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23rd March 2016

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
Australia

By Email: submissions@foodstandards.gov.au

Dear Standards Management Officer,

Re: Submission to Consultation Paper – P1024 Revision of the Regulation of Nutritive Substances and Novel Foods

Aspen Nutritionals Australia Pty Ltd (Aspen Nutritionals) welcomes the opportunity to comment on the revision of the regulation of nutritive substances and novel foods provided by Food Standards Australia New Zealand.

Please find attached our comments to the consultation paper.

Yours faithfully,

[redacted]
Senior Scientific and Regulatory Affairs Associate
Aspen Australia
[redacted]

* Aspen Australia is comprised of Aspen Asia Pacific Pty Ltd (ABN 75 146 444 484) and its subsidiaries, including Aspen Pharmacare Australia Pty Ltd (ABN 51 096 236 985), Aspen Pharma Pty Ltd (ABN 88 004 118 594), Aspen Nutri ionals Australia Pty Limited ACN 160607509 , Orphan Holdings Pty Ltd (ABN 50 115 816 209), Orphan Australia Pty Ltd (ABN 11 067 189 342) and Aspen Products Pty Ltd (ABN 17 003 144 170).

OVERARCHING COMMENTS

Aspen Nutritionals is a market leader in infant and toddler nutrition products in Australia. Our products include infant formula, follow-on formula, specialty formula, and supplementary milk drinks for young children. These products are regulated under *Standard 2.9.1 – Infant Formula Products* and *Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods.*

Aspen Nutritionals agrees that there is a lack of clear meaning in the current definitions of novel food and nutritive substance which creates uncertainty and ambiguity. We recognise that sometimes these definitions are interpreted differently between jurisdictions as well as between businesses which pose problems in implementing and enforcing these provisions. Hence Aspen Nutritionals welcomes this review.

As a member of Infant Nutrition Council (INC), Aspen Nutritionals also supports the INC submission for the revision of the regulation of nutritive substances and novel foods. Hence, we have not provided specific comments to the questions outlined in the consultation paper. Instead, we included a summary of our overall position and our concerns for your consideration.

Scope of the Consultation Paper

Aspen Nutritionals notes that this proposal excludes products regulated under Standard 2.9.1 from consideration as the regulatory approach for the addition of new substances to infant formula will be reviewed in *P1028 – Regulation of Infant Formula.*

The rationale underpinning this decision is not clear and we believe requires further consultation and consideration by FSANZ. We note here some of the comments made in consultation papers P1024 and P1028 regarding this topic.

Consultation paper P1024 states:

> Standards 2.9.1 – Infant Formula Products and 2.9.2 – Foods for Infants are excluded from consideration in this Proposal. The Ministerial Policy Guideline on the *Regulation of Infant Formula Products*[1] provides guidance on the pre-market assessment of substances added to infant formula products that will be considered separately by FSANZ as part of Proposal P1028 – Regulation of Infant Formula. Additional proposals may follow on from Proposal P1028 to address other formulae regulated by Standard 2.9.1. Standard 2.9.5 – Food for Special Medical Purposes is also excluded from this Proposal

And consultation paper P1028 states:

> Proposal P1028 will consider the regulation of nutritive substances and novel foods in infant formula, because infant formula products (and food for infants) are

[1] http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx

> excluded from the scope of Proposal P1024. FSANZ will consider the basis for requiring pre-market assessment of new substances for use in infant formula, and subsequently the procedure and information required to determine the safety and the nutritive or health benefit of these substances.
>
> and
>
> Although the approach implemented under P1024 for general foods may be able to be considered for infant formula, FSANZ will consider infant formula separately given the vulnerability of formula-fed infants and the current regulatory environment.

We are of the view that this is not sufficient justification for infant formula products to be excluded from the P1024 review when the current regulation of novel foods and nutritive substances applies to all foods including infant formula products. There is scope within the proposed framework for nutritive substances and novel foods to include additional criteria for foods for infant formula. While the issue around vulnerability of infants is valid, Aspen Nutritionals sees no justification as to why this can't be addressed within P1024.

