Infant Nutrition Council

Industry supporting both Breastfeeding & Infant Formula

AUSTRALIA & NEW ZEALAND

24 March 2016

Food Standards Australia New Zealand
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Dear Sir/Madam

The Infant Nutrition Council (INC) appreciates the opportunity to make a submission on ***Call for Submissions – Proposal P1024 Revision of the Regulation of Nutritive Substances and Novel Foods***.

INC is the association for the infant formula industry in Australia and New Zealand and represents manufacturers, marketers and brand owners who between them are responsible for more than 95% of the volume of infant formula manufactured, sold and exported in Australia and New Zealand.

INC aims to:

1. Improve infant nutrition by supporting the public health goals for the protection and promotion of breastfeeding and, when needed, infant formula as the only suitable alternative; and
2. Represent the infant formula industry in Australia and New Zealand.

The INC is a responsible body that voluntarily restricts its marketing practices to support government policies for the protection and promotion of breastfeeding. The companies represented by INC are:

Members:

- Aspen Nutritionals Australia Pty Ltd
- Fonterra Co-operative Group Ltd
- H. J. Heinz Company Australia Ltd & H. J. Heinz Company NZ Ltd
- Nestlé Australia Ltd & Nestlé New Zealand Ltd
- Danone Nutricia Pty Ltd
- The a2 Milk Company Pty Ltd
- Synlait Milk Ltd

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Associate Members:

- Abbott Nutrition Pty Ltd
- Australian Dairy Park Pty Ltd
- Bayer Ltd
- Bodco Dairy Ltd
- Burra Foods Pty Ltd
- Cambricare New Zealand Ltd
- Cargill Australia Pty Ltd
- Dairy Goat Co-operative Ltd
- DSM Ltd
- Fresco Nutrition Ltd
- GMP Dairy Ltd
- GrainCorp Ltd
- Jamestrong Packaging Pty Ltd
- Murray Goulburn Co-operative Co Ltd
- Peerless Foods Pty Ltd
- Nature One Dairy Pty Ltd
- New Image Group Pty Ltd
- New Zealand New Milk Ltd
- Nuchev Food Pty Ltd
- Snow Brand Australia Pty Ltd
- Tatura Milk Industries Pty Ltd
- The Infant Food Co. Ltd
- Westland Co-operative Dairy Company Ltd
- Yashili Dairy New Zealand Pty Ltd

The INC believes that breastfeeding is the normal way to feed infants as it has numerous benefits for both mothers and babies. When an infant is not given breast milk the only suitable and safe alternative is a scientifically developed infant formula product. For these infants, infant formula is the sole source of nutrition for around the first 6 months. It is important that scientific advances in infant nutrition are captured and incorporated into these products to ensure the best possible outcome for infants that are unable to have the benefit of breast milk.

Yours sincerely

Jan Carey
Chief Executive

Introduction

The Call for submissions – Proposal P1024 excludes three standards from its scope: Standards 2.9.1, 2.9.2 and 2.9.5. The comments in this submission consider the issues raised and the options presented for three key reasons:

- the current regulation of novel foods in relation to Standard 2.9.1 Infant formula products, is no different to the regulation of novel foods in the general food supply. The novel foods system applies to all foods including those covered by Standard 2.9.1;
- the term 'nutritive substances', outside the structure and definitions of the Food Standards Code, is used in 6 standards in the Food Standards Code. All but one standard (Standard 1.3.2 Vitamins and Minerals) are in Part 2.9 including Standard 2.9.1. Consideration of the future regulation of nutritive substances cannot effectively be conducted if most of the Standards that apply the term are excluded from the scope of Proposal P1024; and
- Proposal P1028 (in Supporting Document 2, Section 6) states that the reason for Proposal P1028 to be considering the regulation of nutritive substances and novel foods in infant formula is "*because infant formula products (and foods for infants) are excluded from the scope of Proposal P1024*". INC suggests this is not justification for consideration by Proposal P1028. Further, P1028 only covers infant formula and Standard 2.9.1 also covers follow-on formula products and infant formula products for special dietary use.

