28 July 2017

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Dear Sir/Madam

Attached are the comments that the New Zealand Food & Grocery Council wishes to present on the ***Consultation Paper – Proposal P1024 Revision of the Regulation of Nutritive Substances & Novel Foods***.

Yours sincerely

[redacted]

Katherine Rich
Chief Executive

Consultation Paper – Proposal P1024
Revision of the Regulation of Nutritive Substances & Novel Foods

Submission by the New Zealand Food & Grocery Council

28 July 2017

NEW ZEALAND FOOD & GROCERY COUNCIL

1. The New Zealand Food & Grocery Council ("NZFGC") welcomes the opportunity to comment on the ***Consultation Paper – Proposal P1024 Revision of the Regulation of Nutritive Substances & Novel Foods*** (the Consultation Paper).

2. NZFGC represents the major manufacturers and suppliers of food, beverage and grocery products in New Zealand. This sector generates over $34 billion in the New Zealand domestic retail food, beverage and grocery products market, and over $31 billion in export revenue from exports to 195 countries – some 72% of total merchandise exports. Food and beverage manufacturing is the largest manufacturing sector in New Zealand, representing 44% of total manufacturing income. Our members directly or indirectly employ more than 400,000 people – one in five of the workforce.

OVERARCHING COMMENTS

3. NZFGC appreciates the opportunity to provide further input on issues of significance to Proposal P1024 on nutritive substances and novel foods.

4. We recommend a further consultation that particularly considers eligible food criteria and the proposed framework before work on drafting a proposed regulatory measure proceeds. We are firmly of the view that elements set aside in the current Consultation Paper warrant a further discussion paper and comment on aspects of these which might be expanded on in a subsequent discussion paper.

5. NZFGC and other stakeholders would then have the opportunity to consider the package as a whole with each of the elements fully described, to ensure that the individual elements still contribute to a coherent overall regime. This may involve revisiting elements that were thought to be 'locked down' to refine them once more if necessary.

6. 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.

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.

8. Finally, we would particularly note the concerns around microorganisms raised by the Infant Nutrition Council and which also apply to many industries, particularly the dairy industry but also wine, baking etc. This includes the proposal to restrict grandfathering microorganisms to food culture microorganisms only, and not microorganisms used for other purposes and the prospect of a positive list in regulation (deemed unworkable, not feasible and more restrictive than any other regulatory regime worldwide in relation to such substances).

DETAILED COMMENTS

Pre-market assessment by industry

9. NZFGC is very disappointed that pre-market assessment and notification by industry (self-assessment) 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. In our view, 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.

10. 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

11. 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).

12. 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.

13. 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

14. 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.

Framework

15. NZFGC 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.

16. NZFGC therefore does <u>not</u> support the modified approach.

17. NZFGC 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

18. NZFGC notes 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.

19. These issues are fundamental to the proposed framework to the extent that they warrant a further consultation paper from FSANZ before a draft regulatory measure is developed as part of a further call for submissions. They are fundamental and integral to the regime's overall integrity and the package needs to be further considered as a whole. In relation to each set aside element we point to:
    - *eligible food criteria* – full description and parameters that address previous concerns around appropriate targeting of food safety risk, fractionation and concentration processes not being inherently unsafe, whether the finished product will significantly alter total dietary intake of nutrients, the need to account for different addition rates of ingredients (with comparison in the final product) instead of forcing a focus solely on comparison between ingredients etc.
    - *data requirements for eligible foods* – a tiered approach commensurate with risk and the three-pathway framework
    - *responsibilities for holding dossiers* for assessment against the eligible food criteria – a renaming of 'dossiers' for pathways other than FSANZ pre-market assessment (such as 'data files') to draw distinctions between the three levels of data and evidence commensurate with risk of food
    - *consideration of overseas approvals* in the context of a new framework particularly the extent of regulatory oversight for such approvals which might meet any of the three pathways including the eligible food criteria pathway.

Proposed Approach

Concept of a novel food in the new framework

20. NZFGC 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.

21. NZFGC 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.

22. 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.

