DANONE NUTRICIA

Early Life Nutrition

RESPONSE TO FSANZ

Call for submissions – Proposal P1024

Revision of the Regulation of Nutritive Substances & Novel Foods

24th March 2016

INTRODUCTION

Nutricia is a division of the French multinational company, Danone. Nutricia is recognised as the leader in specialised nutrition and operates in a unique position in the global market as the only company whose entire business is based on nutritional products.

Nutricia is the manufacturer of Infant Formula Products and Toddler Supplements. This response is being submitted to the FSANZ Call for Submissions for Proposal P1024.

It is noted that the scope of this excludes Standard 2.9.1 Infant Formula Products. Nutricia is a member of the Infant Nutrition Council and fully supports the INC position that Standard 2.9.1 should be within the scope of Proposal P1024.

GENERAL COMMENT

Nutricia supports the adoption of Option 3 Develop an Alternative Framework (section 4.2.3) for general foods. The reasons for this are detailed in our responses below.

SPECIFIC RESPONSES TO QUESTIONS

Question: *How do the current novel food and nutritive substance definitions affect your organisation, either as a food business or a food enforcement agency?*

It has been noted that the need for this review has come about due to the decision by the Supreme Court of New South Wales in 2009, that the definition of '***nutritive substance'*** was ambiguous.

This ambiguity had resulted in Nutricia being in conflict with the NSW Food Authority and NSW Ministry for Primary Industries. The resulting cost to the business was substantial.

This incident also resulted in considerable concern to parents and carers of infants.

It is essential that this ambiguity be removed from the Food Standards Code (FSC).

Question: *Do you believe there are problems with the current definitions in addition to those outlined in the assessment summary? If so, describe the problems.*

Nutricia is concerned that this is the first instance where work is being undertaken to remove this ambiguity. Also, we continue to be concerned that Infant Formula Products are excluded from the very review that is intended to resolve the issues denoted by the Supreme Court of NSW.

Question: *Do you believe there are problems with the current provisions more broadly (not just the definitions) in addition to those outlined in the assessment summary? If so, describe the problems.*

There is a level of overlap, of definitions, that make sections of the FSC unworkable. Nutricia supports the position of defining '***new food substances***' that could then be assessed for safety and benefit, as appropriate.

Question: *Are there elements of the status quo that you support maintaining in the Code? If so, please provide details and reasons for your support.*

No. Nutricia supports a comprehensive review of the current provisions, with the adoption of Option 3.

Question: *Can you identify any problems with the status quo in addition to those highlighted in this report? If so, please provide details.*

The current provisions cause uncertainty and resulting issues of enforcement.

Global companies find this lack of clarity causes costs of duplication leading to costs of time and money. This has the potential to lead to WTO issues.

Question: *Do you support amending the definitions of 'novel food' and 'used as a nutritive substance' in the Code? If so, FSANZ welcomes reasoned suggestions for amended definitions that will address the problems identified in sections 1 and 2.*

No comment at this time.

Question: Are the EFC appropriate for identifying foods that do not need regulatory approval?

Yes, Nutricia supports the provision of Eligible Food Criteria for the Eligible Food Criteria Pathway.

Question: *Are there foods that may meet the EFC that you consider should be subject to pre-market assessment? If so, please describe the properties of these foods.*

Nutricia has no comment at this time.

Question: *Are there foods that would not meet the EFC, but you consider should be eligible? If so, please describe the properties of these foods.*

Nutricia has no comment at this time.

Question: *What type of information should be held by food businesses to support the safety of eligible foods? Please describe the type of information and why this information would support safety.*

Safety assessment dossiers would vary according to the history of usage of the food and would need to provide sufficient data to guarantee safety. It would be envisage that there would need to be a range of requirements that would vary according to the scale of any potential risk.

Details of who would hold the data and the level of access would need to take into account issues such as IP of the information.

Question: *Are the exclusions to the EFC appropriate in identifying foods that should be subject to pre-market assessment, despite otherwise meeting the EFC?*

The FSANZ discussion papers refer top foods with pharmacological properties however this is not properly defined.

Nutricia is concerned that FSANZ must not re-introduce new terms that will result in further ambiguity, as part of this review that is intended to remove ambiguity and the associated costs.

Question: *What do you consider would constitute a 'reasonable potential' for a food to have pharmacological effects at the intended levels of consumption? See SD3 for discussion on this issue.*

Nutricia has no comment at this time.

Question: *Do you regard the investigation of an alternative approach to regulating nutritive substances and novel foods in the Code as a viable option?*

Yes.

INC considers "gateway tests to determine an appropriate assessment pathway" should be developed further in light of the industry's experience, especially in relation to the preparation of applications.