INC sets out in this submission its views on the options described in Proposal P1024 with particular reference to infant formula products. At the outset, INC expresses support for the framework proposed as Option 3 for general foods but also supports this framework being applied to infant formula products, with consideration of some differential elements specific to the target population that also address the specific Policy Guideline on the Regulation of Infant Formula Products.

The submission describes how the issues and problems identified in Proposal P1024 that apply to the general food supply are the same as the issues and problems of the regulatory arrangements for nutritive substances and novel foods for infant formula products, particularly in relation to definitional issues. INC therefore considers Options 1 (no change) and 2 (amend the current definitions) do not advance the system at all and risk perpetuating the problems and issues into the future. INC therefore proposes that, with appropriate differentiation, the framework proposed in Option 3 (although it requires further development as noted subsequently in this submission) should be applied to Standard 2.9.1. The differentiation proposed in the body of this submission is designed to address the vulnerability of the target population who are consuming infant formula and the unique role of infant formula as the sole source of nutrition for infants 0 to around 6 months where breastfeeding is not undertaken.

INC also considers that applying the same framework for the future regulation of new substances (currently nutritive substances and novel foods), but adjusting elements of that framework to address the specific considerations necessary for infant formula products, ensures consistency of approach across the Food Standards Code.

Finally, the term 'nutritive substance' appears in eight standards in the Food Standards Code. Outside the two standards covering structure and definitions of the Food Standards Code, the term is used in six other standards. All but one standard (Standard 1.3.2 Vitamins and Minerals) are in Part 2.9 including Standard 2.9.1. Consideration of the future regulation of nutritive substances cannot effectively be conducted if most of the standards that apply the term are excluded from the scope of Proposal P1024.

INC strongly supports Standard 2.9.1 being included within the scope of Proposal P1024 going forward.

Detailed Comments

INC has responded to the questions asked in the Call for Submissions but notes there were no specific questions concerning Option 3 as described. INC therefore provides the following.

Option 3 Develop an Alternative Framework (section 4.2.3)

INC supports the framework proposed as Option 3 for general foods also being applied to infant formula products, with potential consideration of some differential elements specific to the target population.

INC notes the alternative framework proposed by FSANZ takes a proportionate approach to risk that reflects 4 main elements:

- identifying foods that do not require regulatory approval before market entry – the Eligible Food Criteria Pathway
- pre-market assessment either by industry (self-assessment) – the Pre-Market Assessment by Notification Pathway
- the regulatory assessment process – the Pre-Market Approval Pathway
- description of data and documentation requirements for assessment/approval.

INC considers a proportionate approach to risk to be a more efficient approach to managing the market entry of new food substances and that, with appropriate differentiation, the framework proposed in Option 3 should therefore be applied to Standard 2.9.1.

The differentiation proposed is in relation to the prerequisite requirements for the Eligible Foods Criteria Pathway and the Pre-Market Assessment by Notification Pathway and for the content of the documentation, data and documentation requirements for both. These different requirements would need to be designed to address the vulnerability of the target population who are consuming infant formula and the unique role of infant formula as the sole source of nutrition for infants 0-6 months where breastfeeding is not undertaken.

The policy principles in the Policy Guideline on the Regulation of Infant Formula Products which are relevant in this context are:

(i) Pre-market assessment, relative to principles (d) and (e), should be required for any substance to be used in infant formula and follow-on formula that:
   i. Does not have a history of safe use at the proposed level of these products in Australia and New Zealand
   ii. Has a history of safe use in these products in Australia and New Zealand, but which, having regard to source, has a different form/structure, or is produced using a substantially different technique or technology.

INC believes these Policy principles encompass an interpretation that does not exclude the application of the Option 3 Framework including eligible food criteria and industry pre-market self-assessment[1].