Existing permissions for novel foods

23. NZFGC 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?

24. NZFGC 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?

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

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

Consideration of nutritive and related substances

27. NZFGC 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".

28. NZFGC 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.

29. No, NZFGC 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

30. NZFGC 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.

31. 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. We would be pleased to consider further consultation on:
    - the factors that should be considered when assessing the "complexity" or risk of a food in order to develop a tiered application process
    - the form and description of simplified data collection options, including leveraging of data from similar population groups e.g. between EU and ANZ.
    - general safety requirements with additional requirements considered on a case by case basis for example, not mandating clinical trials across the board to demonstrate safety when a substantial body of evidence already exists as to safety.

32. NZFGC 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.

Exclusive permissions

33. 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?

34. Yes, NZFGC 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.

35. NZFGC does not hold data relating to costs or benefits associated with the grant and use of exclusive permissions. However, there would be industry costs associated with preparing the justification for the granting of an exclusive permission in any application seeking such a permission. NZFGC members may be able to provide data relevant to this question.

36. NZFGC does not hold data relating to benefits associated with the grant and use of exclusive permissions. However, 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?

37. NZFGC 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.

38. 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 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)?

39. 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.

40. 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?

41. 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.

42. 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*".

43. We recommend 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.

44. Setting exclusivity at no less than 3 years takes account of regulatory assessment. By way of example, in the US, the review of novel ingredients by the Food and Drug Administration

(FDA) is estimated to take between 6 and 9 months under the new regulation established in 2016. By comparison, in the EU since implementation of the novel food regulation (EC No 258/97), the average time from submission to authorisation has averaged approximately 36 months. As this range of times suggests, the regulatory timeline depends on extent of coverage and has a significant impact on when new products are placed on markets in different countries/regions.

45. Since the data requirements for reviewing novel foods by different regions/regulatory agencies are similar (or the same), often applications are submitted to multiple regulatory agencies within a relatively short period. Moving forward, not only is timing an issue but consideration of how each country treats proprietary data will be required. It may be that the implementation of data protections in the EU (beginning in January 2018) could stimulate more applications being submitted there, in advance of applications in other countries.

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?

46. There is variation across the industry and NZFGC members are better placed to respond on these questions.

Transition arrangements for currently marketed foods

47. 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.

48. NZFGC does not support the creation of a positive list of products being grandfathered.

Microorganisms

49. NZFGC supports maintaining the status quo for 'food culture microorganisms' which means that these do not require pre-market approval. NZFGC 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).

50. NZFGC 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".

51. NZFGC 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.

52. NZFGC does not support the proposal for eligible food criterion for microorganisms as proposed. NZFGC 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'.* Several other questions are raised by the proposals in this area:

a) What exactly qualifies as a “food culture microorganism”? e.g. Lactic acid bacteria is used in winemaking, so if it is not for the purpose of “culture” in infant formula where does it sit in other products? What about enzymes for flavour development, mould cultures for blue & washed rind cheeses etc.
b) Does this mean that it is the food and not the microorganisms used to produce that food that are grandfathered? What then happens when a grandfathered food uses a new or different microorganism?
c) Would the microorganisms used in a grandfathered food still need to be on a positive list if that was to proceed? We struggle to envisage making such a list and the potential trade issues that would emerge when something inevitably is not included. And noting that even when using commercial yeast and other cultures, there is always interaction with endemic cultures in the environment.
d) Do the microorganisms used in a grandfathered food need to be commercially cultured? Using environmental microorganisms for common foods has millennia of history. Will they prevent wild ferments for wine, raw milk cheese etc? There is no practical way of identifying all the microorganisms when making such products – their effects are already managed in other ways.

53. NZFGC 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”.

54. If such a proposal was to proceed, however, NZFGC 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).

55. NZFGC 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.

56. No, NZFGC 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

57. See above. NZFGC foresees significant difficulties with the approach proposed for microorganisms. We reiterate 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

58. NZFGC 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.

59. NZFGC 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.