24 March 2016

Food Standards Australia and New Zealand,

PO Box 7186

CANBERRA BC, ACT, 2610

Via email: submissions@foodstandards.gov.au

Dear Food Standards Australia New Zealand,

Submission – P1024 : Nutrients and Novel Foods

The Australian Beverages Council (Beverages Council) is the peak body representing the $7 billion non-alcoholic beverage industry that supports direct employment of more than 46,000 people in Australia and collectively pays more than $1.2 billion in taxes per annum. The Beverages Council provides a single, united industry voice to a range of stakeholders including government, non-government organisations, media and the general public.

Membership of the Beverages Council comprises over 95% of the non-alcoholic industry's production volume and is comprised of multi-national companies as well as many small and medium-sized businesses. A list of members can be found here. The Beverages Council has two dedicated category divisions – Fruit Juice Australia and the Australasian Bottled Water Institute, which represents the unique interests of members manufacturing juice and bottled water products respectively.

Overview

The Beverages Council supports Option 3 - the graduated risk approach.

The Beverage Council does not support Options 1 or 2.

Option 1 proposes to retain the status quo. This fails to address the risks associated with the uncertainty with the current Code provisions and thus is not a real option.

Option 2 involves a minor amendment of the current standard: to amend the current provisions, primarily the definitional elements associated with nutritive substances and novel foods. This option would not meet timely enough end to achieve the appropriate need that is becoming an increasing source frustration for jurisdiction to regulate against products of concern.

The current Code provisions relating to nutritive substances and novel foods, particularly the definitions associated with them, are creating uncertainty in the market place. The uncertainty relates to whether particular foods require permission in the Code before they can be sold in Australia and New Zealand; and therefore whether the foods should be subject to pre-market assessment by FSANZ. This presents different risks for industry and food enforcement agencies in particular.

These definitional changes are integral to the overall Food Standards Code and should be pursued (as part of Option 3) to avoid any further ambiguity.

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Option 3 is more innovative: approach - to develop an alternative approach based on the level of risk inherent in various types of novel foods.

Global trends and opportunities in this increasingly connect world is moving at a faster pace than ever before and whilst the need for border security and local food safety should be at the forefront of our industry, present FSANZ Application and evaluation protocol can be the cause of both global hesitance to enter into Australia or attempt means to circumvent such lead times. Option 3 shows great insight into the NPD / innovation process in the modern food and beverage industry and can address theses issues. The Beverages Council, therefore supports Option 3.

However, it is the finer details of Option 3 that are critical to making this option work. There are opportunities for refinement of Option 3 to ensure it meets all stakeholder requirements as outlined below.

Key Issues

Publication of Dossiers:

The Beverages Council agrees with the principle that regulatory outcomes should be transparent. The Beverages Council also believes that any requirement to disclose confidential information can serve as a disincentive for companies to seek approval for new foods or technologies, and even to invest in developing such in the first place. A balance between these competing principles is required. Thus the Beverages Council does not support full publication of substantiation dossiers. The Beverages Council recommends a similar approach to General Level Health Claims as outlined in Standard 1.2.7. where companies notify FSANZ of a new nutritive substance or novel food and make the dossier available on request to regulatory authorities.

This model ensures that regulators, through FSANZ, have both the awareness of novel foods entering the market and the opportunity to seek additional information and raise any concerns (including as to eligibility for self-assessment) ahead of market entry. The public has access to information about the novel food and its evaluation, while at the same time the confidentiality of sensitive information can be protected.

International Approvals / Recognition:

The Beverages Council believes that a novel foods / ingredient approved in other major regions or countries should be recognised and allowed to be marketed in Australia or New Zealand without further requirement for self- or regulatory assessment. Such regions or countries would include the EU, USA and Canada.

The imposition of such a regulatory burden of compliance in the future for all, where some pre-existing eligible safe foods are deemed safe is compatible with the intent of this model. Allowing for the entire industry to improve its correct due diligence in the process to ensure food safety .

We thank FSANZ for the opportunity to provide this submission regarding**P1024 Nutrient and Novel Foods and support** FSANZ **Option 3** in principle with proviso for refinement as detailed. If you wish to discuss any aspect of this correspondence in more detail I invite you to contact me directly on [redacted]

Yours sincerely,

[redacted]

[redacted]

Technical and Regulatory Affairs Manager

Questions for Submitters

Section 4.2.1
How do the current novel food and nutritive substance definitions affect your organisation, either as a food business or a food enforcement agency?

The Beverages Council believes that current definitions create uncertainty for both manufactures and regulators. This creates lost opportunities for both manufacturers and consumers.

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 assessment summary has adequately addressed that problems with the current definitions.

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 current application only process is onerous and costly, especially if the company elects to proceed with a paid application. The existing Standard does not encourage innovation and can have a negative impact upon investment decisions.

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.

The Beverages Council does not support Option 1 of maintain the status quo.

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

No. FSANZ has identified all the issues with the status quo.

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.

The Beverages Council supports amending the definitions of 'novel food' and 'used as a nutritive substance' in the Code.

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

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.

No.

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

The Beverages Council believes that foods which have received approval for sale as a food (as distinct, for example, as a supplement or additive) in comparable jurisdictions (EU, USA, Canada) should qualify for this path to market.

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

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

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

The EFC should be sufficiently robust to identify foods that require further assessment, being either self-assessment or registration. The Beverages Council, thus does not support the proposal for exclusions to the EFC

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.

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

Yes

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

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

A self-assessment pathway would provide the benefit of reduced time to market over the current application process. In addition, it may encourage companies to bring food products to Australia and New Zealand that are currently available overseas, however the application process makes it currently too burdensome to do so.

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.

As mentioned above, the Beverages Council does not support the publication of dossiers. The Beverages Council recommends a similar approach to General Level Health Claims as outlined in Standard 1.2.7. where companies notify FSANZ of a new nutritive substance or novel food and make the dossier available on request to regulatory authorities. This model ensures that regulators, through FSANZ, have both the awareness of novel foods entering the market and the opportunity to seek additional information and raise any concerns (including as to eligibility for self-assessment) ahead of market entry. The public has access to information about the novel food and its evaluation, while at the same time the confidentiality of sensitive information can be protected.

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.

The Beverage Council supports the regulation of novel foods under a graduated risk approach, the objective being to establish safety in the target foods for consumers at the usage rate. However, the concept of nutritive substances could be considered to be flawed as it is duplicative, confusing, complex and uncertain.

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.

The current period of 15 months is not long enough to achieve a return on investment. This may be a reason why some companies are not pursing novel foods in Australia and New Zealand. A self-assessment pathway will provide a form of exclusivity.

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)?

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

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

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

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.

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

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

The Beverages Council does not support the proposal for no stock-in-trade provisions. There needs to be some provision for products which have a long shelf life or lead time.

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

The peak industry bodies, including the Australian Beverages Council.

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?

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

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?

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).

If a novel food has achieved a history of consumption (say 5 to 10 years) in Australia and New Zealand and no unanticipated issues have emerged, then it would seem appropriate to make provision for foods to be no longer considered novel.

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.

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.

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

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.