frucor
A SUNTORY GROUP COMPANY

24 March 2016

Food Standards Australia and New Zealand

PO Box 10559

The Terrace WELLINGTON, 6143

NEW ZEALAND

Via email: submissions@foodstandards.gov.au

Dear Food Standards Australia and New Zealand

Thank you for the opportunity to provide our submission on **Proposal P1024: Review of the Regulation of Nutritive Substances and Novel Foods.**

Frucor Beverages Ltd. is an Australasian manufacturer of beverages with a brand portfolio that includes leading brands of waters, fruit juices, fruit drinks, energy drinks, sports drinks, sports waters and soft drinks.

Frucor personnel are active members of the New Zealand Beverage Council (NZBC), the Australian Beverage Council (ABC), New Zealand Food and Grocery Council (NZFGC), New Zealand Nutrition Foundation and the NZ Fruit & Vegetable Alliance (NZ FAVA) by providing executive and technical expertise on several working groups within these organisations.

Frucor has been shown to take a lead role within the beverage sector via new product development (NPD), sales and marketing strategies which include a commitment to providing healthier options. On-going innovation to our beverage range includes the offering of smaller pack sizes (smaller volume bottles), specific lower sugar/zero sugar products and functionality.

Our submission is attached separately.

Yours sincerely

[redacted]

On behalf of Frucor Beverages Ltd.

[redacted]
Nutrition & Claims Manager
Frucor Beverages Limited

SUBMISSION / Responses to Questions for

Proposal P1024 : Proposal P1024: Review of the Regulation of Nutritive Substances and Novel Foods.

Overarching comments:

Options
Frucor Beverages Limited concurs with, and identifies further, issues and problems described in Proposal P1024 that apply to the non-alcoholic beverage sector in relation to the regulatory arrangements for nutritive substances and novel foods. This includes the issues and problems with definitions. Frucor therefore considers Options 1 (status quo) and 2 (amend the current definitions) do not present the best solution or opportunities to advance the regulatory system. These options present the risk of these problems and issues continuing into the future, especially given the difficulties that other countries have experienced with definitions.

Frucor Beverages Limited therefore proposes that, with further development and refinement, the framework proposed in Option 3 should be pursued and evolved.

3.3 Summary of risk assessment

Questions:

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

Response: We consider novel and nutritive substances that fall outside vitamins and minerals, and the listed allowable/ prohibited novel foods and Std 1.4.4 prohibited and restricted plants and fungi in the following way if not in either of these lists: If a new ingredient has been used elsewhere by another population then we consider these are not novel.

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

Response: We agree that the current definitions pose problems of ambiguity and do not make it clear for code users. The problems outlined in the consultation paper are that:

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

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

In addition, the novel foods definition refers to 'traditional use'. This creates problems with the rapidly changing ethnic population in Australia and New Zealand.

3. Do you believe there are problems with the current provisions more broadly (not just the definitions) in addition to those outlined in assessment summary? If so, describe the problems.
   Response: Need code to allow for innovation but also to offer a level of protection for the consumer in terms of safety.

4.2 Options

4.2.1 Option 1: Status quo

Questions:

4. Are there elements of the status quo that you support maintaining in the Code? If so, please provide details and reasons for your support.
5. Can you identify any problems with the status quo in addition to those highlighted in this report? If so, please provide details.

Response: The ambiguity of the existing code allows for unintended freedom to explore new ingredient without boundaries or consideration for efficacy or safety. It would be up to the manufacturer to determine a dosage level based on typical usage levels of these ingredients used in dietary supplements e.g. daily dosage – not necessarily determined by agreed safe limits but FDA and GRAS data may be considered.

Examples: The "Non-traditional food" definition is problematic given the context of the definition "a history of human consumption" appears to be limited only to Australia New Zealand, therefore this technically means that ingredients traditionally used in other parts of the world would not qualify.