The Eligible Food Criteria and Pre-Market Assessment by Notification Pathways provide for speed to market for industry and consumers, and promotes innovation without excessive regulatory burden. INC considers that today, in practice, we apply some aspects of each of the Eligible Food Criteria and Pre-Market Assessment by Notification Pathways to Standard 2.9.1. For example, an industry pre-market assessment element is embodied in provisions for infant formula products for special dietary use such that the composition of infant formula

[1] INC supports the intent behind these policy principles but is of the opinion that they were shaped without adequate regard to the implications of their implementation, for example with respect to industry's ability to ensure security of supply of infant formula products.

products "*may be specifically formulated for premature or low birthweight infants provided that in all other respects they comply with this Standard*" (clause 25) and "*may be specifically formulated to satisfy particular metabolic, immunological, renal, hepatic or malabsorptive conditions…*" (clause 27). Industry undertakes a pre-market safety assessment of changes to formulations for these specialised products to ensure their safety by the most vulnerable population group.

Even so, INC believes there should be differentiation in the framework for dealing with infant formula products compared to general foods that will need further evaluation.

INC considers that:

- the Eligible Food Criteria Pathway needs clear criteria in terms of defining eligibility with information to be held relevant to infants as the target population group, for example, comparable levels in human breast milk (if applicable)
- For Infant formula products, the documentation requirement on safety for *all* pathways should include a focus on safety assessment and data that is relevant to infants as the target population group.
- the Pre-Market Assessment by Notification Pathway (industry self-assessment) should be based on criteria such as mutual recognition and a list of recognised/reputable authorities for such recognition, in addition to the proposed criteria for general foods (extensions of use and minor deviations from the EFC).

INC has provided separately some examples of how the Option 3 framework might operate if it was in place now.

INC suggests that for some substances, using a graduated risk approach, more than one pathway should be available by providing for the ability for companies to choose to use the Pre-Market Approval Pathway even if the product is eligible for the Pre-Market Assessment by Notification Pathway.

Two further enhancements to Option 3 would greatly enhance the process for industry and consumers and for growth and trade purposes:

- development of a streamlined facility for the Pre-Market Approval Pathway for substances that have already been approved in other jurisdictions by authoritative regulatory agencies;
- where relevant FSANZ have the ability to make regulatory changes that reflect formula modifications undertaken and given effect by the Pre-Market Assessment by Notification Pathway.

More work however will be needed on these elements and to map differentiating factors for infant formula products within the Pathways.

Risk Assessment (section 3.3)
Question 1: How do the current novel food and nutritive substance definitions affect your organisation, either as a food business or a food enforcement agency?
Response: FSANZ makes clear that the definition of 'nutritive substance' contained terms identified by the Supreme Court of New South Wales in 2009 as ambiguous and that these terms made interpretation very difficult. These terms have been carried through to the new definition of 'used as a nutritive substance' in the Revised Food Standards Code. Similarly, terms used in the definition of 'novel food' are subject to similar uncertainty, ambiguity and difficulty of interpretation.

The definitions therefore present impediments to developments in the food supply generally and infant formula products. The current regulatory approach to nutritive substances and

novel foods is a limiting factor on innovation and development of infant formula products and does not facilitate speed to market.

The lack of clarity inhibits the use of innovative substances because the regulatory application process carries high inherent risks of either rejection of applications for new substances or prosecution (if a business makes the judgement that a substance is not novel or a nutritive substance).

If definitions persist then terms such as 'extracted' and 'refined' need to be defined.

Question 2: Do you believe there are problems with the current definitions in addition to those outlined in the assessment summary? If so, describe the problems.
Response: INC concurs with the problems associated with the definitions as described in the assessment summary. These are all problems experienced by the application of the regulatory regimes for both nutritive substances and novel foods in relation to infant formula products. INC has identified other problems as described in response to Question 3.

Question 3: 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.
Response: Definitional overlap is also identified as problematic because enquiries have been made to the Advisory Committee that may be considered 'in the context of either definition'. The Call for Submissions suggests (p10) that the overlap in definitions is evidenced by the data requirements for applications to amend the Code. INC does not consider the data requirements to be evidence of this. This is because the data requirements for other specific substances cover similar requirements and yet they are not considered as reflecting definitional overlap. That aside, INC considers a single definition or approach to 'new food substances' would be an efficient approach and could be applied to Standard 2.9.1. This would reflect the more detailed level of substances in the Policy Guideline on the Regulation of Infant Formula Products.

