innovation. Examples of this include: Pepsi Max Vanilla, which was first launched in Australia and then globally. For G Active and Mountain Dew Kickstart, Australia was the first international market outside of USA to launch.

Transition Arrangements for Currently Marketed Foods

Issue	Submitter comments
Question: Please indicate whether you support the 'grandfathering' of foods which are available for sale in Australia and New Zealand at the time of gazettal (of a new framework in the Code).	
Support.	The ABCL supports changing the definition of novel foods and providing a cut-off date. This aligns with other similar countries and removes ambiguity.

	The ABCL agree with FSANZ statement that a demonstrated history of safe use of a food in other markets can provide a level of confidence in the assessment of safety of new or novel foods. We urge FSANZ to consider a default policy / expectation that substances that are approved as novel foods in EU and Canada, have GRAS status or are approved as substantially equivalent in the US and have FOSHU status in Japan, be considered to be an eligible food. We say this on the basis that these countries have a risk based approach to the approval of these substances and would not require a regulatory process simply for the sake of it.
Question: Do you consider there are categories of foods that should not be grandfathered? If so, please provide justification for your view.	
No.	The ABCL does not see any issues this.
Question: Would the proposed approach for microorganisms present problems for your business? If so, please elaborate.	
Yes.	The ABCL would support all foods produced with live food culture microorganisms (FCMs) sold in ANZ at the time of gazettal being 'grandfathered', and not subject to the new framework. As stated in the Consultation Paper the ABCL is concerned with the proposed positive list of microorganisms as this will not encompass the wide variety of microorganisms that may be present in food cultures. We note that there is greater interest in fermentation with the rise in fermented drinks, such as Kombucha and Kefir, which provide greater choice and potentially more benefit to the consumer. We urge FSANZ to allow for greater innovation in these categories. We would support FSANZ recognising the inherent safety these fermentative and flavour producing FCMs occasion to food production. FSANZ have considered EFSA list of microorganisms with QPS. The ABCL would again encourage FSANZ to consider a default policy / expectation that microorganisms which are approved in the EU, US, Canada and Japan be considered as eligible food.