Question: *In particular, taking account of FSANZ's primary objective of protecting public health and safety, is the draft framework presented in option 3 a viable option? What aspects of the draft framework do you think are viable or not viable? Please provide supporting statements for your view.*

Nutricia is of the view that Option 3 would meet the FSANZ objectives, and in particular the objective to provide for public health and safety.

Question: *Do you have suggestions for the type of foods that would not meet the EFC, but may be suitable for industry self-assessment?*

Nutricia would support a provision for foods that have been assessed and accepted by other, nominated, authorities, such as EFSA or the US FDA.

Question: *Please provide details of how a self-assessment pathway may or may not provide benefits to industry.*

Nutricia has no comment at this time.

Question: *Would notification and publication of dossiers provide enough regulatory oversight and consumer confidence in relation to the safety of new foods? Please support your answer with detail of why you believe this is the case.*

Nutricia supports the provision of dossiers and data for relevant regulators, only.

Question: *Can you identify any negative impacts that may result from combining the regulation of novel foods and nutritive substances (other than vitamins and minerals) that may occur under a graduated risk approach? Please explain these impacts.*

Nutricia has no comment at this time.

Question: *Do you support retaining the provision to grant exclusive permission in the Code for foods approved by FSANZ? Please provide reasons for your view.*

Yes, Nutricia does support this.

Question: *Can you identify any issues that may arise if exclusive permissions are available for FSANZ approved foods, but not available for industry self-assessed foods? Would the self-assessment process for non-eligible foods provide a trade-off against the lack of an exclusive permission for self-assessed foods (section 4.2.3)?*

Nutricia considers that if dossiers and data sets for the Pre-Market Assessment by Notification Pathway are not public that notification will deliver a level of exclusivity The exclusivity of the Pre-Market Approval Pathway remains attractive for substances not meeting the gateway test for industry self-assessment. The practicality of how the system will function, should be an important consideration for the next round of consultation.

Question: *Do you support a cut-off date? Please provide reasons for your view.*

Nutricia has no comment at this time.

Question: *Do you see a need for grandfathering provisions? Please provide reasons for your view.*

Yes, grandfathering provides confidence that substances currently added to foods - particularly those currently defined as 'nutritive substances' – will continue to be permitted.

Question: *Do you see a need for a stock in trade provision? Please provide reasons for your view.*

Yes, there may well be a need for an extended period.

Question: *Do you have any concerns regarding the proposed 6 month transition period? Please explain your concerns, noting the length of time the development of any future standard is likely to take and will therefore be clearly signposted before changes are made to the Code.*

Yes, there may well be a need for an extended period.

Question: *Do you have any comments regarding the proposal not to allow a stock-in-trade provision during the transition period?*

Nutricia has no comment at this time – however there may need to be consideration of extended provisions, to be determined further into the review.

Question: *Do you have any suggestions as to which peak bodies should be involved in familiarising industry of the new provisions?*

Nutricia has no comment at this time.

Question: *Do you have any suggestions on how the implementation process could be approached, especially with respect to enhancing awareness and understanding of the potential new provisions under Option 3?*

Nutricia has no comment at this time.

Question: *Are there any particular comments you feel are appropriate to ensuring satisfactory post-market surveillance?*

Nutricia has no comment at this time.

Question: *The exclusions make reference to 'reasonable potential' and 'reasonably expected'. FSANZ's intent is to capture foods that are pharmacologically active or have biological activity beyond basic nutrition at the levels they are intended to be used. Can you make suggestions in relation to how such foods might be captured to ensure they are subject to pre-market assessment?*

Nutricia has no comment at this time.

Question: *What costs have you experienced in making novel food or nutritive substance applications (for permission in the Code) or enquiries to the ACNF under the current system? If possible, include information on size and types of costs (e.g. commissioning research, staff time spent preparing an application). If possible, indicate the costs which relate only to the Australian/New Zealand market. If this is not possible please clearly indicate these are the global costs of obtaining these data and which other regulatory authority they have been prepared for.*

Nutricia has no comment at this time.

Question: *What other costs have you experienced as a result of the current novel food and nutritive substance provisions (i.e. costs not related to applications and enquiries)? For example, costs of obtaining legal advice on whether a substance is a novel food or a nutritive substance.*

Nutricia has no comment at this time.

Question: *How (if at all) do the current provisions influence your business's decisions regarding developing and launching new products?*

Nutricia has no comment at this time.

Question: *What (if any) kinds of opportunity costs have you experienced due to the time taken to assess applications? For example, missing a 'window' during which a retailer will accept new products within a particular category.*

The extended time frame does not allow for efficient return on investment.

end