4.2.2 Option 2: Amend the current definitions

Questions:

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

Response: As already discussed in our response to Qn5, we see the "new in ANZ definition" as being onerous and would prevent the use of ingredients already in use traditionally in other cultures and countries. These may already have FDA GRAS status.

Industry current practice already uses this approach, provided the ingredients are not listed as prohibited within the current food standards code.

We are in favour of one definition which covers ingredients/substances that are newly discovered or synthesised; new sources; intended use that is different to traditional use.

4.2.3 Option 3: Develop an alternative framework

4.2.3.1 Identifying foods that do not require regulatory approval

Questions:

7. Are the EFC appropriate for identifying foods that do not need regulatory approval? **YES**

8. Are there foods that may meet the EFC that you consider should be subject to pre-market assessment? If so, please describe the properties of these foods.
9. Are there foods that would not meet the EFC, but you consider should be eligible? If so, please describe the properties of these foods.

Response: Encapsulation; Enzymatic Processing

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

Response: AFGC PIF with associated documentation, including an MSDS; Search data on safety of the ingredient.

11. Are the exclusions to the EFC appropriate in identifying foods that should be subject to pre-market assessment, despite otherwise meeting the EFC? YES
12. What do you consider would constitute a 'reasonable potential' for a food to have pharmacological effects at the intended levels of consumption? See SD3 for discussion on this issue.

In summary, a self-assessment pathway to market for a non-eligible food could operate according to the following process:

1. The food meets a gateway test and is therefore suitable for self-assessment by a food business

2. The food business[8] establishes the food as safe for consumption at the intended levels of use (subject to the data and assessment requirements in the Code and guidelines)

3. The food business notifies food regulators/authorities of its intention to market the food and submits a dossier which is published online (dossier details discussed in section 4.2.3.3)

4. The food business markets / supplies the food to consumers or to food manufacturers who may use the food as an ingredient in processed foods.

4.2.3.3 Data and dossier requirements

Questions:

13. Do you regard the investigation of an alternative approach to regulating nutritive substances and novel foods in the Code as a viable option? **YES**
14. In particular, taking account of FSANZ's primary objective of protecting public health and safety, is the draft framework presented in option 3 a viable option? **YES** What

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

15. Do you have suggestions for the type of foods that would not meet the EFC, but may be suitable for industry self-assessment?
    Response: Encapsulated ingredients e.g. coated ingredients to enable technically difficult compounds to be utilized in processing of final product e.g. dispersibility/homogeneity, and taste/masking of bitter flavours;
16. Please provide details of how a self-assessment pathway may or may not provide benefits to industry**.**
    Response: The benefits to industry would be flexibility for innovation. However industry bodies would need to enable and support small enterprises or recommend consultants.
17. Would notification and publication of dossiers provide enough regulatory oversight and consumer confidence in relation to the safety of new foods? Please support your answer with detail of why you believe this is the case.
    Response: YES, however 1) the application process to deliver a dossier which meets FSANZ requirements may hinder and delay the NPD process for most companies. Industry bodies and or suppliers may assist in preparation of these dossiers but this process could take years given current experience for relatively simple applications. 2) We would have not have an issue with the notification but do support the public disclosure of the dossier. Dossiers represent commercial and confidential intellectual property which provides individual companies with a unique point of difference to competitor products. Generic dossiers may be represented if mutually agreed to e.g. by industry and suppliers but publication may still pose and issue and would need further discussion – this would allow smaller players to piggy-back on sector initiatives.

4.3 Draft framework - other considerations

4.3.1 Impact of the draft framework on current standards

Questions:

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

6 Other matters

6.2 Exclusive permission for brand and class of food

Questions:

19. Do you support retaining the provision to grant exclusive permission in the Code for foods approved by FSANZ? **YES** Please provide reasons for your view.
    Response: This supports industry innovation and recognises the extensive investment by industry in the development of a novel ingredient or food and the need to achieve a return on this investment. It allows local industry to maintain a competitive edge when these goods are potentially exported.

