28 July 2017

Project Manager
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Dear Sir/Madam

Please find attached comments on the ***Consultation Paper – Proposal P1024 Revision of the Regulation of Nutritive Substances & Novel Foods***.
Regards

Jennifer Yee Collinson

[redacted]

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Consultation Paper – Proposal P1024

Revision of the Regulation of Nutritive Substances & Novel Foods

Submission by Frucor Suntory

28 July 2017

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FRUCOR SUNTORY NEW ZEALAND LTD

1. Frucor Suntory welcomes the opportunity to comment on the ***Consultation Paper – Proposal P1024 Revision of the Regulation of Nutritive Substances & Novel Foods*** (the Consultation Paper).

Frucor Suntory 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 takes 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.

OVERARCHING COMMENTS

2. We support the NZ Food & Grocery Council recommendation for further consultation that particularly considers eligible food criteria and the proposed framework before work on drafting a proposed regulatory measure proceeds.

3. We are very disappointed that the proposed three-pathway framework has been modified to remove the industry self-assessment notification pathway. We strongly recommend that pre-market assessment and notification by industry (self-assessment) continue to be developed and put in place
   - options for this include deferred commencement pending amendment to the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act – to enable a centralised assessment to meet jurisdictional demands) and/or a 'preferred company' approach.

4. We strongly support amendment of the framework to accommodate recognition of approvals by specified overseas authorities and the acceptance of food that has a demonstrated history of human consumption overseas through the appropriate pathway.

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DETAILED COMMENTS

Pre-market assessment by industry

5. Frucor Suntory express great disappointment in the removal of the option that allows for pre-market assessment and notification by industry (self-assessment) which no longer features as an option in the modified regulatory framework. We strongly recommend that pre-market assessment and notification by industry (self-assessment) continue to be developed since we believe it is not the option that cannot be accommodated by the FSANZ Act but rather the administration and implementation of the option that presents difficulty to meet jurisdictional demands. We support the view that the option should continue to be developed noting that one possibility is to defer commencement while changing the FSANZ Act is pursued to enable a centralised assessment to meet jurisdictional demands but also noting that industry is open to considering other possibilities for a self-assessment pathway such as a 'preferred company' arrangement for undertaking self-assessment.

6. We recommend that a further consultation paper includes within its scope a self-assessment pathway with a broader range of possibilities that could be reviewed.

7. We strongly support amendment of the framework to accommodate recognition of approvals by specified overseas authorities and the acceptance of food that has a demonstrated history of human consumption overseas through the appropriate pathway (which could be any one of the three pathways).

8. Consideration should also be given to continuing investigation of any proposals from submitters that would allow industry self-assessment of low risk foods and ingredients to proceed.

9. We note that the current proposal is supportive of industry conducting the identification of eligible foods within set parameters which does not require regulatory and scientific oversight to be centralised. The same rationale could be applied to industry assessment and notification, and therefore should continue to be considered. Similar protections could be implemented for the identification of eligible foods, such as industry needing to hold records to substantiate decisions.

10. We consider that without the development of a streamlined pathway, such as the self-assessment notification pathway, the revision of the framework will not be able to deliver on the need to introduce a risk-proportionate regulatory regime that addresses both innovation and food safety. For innovation, speed to market after significant research and development investment is key to generating the return on that investment. The modified framework may address uncertainty associated with the definitions of novel food and nutritive substance and possibly the immediate problem for enforcement, but it will not address the fundamental issues that have prevented significant utilisation of the system by industry nor will it address innovation.

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Framework

11. Frucor Suntory considers that the original three-pathway framework should continue to be developed while recognising that:
    a) commencement of the self-assessment notification pathway may need to be delayed while alternate ways to meet the jurisdictional demands are developed such as amendment of the FSANZ Act
    b) eligible food criteria might be expanded to better capture low risk foods.

12. Frucor Suntory therefore does not support the modified approach.

13. Frucor Suntory still supports continuing work on all the elements that are necessary for a three-pathway framework (the eligible food criteria pathway, the self-assessment notification pathway and the FSANZ assessment pathway) and the alternate options identified above.

Issues for subsequent consultation

14. Frucor Suntory supports the NZFGC submission noting that several issues have been set aside to be dealt with in a further call for submissions: eligible food criteria, data requirements for eligible foods, responsibilities for holding dossiers for assessment against the eligible food criteria and consideration of overseas approvals in the context of a new framework.

Proposed Approach

Concept of a novel food in the new framework

15. Frucor Suntory supports removal of the current definition from the Food Standards Code and the criterion of a cut-off date of commencement of the provisions. The third criterion, of being subject to the eligible food criteria and data requirements, needs to be further developed in order for an understanding of the impact to be assessed.

16. Frucor Suntory supports flexibility in relation to responsibility for holding data on novel foods so that due diligence can be conducted by the user/manufacturer of the novel food to confirm requirements have been met and potentially develop records of declarations as to the food's status.

