28July 2017

DAIRY COMPANIES ASSOCIATION OF NEW ZEALAND

SUBMISSION ON

PROPOSAL P1024 – REVISION OF THE REGULATION OF NUTRITIVE SUBSTANCES & NOVEL FOODS

1. Summary:

1.1. We appreciate that FSANZ has consulted on further aspects of the proposed framework for nutritive substances and novel foods.

1.2. Unfortunately, many important elements are not addressed in the discussion document and because of this DCANZ does not support the revised framework proposed in this discussion document. Of specific concern to us is:

- The omission of important issues, such as eligible food criteria, data requirements for eligible foods and consideration of overseas approvals, from this paper
- The proposal does not address the fundamental issues which impede significant use of the Nutritive Substances and Novel Foods approval process by industry.
- The proposal does not encourage or further enable industry innovation.

1.3. The current proposal should include recommendations with respect to a review of the FSANZ Act to enable a risk based framework, including an industry self-assessment notification pathway, to be considered in future reviews of this Standard.

1.4. We are concerned at the clarity of intent expressed in the significant discussion of microorganisms in this consultation paper and that this area of consideration was not indicated in the scope of the original proposal.

2. Introduction

Dairy Companies Association of New Zealand

2.1. The Dairy Companies Association of New Zealand (DCANZ) represents the common policy interests of New Zealand processors and exporters. Our 11 members account for 98% of the milk processed in New Zealand and export to over 100 different markets.

2.2. DCANZ works in the best interests of the New Zealand dairy industry as a whole, through engagement on matters of public policy both within New Zealand and internationally. The priority policy focus areas for DCANZ are: trade policy, food safety, biosecurity and reputation (including animal welfare and environmental sustainability). There is a high degree of interconnectivity and interdependency between all four of these areas.

2.3. The contact for any further discussion of this submission is:

Dianne Schumacher
[redacted]

3. General Comments

Issues for Subsequent Consultation

3.1. Section 1.3 of the discussion document acknowledges that not all issues of relevance to this proposal are addressed in this paper. The discussion and resolution of these and other issues is integral to the proposal. We submit that this proposal should not proceed to the next regulatory stage until these issues are consulted on and addressed. The omitted and/or inadequately discussed issues which we wish to specifically comment on include:

- Eligible Food Criteria
- Data Requirements for Eligible Foods
- Consideration of overseas approvals
- Lack of clarity in approach proposed to micro-organisms

3.2. This discussion paper does not address many of the issues which FSANZ had raised previously in the earlier proposal. It appears that concerns regarding enforcement, rather than the opportunities to enable innovation, have been the principle consideration in the review of submissions. Whilst those aspects of the proposal covered in this paper resolve many of the enforcement concerns, the possibility to enable and facilitate innovation appears to have been lost.

Removal of Self-Assessment Notification Pathway

3.3. We are concerned that this consultation paper does not include a streamlined pathway (e.g. a self-assessment notification pathway) expanding on the framework which FSANZ proposed in the earlier consultation paper. The non-inclusion of such a pathway has a major impact on FSANZ's ability to introduce a risk-proportionate regulatory solution which enables innovation without impacting food safety.

3.4. We are advised that the FSANZ Act does not permit the adoption of a centralised assessment pathway as discussed in the earlier discussion paper. We submit, however, that this current proposal should include recommendations with respect to a review of the FSANZ Act to enable such a proposal to be considered in future reviews of this Standard.

3.5. The major value of this consultation paper appears to be the improved clarity of definitions and processes pertinent to the proposal. It does not propose and assess alternative approaches; rather it appears to endorse the current approach with relatively minor variations and improvements. We are concerned and saddened that FSANZ has not utilised the opportunity provided by this this consultation paper to make significant and positive change which both empowered food innovation and provided international regulatory leadership in this space.

4. Specific Comments

The Eligible Food Criteria (EFC)

4.1. If the proposal is to proceed as outlined in the discussion paper it is critical that the EFC is appropriate and precise. If this is not achieved, a large number of applications will be required to progress through a FSANZ pre-market assessment which would significantly increase costs and time to market for food companies without a decrease in food safety risk.

4.2. We are not able to support the proposed regulatory framework, including the EFC, without further consultation on, and amendments to, the criteria. This was a concern expressed by industry in the earlier consultation about the clarity of the EFC and whether the EFC would appropriately target food safety risk while supporting innovation. We submit that additional targeted consultation is required on the EFC, prior to the drafting of a revised Nutritive and Novel Foods Standard

4.3. We appreciate that FSANZ recognise that the EFC requires further work and would welcome the opportunity to work with FSANZ on this.

4.4. We submit that the following issues be addressed in the further development of the EFC:

- The EFC should support a risk-proportionate approach to balancing innovation and food safety with a focus on whether there would be a significant alteration in total dietary intake of nutrients.
- Recognition of the long and safe history of use of dairy ingredients produced through a variety of processes, including fractionation and concentration of various milk components.
- The basis of assessment should be based around the ingredient contribution to the final product and include a comparison against what could also be achieved through use of other ingredients. In the case of dairy ingredients (e.g. cheese, milk protein concentrates, sweet whey) this approach is more appropriate than adopting a standard comparison of dairy ingredients with liquid milk.