20. Can you identify any issues that may arise if exclusive permissions are available for FSANZ approved foods (with permission provided in the Code), but not available for industry self-assessed foods? Would the self-assessment process for non-eligible

foods provide a trade-off against the lack of an exclusive permission for self-assessed foods (section 4.2.3)?

Response: Frucor considers that if documentation and data sets for the Pre-Market Assessment by Notification Pathway are not public, then notification delivers some level of exclusivity and has the advantage of speed to market. The exclusivity of the Pre-Market Approval Pathway remains attractive for substances not meeting the gateway test for industry self-assessment

7 Transition and implementation

7.1 Proposed transitional period

Questions:

21. Do you support a cut-off date? **YES** Please provide reasons for your view.
    Response: Allows industry to work towards a deadline.
22. Do you see a need for grandfathering provisions? Please provide reasons for your view.
23. Do you see a need for a stock in trade provision? Please provide reasons for your view.

Response: YES, a clear cut-off date is required for both enforcement and industry to ensure compliance is met by this date e.g. A 12 months transition period with cut-off date of no stock in trade after this deadline.

7.2 Implementation

7.2.3 Post-market surveillance

Questions:

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

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

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

Response: Allows time for companies to achieve compliance.

26. Do you have any suggestions as to which peak bodies should be involved in familiarising industry of the new provisions?
    Response: FGC (Food and Grocery Council) MPI, NZBC (Beverage Council), NZIFST, Crown Research agencies, HVN Science Challenge (UoA)
27. Do you have any suggestions on how the implementation process could be approached, especially with respect to enhancing awareness and understanding of the potential new provisions under Option 3?
    Response: FSANZ workshops via above bodies.
28. Are there any particular comments you feel are appropriate to ensuring satisfactory post-market surveillance?

    Response: Guidance documents for navigating the new standard and supportive and robust regulatory compliance via industry self-regulation.

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

    Response: Foods that fall into this category are of interest due to their unique nature and are generally given an initial assessment by qualified food technologists or scientists as to the suitability of the ingredient in terms of safety and suitability for manufacturing e.g. there may be a request for toxicology data, safety information; also there may be physical/chemical characteristics which may need to be met to allow the product to be processed.

30. Why is it important for novel foods permitted in the Code to be declared 'not novel' after a certain period of time?

    Response: As the product shifts from being totally new in the food supply

    Please explain the impacts on your business of novel food permissions remaining in the Code (as novel foods).

Refer SD1

31. What costs have you experienced in making novel food or nutritive substance applications (for permission in the Code) or enquiries to the ACNF under the current system? If possible, include information on size and types of costs (e.g. commissioning research, staff time spent preparing an application). If possible, indicate the costs which relate only to the Australian/New Zealand market. If this is not possible please clearly indicate these are the global costs of obtaining these data and which other regulatory authority they have been prepared for.
    Response: Commissioning research – pilot investigation $5000-10,000.
32. What other costs have you experienced as a result of the current novel food and nutritive substance provisions (i.e. costs not related to applications and enquiries)? For example, costs of obtaining legal advice on whether a substance is a novel food or a nutritive substance.
33. How (if at all) do the current provisions influence your business's decisions regarding developing and launching new products?

Response: The current provisions lack clarity and potentially hinder the NPD process. Having eligible food criteria allows a decision to be made as to whether the new or novel food ingredient is permitted to be used.

34. What (if any) kinds of opportunity costs have you experienced due to the time taken to assess applications? For example, missing a 'window' during which a retailer will accept new products within a particular category.
    Response: There are windows of opportunity for products to be presented to retailers/supermarket buyers, some of which are seasonal windows e.g. period leading up to Christmas.
35. (For food regulators) What types of enforcement costs does your organisation experience as a result of the current nutritive substance and novel food standards? E.g. dealing with enquiries about whether a food is novel or a nutritive substance, notifying food businesses that their food is a nutritive substance or novel food and requires pre-market assessment by FSANZ. N/A
36. (For food regulators) How would (if at all would) the types of enforcement costs change if Options 2 or 3 were introduced? N/A

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