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DAIRY COMPANIES ASSOCIATION OF NEW ZEALAND SUBMISSION

TO FOOD STANDARDS AUSTRALIA NEW ZEALAND

ON

PROPOSAL P1024 REVISION OF THE REGULATIONOF NUTRITIVE SUBSTANCES AND NOVEL FOODS

24/3/2016

The Dairy Companies Association of New Zealand (DCANZ) appreciates the opportunity to make a submission on this matter in light of its relevance and importance to our member companies. DCANZ member companies collectively account for more than 98% of the milk processed in New Zealand and the vast majority of New Zealand's dairy exports. The role of DCANZ is to represent commonly held policy positions of our eleven member companies.

DCANZ supports the intent of the Food Standards Australia New Zealand in reviewing the regulation of nutritive substances and novel foods in Australia and New Zealand. We support in principle the risk graduated approach FSANZ propose within this Standard revision proposal.

The key challenge of regulatory control in this area is to ascertain the safety of novel foods and nutritive substances whilst ensuring the regulatory burden on the food industry is proportionate to the risk of the substance under consideration. Although the intent and direction of P1024 is encouraging, it is important that clarity is sought in a number of areas of the proposal. This revision of this standard has the potential to impact on the regulatory status of both new dairy ingredients and dairy foods

Proposal P1024 focuses on the principles of, and the framework for, the assessment of novel foods and nutritive substances with detailed discussion in specific areas. Whilst DCANZ supports the broad principles outlined in this discussion paper (particularly the risk graduated approach), we look forward to future discussions, workshops and proposals as this standard revision progresses.

Specific comments:

1) Eligible Food Criteria

Section 4.2.3.1 "One method of identifying foods that do not require regulatory approval is to establish criteria. FSANZ has developed a draft set of criteria for discussion based largely on the considerations of the NFRG and the ACNF over more than a decade. The draft set of criteria have been termed 'eligible food criteria' (EFC)."

There are areas within the EFC that require clarification. Specifically these include:

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a) The adoption of positive lists for microbial cultures (currently proposal specifically references only the European Food Safety Authority (EFSA) microorganisms with a Qualified Presumption of Safety (QPS)). Will there be additional means of ensuring microbial culture compliance?

b) The exclusion of enzymatic processing from consideration within the EFC. This has the potential to result in a novel food assessment requirement for all foods processed using a "new" enzyme or where an enzyme is used within a new process or substrate

c) Proposal P1024 suggests that "simply processed" foods will be used as a point of comparison as to whether an ingredient meets the EFC. However, as drafted, the EFC provide no clarity or certainty over which dairy ingredients will be considered "simply processed", "extracts" or "substances". The manufacture of the majority of dairy products involves a number of defined food processes (e.g. Cheese production: pasteurisation, separation, ultra-filtration, lactic fermentation, enzymatic, whey separation, specific varietal considerations-cheddaring, stretching, mould coating/injection, maturation). Would this number of processes in a "new" food be permitted within the consideration of the EFC? It is important that there is recognition of our existing range of dairy ingredients and products.

d) Concentration issues. There is a significant emphasis in Proposal P1024 on the concentration and extraction of substances in and from established foods. Lactoferrin is used as an example of a dairy extract which is considered as a novel food due to the extraction of a minor milk component which could significantly impact on human dietary intake. Whilst this is appropriate, there is concern that the proposal could require safety assessments for all ingredients/foods that utilise concentration of dairy components – for example, had this approach been in place historically, all whey protein ingredients would have required a novel food assessment.

2) Industry Self-assessment

> *4.2.3.2 Pathways for market entry of foods not meeting the EFC; Industry self-assessment…….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 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.*

The inclusion of a self-assessment pathway in Proposal P1024 is a major advance on the current approval processes and FSANZ are to be congratulated on this inclusion in the proposal There is

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however significant detail around this pathway yet to be discussed and determined. The specificity of criteria and robustness of pathway processes will be essential to ensure that food industry innovation is not negatively impacted.

3) Intellectual Property Protection

Section 4.2.3.3 Data and Dossier requirements – Publication of Dossiers

Proposal P1024 suggests that dossiers submitted either to FSANZ for assessment, or as part of the self-assessment process would be published by FSANZ. This is of concern as these dossiers will often involve significant Intellectual Property. We submit that it would be more appropriate that self-assessment dossiers are held by the food manufacturer and are available upon request from jurisdiction authorities.

Implications for Foods currently compliant with the new Zealand Food (Supplemented Food) Standard

Section 6.1.2 Potential alignment of trans-Tasman regulations for the addition of substances to foods.

> *The base regulatory approach for the addition of substances to foods differs – the Code prohibits unless permitted (pre-market approach) whereas the New Zealand [Supplemented Food] Standard is open and prohibits by reference (post market approach).*
>
> *It is possible that improved regulation of nutritive substances and novel foods in the Code may assist in more closely aligning the Code and the New Zealand Standard. The ideal outcome is for the New Zealand Standard to be repealed because it is no longer required. Whether this ideal can be achieved as a result of this Proposal remains to be seen. If achieved, this would resolve the current inconsistency in permissions for substances that can be added to supplemented foods under the New Zealand Standard and to other foods regulated under the Code.*

Section 7.1 Proposed transitional period

> *FSANZ considers a cut-off date could be specified – similar to the cut-off date approach for novel foods in the EU and USA. A cut-off date would objectively identify foods that would be subject to an alternative framework in the Code. The cut-off date could, for example, be the gazettal date of a new standard in the Code.*
>
> *There is also the option of grandfathering provisions applying to foods on the market before that cut- off date. One option may be a 6-month transition period to allow sufficient time to implement new processes to comply with new provisions.*

DCANZ supports the application of a cut-off date and grandfathering provisions, but highlights that these provisions will need to recognise and encompass supplemented foods manufactured in compliance with the New Zealand Food (Supplemented Food) Standard 2013.

4) Consistency of interpretation and enforcement within jurisdictions

Section 7.2.1 Enforcement and Compliance

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Further discussions with jurisdictions responsible for enforcement of any new provisions will be required to develop an approach to the implementation of the record-keeping and notification arrangements, should the graduated approach proceed

The adoption of the graduated approach (particularly with respect to self – assessment for lesser risk foods and substances) would provide a significant improvement on the current FSANZ assessment process. However it is important that all jurisdictions (New Zealand and Australian States and Territories) commit to consistent implementation, enforcement and compliance processes resulting in equivalent outcomes for novel food and nutritive substances across Australia and New Zealand. This is potential concern with respect to other recently revised FSANZ standards (e.g. Health Claims).

5) DCANZ looks forward to further development of Proposal P1024

The release of this discussion paper is welcomed by DCANZ. We submit that the revision of this standard is important in the context of the Australia New Zealand regulatory framework in ensuring the safety of novel foods and nutritive substances whilst adopting a pragmatic approach to the assessment of such foods and substances.

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