Consideration of nutritive and related substances

4.5. DCANZ notes that, under the proposed framework, vitamins, minerals, electrolytes and L-amino acids will continue to require pre-market approval by FSANZ (for inclusion in the standards that currently contain these permissions). DCANZ submits that there are no other nutritive type substances (in addition to vitamins, minerals, electrolytes and L-amino acids) that should automatically be subject to pre-market approval by FSANZ. All other nutritive type substances should be assessed against the EFC to determine what approvals are required under the framework.

Approvals of other competent authorities

4.6. DCANZ supports in principle the recognition of appropriate regulatory approvals of other competent authorities and encourage FSANZ to continue investigating this. Whilst we accept that consideration of overseas approvals is likely to be included in the EFC, there needs to be mechanisms to maximise and enable the use of such approvals to streamline processes in all pathways.

Infant Formula

4.7. The principles of the approval process utilised for infant formula ingredients should be consistent with that applied to general foods, with the caveat that there is recognition of the greater vulnerability of the infant population.

4.8. As stated in 4.4 earlier in this submission, care should be taken in restricting the selection of a comparison food. In the case of infant formula we submit that this should also include but not be limited to breast milk.

4.9. The regulatory framework should also recognise the long history of safe use of a range of ingredients (particularly dairy) in infant formula.

Microorganisms

4.10. DCANZ is concerned that there is a significant lack of clarity in the approach which FSANZ propose to take with respect to microorganisms.

4.11. Currently under the general provisions of the New Zealand Food Act 2014 all food, including those containing microorganisms, must be safe. There are equivalent provisions the Australian jurisdictions' regulatory frameworks. We do not consider that there is sufficient justification to change from this current approach with respect to the use of microorganisms in Australia and New Zealand.

4.12. If however consideration of microorganisms is to be included in the revised Nutritive Substances and Novel Foods, DCANZ endorse the FSANZ proposal of 'grandfathering' permissions of microorganisms intentionally added to foods (such as dairy) currently used in New Zealand and Australia food manufacture on the basis that this:

- Includes microorganisms used in food or ingredients manufactured and/or sold in Australia and New Zealand at the time of gazettal
- Does not include a positive microorganism list referenced in the Standard
- Ensures that the manufacturer retains the responsibility of ensuring that microorganisms used in such foods are safe and suitable with a history of usage.

Transition arrangements

4.13. DCANZ support a 'grandfathering' approach with respect to transition arrangements. Such an approach is a practical solution which provides certainty to industry and prevents unnecessary burden to regulators.

4.14. The consultation document refers to the cut-off being applied to products "on the market" and "foods supplied" at the date of gazettal. For the consideration of ingredients, we assume that this this means that the product will be considered "on the market" or "supplied" if it is manufactured or available for sale in or from New Zealand or Australia at the time of Standard gazettal.

Application process

4.15. The proposal indicates that the reviewed Application Handbook will include the simplification of data requirements. Whilst we agree that this would be helpful, the requirements should be differentially tiered to reflect risk. We submit that the following points should be specifically considered in the further development of the Application Handbook:

- Recognition of the validity of data from similar populations (e.g. EU).
- Consideration of differing data requirements reflecting the varying levels of risk from different foods.
- Ensure that food safety continues to be the focus of the assessment criteria.
- The criteria should be outcome focussed, enabling different approaches dependant on risk and the availability of alternative means of establishing the safety of the food ingredient (e.g. A prescriptive approach to clinical trial requirements without recognition of other

evidence would be inappropriate). The may be a requirement for some prescription but this should be minimised where possible.

Exclusive permissions and utilisation of the regulatory framework

4.16. With reference to Section 3. The review of exclusive permissions, the exclusive permission provision of the current Standard is based on the specific policy principle: "*To provide an assessment process that aims to protect commercially sensitive information and recognise industry's intellectual property to the maximum extent possible"*

4.17. We submit that the exclusive permission provision should be retained and the time period extended to at least 3 years in order to provide a tangible benefit to innovative food and ingredient manufacturers. Whilst we accept that there is some stakeholder opposition to the provision for exclusive permissions we submit that this does not outweigh the facilitation of innovation which the exclusive permission option provides. Failure to protect commercially sensitive information significantly inhibits innovation in the Australia New Zealand food industry.

4.18. The consultation paper discusses the relatively low usage of the exclusive permissions provision. We suggest that the length of the exclusive permission period is a factor in this. Additionally, the current need to provide 'benefit' together with safety evidence, in variance to the approach taken in other countries/regions, potentially impacts on the food industry's usage of the current FSANZ Nutritive and Novel Foods approval framework. The revised framework should focus solely on assessing the safety of new foods and ingredients, as the concept of "benefit" is addressed through other regulatory frameworks, such as the health claims regime.