17. We believe that the self-assessment notification pathway needs to be developed as an option for foods that do not meet the eligible food criteria but that are low risk.

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Existing permissions for novel foods

18. Frucor Suntory notes that conditional use is already a feature of FSANZ assessment of applications of certain foods and that extensions of such conditions requires an application to FSANZ. We also note that where no conditions are specified, novel ingredients may be used in any food for retail sale and that there is no mechanism to remove novel food permissions from the Code after a certain period of time.

Will the removal of permissions from Schedule 25 create problems relating to requirements for specifications for these foods?

19. Frucor Suntory supports the removal of novel food permissions including those that have no associated conditions placed on them after safety assessment. Those familiar with the processes applied by FSANZ would be aware of the application/proposal process and would know where to look for assessments and those not familiar would quickly find out through due diligence searches. In terms of the Food Standards Code continuing to list the identity and purity of novel foods, this decision should be made on a case-by-case basis.

Which of the novel foods listed in Schedule 25 are used only in foods regulated by specific Part 2.9 standards? Are there other issues associated with removing permissions from Schedule 25?

20. A clean slate approach could be considered. Alternatively, those novel foods that have no associated conditions.

21. Manufacturers find the list of novel foods a useful reference tool but this does not justify its retention in regulation. Frucor Suntory supports the NZFGC suggestion that a guidance document listing the approvals over time would be equally as useful.

Consideration of nutritive and related substances

22. Frucor Suntory notes the considerable uncertainty created by a term that may or may not apply to foods and ingredients and that is so broad as to include "any substance that has been concentrated, refined or synthesised to achieve a nutritional purpose when added to food".

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23. Frucor Suntory recommends removal of the definition 'used as a nutritive substance'. Any standards that include nutritive substance permissions should be revised to reflect removal of this concept. All these could be recast to remove reference to 'nutritive substance' and alternative arrangements made for requirements.

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.

24. No, Frucor Suntory does not believe that any substances should always be subject to pre-market approval. We support an approach whereby substances that may have previously been considered nutritive substances or "used for a nutritive purpose" (e.g. the addition of an ingredient to increase the protein content of a product) will, under the future regulatory framework, be assessed against the eligible food criteria to determine eligibility or whether pre-market assessment (industry or FSANZ) is required. The opportunity for self-assessment with notification should be developed for such products as well as pre-market assessment by FSANZ. Such an approach has the potential to provide consistency across the treatment of nutritive substances and novel foods. However, the effectiveness of the approach cannot be assessed without an understanding of the content of the eligible food criteria and how they will be applied.

Amended data requirements for applications

25. Frucor Suntory notes that the Application Handbook sets out mandatory requirements for applications for novel foods and nutritive substances and that there are different data requirements for different types of novel foods. FSANZ makes clear that there is no explicit tiered approach to data requirements in relation to varying levels of risk that consumption of different foods or substances may present. A tiered approach where data requirements increased with complexity or risk that may be presented by a food should be developed for two reasons: to identify the data requirements for low risk foods for self-assessment with notification and to assist in streamlining applications for FSANZ assessment with medium risk and complexity.

26. We therefore support amendment of the data requirements in the Application Handbook to reflect the varying levels of risk from foods. This might include the requirements for low risk foods as an interim arrangement for self-assessment with notification pending amendment of the FSANZ Act or it might endure beyond amendment of that Act. The principle of 'safety first' should apply, not benefit.

27. Frucor Suntory welcomes the exploration by FSANZ of other administrative, business and risk assessment processes that may provide opportunities for streamlining the application and FSANZ assessment process. Reducing the need or extent of consultation depending on complexity and risk should be key factors driving progress in this area.

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Exclusive permissions

28. The Consultation Paper focuses heavily on the public interest in the information included in applications but this needs to be balanced against the commercial imperative to protect commercial investment in research and development.

Does there remain a requirement to provide exclusive permission as a condition of use in the Code?

29. Yes, Frucor Suntory considers the facility should be available irrespective of level of use.

What costs and direct and indirect benefits to the community, Government and industry arise from the grant and use of exclusive permissions? Please provide data if possible.

30. There would be industry costs associated with preparing the justification for the granting of an exclusive permission in any application seeking such a permission. The most significant industry benefit would relate to the capturable benefit that exclusivity delivers as an offset for the research and development required for the novel element.

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?

31. Frucor Suntory believes that by supporting the provision of exclusive permissions in Australian and New Zealand food laws, rather than making Australian and New Zealand food regulators bear the onus and cost of protecting industry's intellectual property, they are supporting innovation in the food supply and the research and development that is and might be in the future conducted in the two countries.

32. There are well-reported statements from both Governments concerning support for innovation and related export growth and it is these aspects that exclusive permissions are delivering on.

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

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products?

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)?

