Ministry for Primary Industries
Manatū Ahu Matua

28 July 2017

Project Officer Proposal P1024
Food Standards Australia New Zealand
PO Box 10559
The Terrace
WELLINGTON 6036

Dear Sir/Madam

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

Thank you for the opportunity to comment on this proposal. The Ministry for Primary Industries (MPI) has the following comments to make.

General comments

MPI supports the need for a review of the regulation of nutritive substances and novel foods and ingredients and acknowledges that this is a complex issue. MPI supports consideration of a streamlined application process, with the removal of the self-assessment notification pathway from the proposed framework in response to feedback received and due to legal limits on a centralised oversight role by FSANZ.

Some aspects of the framework, including grandfathering of existing foods and microorganisms and the list of nutritive substances that are to be excluded from the framework, will depend on the result of further consideration of the eligible food criteria. As the specific details of the eligible food criteria are not within the scope of this consultation, we may change our view or provide further comment on how certain substances are regulated, in due course. For example, if we find that the eligible food criteria does not adequately deal with the regulation of certain nutritive substances, this may require changes to the list of foods/classes of foods requiring a pre-market assessment.

If the proposed framework goes ahead it must be clear where the responsibility lies for the 'eligible criteria' to be met. Everyone through the supplier chain is liable for non-compliance. The supporting document seems to say that the manufacturer is expected to hold the necessary data that the food meets the eligible food criteria. However an ingredient supplier should also have the necessary data for the food as they also have an obligation to sell safe and suitable food.

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2.2.2 Existing permissions for novel foods

Questions for submitters:

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

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? Please elaborate.

MPI supports FSANZ' approach that novel foods listed in Schedule 25 with specified conditions of use need to be retained in relevant standards within the Code to maintain clarity and certainty. The conditions of use in Schedule 25 are there as risk management options identified through FSANZ' assessment of each respective novel food's application. These conditions should only be removed following another assessment.

2.2.3 Consideration of nutritive and related substances

Question for submitters:

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.

MPI supports the consideration of "*nutritive type substances that should be subject to premarket approval by FSANZ*". In addition to vitamins, minerals electrolytes and L-amino acids, we suggest the inclusion of nucleotides, and specific substances such as taurine, L-carnitine, choline, inositols. We note that these and others are listed by the EU under *'COMMISSION REGULATION (EC) No 953/2009 of 13 October 2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses'* http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32009R0953. This would best be considered at the time the eligible food criteria are discussed further.

MPI believes that further consideration should be given to current provisions for use of electrolytes in the Code in order to provide clarity. In particular, electrolytes are not specifically defined, neither are there conditions for the use of 'electrolyte' as a nutrition content claim. Standard 1.2.7 S4—3 does not specifically list conditions to be met for 'electrolytes' to be able to make a nutrition content claim.

Consideration should be given to the impact of removing the express permission to be 'used as a nutritive substance' and the ability to make a nutrition content claim.

Currently a substance that is used as a nutritive substance and a novel food needs to meet section 1.1.1—5 Identity and purity. Consideration should be given to identity and purity requirements that should still be required if 'used as a nutritive substance' is removed from the Code. This may be covered under the eligibility criteria.

3.1 Review of exclusive permissions

Questions for submitters:

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

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

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.

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?

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)?

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.

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.

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.

MPI supports retaining the provision to grant exclusive permissions in the Code for foods approved by FSANZ, if industry continues to support the need for this. As we have stated in our earlier comments, this provides a competitive advantage, for an innovative business seeking approval and enables it to recoup some of the costs associated with providing dossiers for a FSANZ safety assessment. Having an exclusive permission could encourage businesses to keep innovating if they have certainty that other companies would not be able to use their information and data when their dossier is published. However, there are some limitations in the current maximum 15-months period due to this being a relatively short period.

We support further discussion and comparison of this provision with other legal measures such as intellectual property, and patents protections.

3.2 *Transition arrangements for currently marketed foods*

Questions for submitters:

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).

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

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

MPI does not support the grandfathering proposal, and supports instead a sufficient transition period for all foods marketed to comply with the new requirements. The transition period should be long enough to allow foods that are novel, or contain novel or nutritive substances, to eventually comply with the new requirements. This means they would need to comply with the eligible food criteria, undergo a pre-market assessment, or be removed from sale. This ensures that foods for sale are safe and protect public health and safety.

FSANZ has indicated that cut-off dates appear to have been effective in the EU and the USA. However, there is no further comment or analysis of this statement by FSANZ. MPI agrees that a cut-off date would provide legal certainty for existing foods that are not covered by the eligible food criteria. However, there are concerns there is little information about the range of foods which may claim to be on sale and whether these are in fact suitable for sale under a blanket grandfathering provision. Furthermore, grandfathering could also raise a potential enforcement issue in certain cases in determining whether or not a product could be considered to be "on the market" prior to the cut-off date. MPI suggests the foods and categories of foods that may be considered for grandfathering cannot be fully assessed until the eligible food criteria is able to be considered further. Therefore, we do not believe these foods should be grandfathered automatically as some may not have had any pre-market assessment. We have suggested that a market scan by jurisdictions or FSANZ and an assessment of such foods by FSANZ should be considered as part of Proposal P1024. Any new foods that are assessed as being safe could then be added to the permitted list.

Consideration should also be given to the record of views of the ACNF. Some re-assessments will be required as ACNF records do not always reveal all of the details (for example, the amount of a substance that would be added to the diet), and do not cover nutritive substances.

A suitable transition period may provide a means to allow foods to comply with the new framework.

Microorganisms

MPI prefers to continue to consider options for eligibility criteria for microorganisms that are added to food. Microorganisms are used as food culture organisms but we need to also consider other purposes, including use as probiotics, and lactic acid producing bacteria or other bacteria added as competitive inhibitors or competitive exclusions for pathogens. We need to be clear that probiotics or other microorganisms are not only lactic acid producing bacteria, as a wide range of bacteria are added to foods. For example, Bifidobacterium, Streptococcus,

Propionibacterium, Bacillus, Saccharomyces, Penicillium etc. It is also important that the proposed framework can be applied to viruses where they have an ongoing technological function and therefore would not be considered to be a processing aid.

In our previous comments MPI supported an approach that is consistent with that used by EFSA for *Establishing Microbiological Safety of Eligible Foods*. We agreed that it is important to specify that microorganisms must be cultured to maintain genetic stability in order to be considered eligible foods. This will assist in ensuring that a microorganism listed as an eligible food maintains the characteristics that were assessed by EFSA in arriving at a qualified presumption of safety. This approach would need to define what is meant by "genetic stability" and a have clear process to update the list.

In the proposed approach it is not clear what "*all foods*" means when food normally includes ingredients, food additives, vitamins and minerals etc

We suggest that recombinant microorganisms used to produce food using gene technology should be excluded from the framework.

Yours sincerely

[redacted]

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