Aspen Nutritionals recognises that the *Ministerial Policy Guideline on the Regulation of Infant Formula Products* provides guidance on the pre-market assessment of substances added to infant formula products. We are of the view that this guidance is in line with option 3, the alternative framework proposed by FSANZ as part of this consultation paper.

We are also concerned that if P1024 is finalized and gazetted before P1028, there will be a regulatory gap until a process specifically for infant formula products is completed.

For these reasons, the opportunity to remove some of the ambiguity and 'jurisdictional uncertainty' would be best served, in our opinion, if Standard 2.9.1 - Infant Formula Products is included in P1024 going forward.

OVERALL POSITION

Aspen Nutritionals does not support option 1. As FSANZ has outlined in the consultation paper, if Status Quo is continued it may impose a risk to public health and safety due to ambiguity and uncertainty. Further, Status Quo will decrease the number of innovative products to be available for consumers as businesses will choose not to launch a product with new ingredient(s) as a result of uncertainty. Yet, we believe some aspects of the current arrangements could be helpful if adopted in a new approach. The advisory committee for Novel Foods could be modified so that it can give an opinion on the Eligible Food Criteria for further clarity if needed by a business.

As for option 2, we believe some clarity will be given but won't completely solve the issues outlined in this Consultation paper.

Hence, Aspen Nutritionals supports option 3, the alternative framework proposed by FSANZ for all products including Infant formula Products and Formulated Supplementary Foods for Young Children. We note that option 3 consists of 4 main elements. These are:

1. The Eligible Food Pathway
2. The Pre-Market Assessment by Notification Pathway
3. The Pre-Market Approval Pathway
4. Data and dossier requirements for assessment/approval

Aspen Nutritionals is of the view that the above four main elements meet guidance provided in the *Ministerial Policy Guideline on the Regulation of Infant Formula Products* as all new foods will follow an appropriate pathway and pre-market assessment either by FSANZ or industry.

Under the current process, an application to add a nutritive substance can take a number of years for it to be approved. As an example, this was the case when we submitted paid applications to add lutein to our products, the process taking approximately 3 years to gain approval. It is an extremely long and costly process for industry. Therefore we welcome the alternative framework, a proportionate approach to risk.

Further, we believe this approach is also very beneficial for infant formula products as it will allow a faster process for low risk ingredients and hence will provide more safe and innovative products available for infants.

Aspen Nutritionals supports cut-off date and grandfathering provisions. In our opinion, these provisions will remove doubts about foods and/or ingredients that are currently available for purchase.

Data and Dossier

Aspen Nutritionals supports self-assessment and pre-market approval data/dossier to be made available to the relevant regulators and enforcement agencies, and supports transparency for the general public. We would however, suggest that a summary or shortened version of this information is made public rather than the company's complete dossier - at a minimum the information that is made public would include reference to scientific evidence demonstrating the food does not pose a safety risk to human health. This would ensure confidentiality of sensitive information is protected whilst keeping the public's confidence in the safety of new foods supplied to the market. Aspen Nutritionals would recommend FSANZ draw on other countries experiences as to what level of information is published.

Aspen Nutritionals expects any permission of exclusivity is considered carefully by FSANZ. Aspen Nutritionals is concerned that if exclusive permission for a specific brand is permitted, this option will only be of benefit to large corporate companies where resources are more readily available. Smaller companies may be unnecessarily disadvantaged if 'speed to market' is the only criteria for exclusivity of new foods. All companies that have invested resources, time and funds to a new food (same or similar

to another company) should not be prevented from also applying for pre-market assessment with the accompanying data and dossiers.

Aspen Nutritionals is further concerned that if both exclusivity is permitted and data protection is granted, available information may not provide adequate clarity to other companies whether their new food is identical to the authorised food. Our view therefore is that if exclusivity is permitted, data protection should not be granted. Further, if exclusivity is permitted, generic authorisations should be granted over individual authorisations so when the exclusive period is over, it becomes a permissible ingredient for the industry. This will minimise regulatory burden on industry as well as on FSANZ.

The opportunity to remove some of the existing ambiguity and uncertainty in the existing regulations is welcomed, and trust our comments above are considered in this context.