28 July 2017

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA

Email: submissions@foodstandards.gov.au

Danone welcomes the opportunity to make this submission in response to the FSANZ Consultation Paper – *Proposal P1024, Revision of the Regulation of Nutritive Substances & Novel Foods*.

Our detailed comments on the consultation paper and proposals are contained in the attached submission.

We note that as a member of the Infant Nutrition Council, the Dairy Companies Association of New Zealand and the Australian Food and Grocery Council, we also provide our support for the views expressed in their respective submissions.

We thank FSANZ for its consideration of our submission. If you have any questions or require any further information on this submission, please contact [redacted]

Yours sincerely

[redacted]

Ailish Hanley
General Secretary, Danone Oceania

Danone Oceania
Talavera Corporate Centre, Building D, Level 4
12-24 Talavera Road, MACQUARIE PARK NSW 2113 Australia
PO Box 1007, NORTH RYDE BC NSW 1670 Australia
Tel: +61 (0)2 8870 0400 Fax: +61 (0)2 9878 4725

DANONE

SUBMISSION: ***Proposal P1024, Revision of the Regulation of Nutritive Substances & Novel Foods***

Danone supports the overall objective of the revision of the regulation in the *Australia New Zealand Food Standards Code* (the Code) to provide a more streamlined route to market of safe and innovative foods that do not compromise public health. This framework should allow greater certainty for applications whilst at the same time reducing or removing unnecessary trade barriers for such foods imported into Australia/New Zealand (ANZ).

As a member of the Infant Nutrition Council (INC), the Dairy Companies Association of New Zealand and the Australian Food and Grocery Council (AFGC), we also provide our support for the views expressed in their respective submissions.

1. Proposed modified regulatory framework

i. Danone is concerned that the proposed modified regulatory pathway does not include a potential pre-market self-assessment notification mechanism. We submit that this has been discarded prematurely and without a rigorous legal review of potential options and/or adoption of such a pathway in the regulatory framework.

ii. In our view, the establishment of a self-assessment pathway is clearly a critical element of any new framework in order to encourage industry innovation and is in line with the practice in similar industries. For example, a self-assessment notification process is permitted for therapeutic goods under the purview of the Australian Therapeutic Goods Administration (TGA). This involves low risk (and safe) ingredients and products being listed on a publically available data base (ARTG), based on a certification of science and/or claims by manufacturers/sponsors. Scientific dossiers are then held by the manufacturer/sponsor and are required to be provided when requested by the TGA. This would also align with the responsibility of FSANZ to help facilitate innovation across industry.

iii. Danone submits that in this context, the self-assessment pathway should be retained as a potential option pending a legal review. For example, such a review could determine that the pathway would be permitted through a change in the *FSANZ Act* and therefore, the option should remain under consideration until this is determined.

iv. We are also concerned about the lack of detail provided by FSANZ in relation to its new modified approach, limiting our ability to provide detailed comment at this stage. More detail needs to be provided before a decision is taken to proceed to a draft regulation stage.

v. If the self-assessment notification pathway is determined by the review to not be viable through *FSANZ Act* amendments, it is critical that the Eligible Food Criteria (EFC) be framed only after further consultation to assist with risk based criteria for future applications.

vi. Therefore, based on the above concerns, we cannot support the modified approach as currently outlined in the consultation paper.

2. Consideration and acceptance of overseas regulatory approvals

i. Danone submits that the acceptance of overseas regulatory approvals, under agreed criteria set by FSANZ, is a vital element of any new framework. This would provide an exemption for access to the ANZ market of any foods that have been assessed and accepted by other internationally recognised food regulatory agencies such as the European Food Safety Authority and the US Food and Drug Administration. In our view, no other additional requirements should be required by FSANZ.

ii. We are concerned that a failure to accept international approvals could result in novel foods or ingredients not being brought into the ANZ market, or at the very least, being significantly delayed pending FSANZ approval. There would also be significant additional costs where a manufacturer cannot receive an exemption. For example, this could require changes to recipes and formulations specifically for products in the ANZ market. In many cases, the ANZ market may not be large enough to justify the cost of these individual changes to be made to satisfy the additional approval process. Recognition of overseas approvals will therefore be a key aspect of the efficiency of the system.

iii. We also acknowledge that the acceptance of overseas approvals will significantly reduce resource and oversight requirements of the regulatory approvals framework within ANZ. This would be a significant factor in alleviating the concerns of government agencies over the establishment of an industry based self-assessment notification pathway.

iv. Danone appreciates that FSANZ has recognised that consideration of overseas approvals needs to be further explored through a subsequent consultation process.

3. Inclusion of Standard 2.9.1 in scope of review

i. Danone is concerned at the proposal of FSANZ to exclude Standard 2.9.1 from the scope of P1024. We strongly support its inclusion and as a member of INC, we endorse its position on this issue outlined in its submission.

ii. We do not support a view that Standard 2.9.1 should be excluded based on the vulnerability of the population group. In fact, we believe that its exclusion may create significant issues in terms of consistency, timing and approach for the infant population group.

4. Exclusive permissions

i. Danone submits that significant uncertainty remains as to why an exclusivity exemption under the *FSANZ Act* is necessary when other legal options are available to protect new product developments, such as applying for a patent (i.e., IP and patent law).

ii. There is a lack of evidence at present to justify FSANZ being able to prevent competitors using a novel food that FSANZ determines is safe through the issuance of an exclusive permission. For example, it has been suggested that an exclusive permission is needed to ensure that an applicant can recoup the costs of processing a novel food. However, as even the consultation paper notes, little analysis has been conducted on the cost/benefits of this

and what alternatives have been considered (for instance, a notification regime where other entities could elect to part-fund the costs, or an option in which all parties could benefit because the likely or possible benefit to competition).

iii. If an exclusive exemption mechanism is deemed to be appropriate, then we submit an exclusive period of three to five years would be sufficient. This would be in line with data protection provisions included in the current EU *Regulation on Novel Food,* which states "newly developed scientific evidence and proprietary data will not be able to be used for the benefit of another application for 5 years after the novel food has been authorised".

5. Transition arrangements (Grandfathering) – existing permissions for currently marketed foods

i. Danone supports the exemption of all existing permitted foods from the framework at the time of gazettal, including all foods produced and sold in ANZ as well as produced for export.

ii. We do not believe it is necessary for FSANZ to develop a positive list of acceptable foods and ingredients for exemption. As a member of the AFGC, we support its submission that proposes a 'clean slate' approach to novel foods.

6. Eligible Food Criteria (EFC)

i. Danone notes that several important elements are not addressed in the consultation paper and have been set aside to be dealt with in a further round of public consultation. We particularly note the importance of the issue of eligible food criteria, data requirements for eligible foods and designation of responsibilities for holding dossiers.

ii. We support further work on the eligible food criteria and reiterate that the draft proposal from March 2016 did not provide sufficient clarity for infant formula product ingredients. The development of the eligible food criteria must follow a risk-proportionate approach to balance innovation and food safety and focus on the total dietary intake of nutrients.

iii. We strongly submit that the issue of eligible food criteria is fundamental to the proposed framework and a further round of consultation is required before any new measure is drafted.

7. Microorganisms

i. Danone supports maintaining the status quo of permissions for all microorganisms used across foods when there has been a safe history of use and no evidence of market failure.

ii. We also support the manufacturer retaining responsibility for ensuring that microorganisms used in foods are safe and suitable for use and oppose establishing a positive list of microorganisms for inclusion in the Food Standards Code.