33. Often, measures operate in tandem or as alternates in specific circumstances. It is not a case of the adequacy of other existing measures but a question of what more can be done specifically through food law to foster research and development investment by the food industry.

34. Unlike in industries such as the pharmaceutical industry, where patents can be granted for specific chemical entities, it is difficult (or impossible) to patent a food or even a substance found in food. This is also difficult when trying to patent manufacturing processes for foods. Therefore, a regulatory solution for granting protections for food companies remains the best opportunity. This is reflected by the EU's incorporation of this protection into its new regulation (as referenced in the Consultation Paper).

Is the current 15-month period applied to exclusive permissions sufficient?

35. No, the current fifteen months exclusion period is insufficient. It does not provide sufficient time for the applicant to gain a tangible benefit from this provision due to the time it takes to commercialise product post regulatory approval. This is most likely the reason that the current provisions are underutilised.

36. We note that the EU recognises the need to protect innovation and has a 5 year data protection mechanism for its novel food regime (see section 30 of Regulation (EU) 2015/2283 on novel foods, amending Regulation (EU) No 1169/2011). The rationale for the EU protection is to "*stimulate research and development within the agri-food industry, and thus innovation*".

37. We support the recommendation for the period of exclusivity is extended to be no less than 3 years. However, data protection aspects would benefit from re-evaluation and this may lead to a higher period of exclusivity.

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? 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?

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~~38.~~ The innovation activity undertaken by Frucor Suntory group occurs in both New Zealand and Australia. If the period for exclusive permissions is increased this may allow products to move more quickly into the respective markets. Some of our new product innovations may be seeded in either New Zealand or Australia firstly and then rolled out in the other market shortly after, allowing for fine-tuning and tailoring to consumer tastes and preferences if required. Some products are introduced into one Australian state first and depending on their success, then rolled out nationally.

Transition arrangements for currently marketed foods

39. Grandfathering is the only pragmatic approach for transition under this kind of regime. The Consultation Paper refers to the cut-off being applied to products "on the market" and "foods supplied" at the date of gazettal. We understand this includes foods/ingredients that are available for sale in New Zealand or Australia on the date of gazettal.

40. Frucor Suntory does not support the creation of a positive list of products being grandfathered.

Microorganisms

41. Frucor Suntory supports maintaining the status quo for 'food culture microorganisms' which means that these do not require pre-market approval. Frucor Suntory supports the status quo of permissions for derivatives of microorganisms in the relevant standards (e.g. processing aids), requiring pre-market assessment for both the derivative and type source strain, as aligned with the EU Qualified Presumption of Safety (QPS).

42. Frucor Suntory recommends that microorganisms used for other purposes should not be subject to pre-market assessment. We do not support the proposal to expand the scope of P1024 to cover the regulatory and safety requirements for microorganisms added for a purpose *other than* as a "food culture microorganism".

43. Frucor Suntory does not support a framework that changes status quo in recognition of inherent safety of microorganisms used across a number of foods and is concerned about risk of trade barriers from such an approach.

44. Frucor Suntory does not support the proposal for eligible food criterion for microorganisms as proposed. Frucor Suntory supports the principle that microorganisms are cultured using processes that maintain their stability. However clarification is needed before this could be included as a criterion, and clarity is needed from FSANZ as to what is meant by *'microorganisms are eligible if they are listed in the Code and are cultured to maintain genetic stability'.*

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45. Frucor Suntory does not believe there is any industry support for the development of a 'positive' list defined in regulation for microorganisms, whether for food culture microorganisms or for microorganisms added for a purpose *other than* as a "food culture microorganism".

46. If such a proposal was to proceed, however, Frucor Suntory would strongly recommend this be undertaken in a proposal specific to this topic. We believe that there would be a substantial amount of work and resources necessary for such a proposal and unless separated would likely lead to a longer development and implementation period for the outcomes of P1024.

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).

47. Frucor Suntory supports the 'grandfathering' of all foods at time of gazettal of a new framework in the Food Standards Code but to ensure a smooth transition this must include foods produced in New Zealand and Australia for export as well as foods available for sale in Australia and New Zealand.

Do you consider there are categories of foods that should not be grandfathered? If so, please provide justification for your view.

48. No, Frucor Suntory does not consider that there are any categories of foods that should not be grandfathered.

Would the proposed approach for microorganisms present problems for your business? If so, please elaborate

49. Frucor Suntory reiterates the potential for trade implications and the need to take into account the significant volumes of foods manufactured in Australia and New Zealand for export.

Part 2.9 standards – scope and timing

50. Frucor Suntory continues to strongly support expansion of the scope of P1024 to include all standards in the Code EXCEPT those currently not subject to Standard 1.5.2 such as Standard 2.9.5.

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51. Frucor Suntory supports the scope extension to include Standard 2.9.1. Conditions specific to infants can be addressed from within a coherent overall framework for novel foods. A carve out for population groups risks issues related to consistency, timing and approach.

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