The Call for Submissions suggests (p10) that the existence of the Advisory Committee on Novel Foods is an acknowledgement that the definitions of non-traditional food and novel food rely on uncertain concepts. The Advisory Committee comprises regulatory agency representatives only and as such is a committee that reflects the regulators view of novel foods not the science or the likelihood of 'traditional' (otherwise there would be ethnic and scientific experts advising on applications). However, we agree the concepts are uncertain to the extent that they can be interpreted differently.

Options
***Option 1 Status Quo* (section 4.2.1)**

Question 4: Are there elements of the status quo that you support maintaining in the Code? If so, please provide details and reasons for your support.
Response: INC considers a new approach to the regulation of nutritive substances and novel foods is needed. There may be aspects of the current arrangements that could be adapted in a new approach. For example, an Advisory Committee that is either expanded or additional that might advise on the evidence from a scientific perspective rather than or in addition to a regulatory perspective would be valuable.

Question 5: Can you identify any problems with the status quo in addition to those highlighted in this report? If so, please provide details.
Response: The problems with the status quo identified in the report are legal clarity, uncertainty and enforcement issues. An additional problem relates to the absence of any mutual recognition of pre-market assessments conducted by reputable agencies overseas. Companies working in the global context are particularly frustrated by the duplication, cost and time to repeat work already conducted expertly elsewhere. There is also the issue of

limiting the population base for novel foods to 'Australia and New Zealand'. As an example, younger infants are considered reasonably homogeneous worldwide primarily because they all generally feed on breastmilk from 0 months to around 6 months of age as a sole source of nutrition.

Option 2 Amend the current definition **(section 4.2.2)**
Question 6: 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.
Response: INC notes the difficulty that the current definitions of 'novel food' and 'used as a nutritive substance' have presented and notes that the use of definitions in this area by other international jurisdictions has proven to be problematic. INC also notes that there is a trade-off between flexibility to future proof definitions and the loss of clarity this has generated.

There is an issue about whether the term 'used as a nutritive substance' is redundant. We note the term is not used overseas except in China where it has an entirely different function. We also note in China there is no 'nutritive substances' standard as there is for novel foods. We are of the view that the term is redundant.

However, proper consideration of this issue cannot be undertaken while Standards in which the term is used are excluded from the scope of Proposal P1024. Neither could that consideration be undertaken in Proposal P1028 since that concerns only part of one standard out of the five in Part 2.9 in which the term is used.

INC is concerned that the exclusion of Standard 2.9.1 and other Part 2.9 Standards from the scope of Proposal P1024 may lead to approaches that have imperfect outcomes because the Standards most affected by the term 'nutritive substances' are not taken into account.

Even if the definition of novel food was amended to accommodate what have been grouped as nutritive substances to date as well to accommodate substances that might be developed in the future, the prospect is the same problems would continue to be experienced – how to increase legal clarity whilst maintaining flexibility.

Identifying foods that do not require regulatory approval (section 4.2.3.1)
Question 7: Are the EFC appropriate for identifying foods that do not need regulatory approval?
Response: Yes, INC supports the provision of Eligible Food Criteria for the Eligible Food Criteria Pathway and makes the following comments about each criterion:

> ***EFC1*** – FSANZ proposes the development of a list of eligible micro-organisms. New micro-organisms not on the list would "need to undergo a form of pre-market assessment"[2] before they could be marketed. The proposal is that the list would be generated in the first instance from the EFSA list of micro-organisms with a Qualified Presumption of Safety.
>
> INC does not support a positive list of strain-specific micro-organisms where it relates to the purpose of addition based on a beneficial effect. INC considers that a list potentially prescribed to strain level may not be exhaustive and considers that there is currently a permission for addition as an optional ingredient that is not strain specific relating to L(+) lactic acid cultures (Standard 2.9.1). INC considers this area is complex and fraught with difficulties. The issues of scope of the list and the currency and maintenance of the list need to be considered. There is also the complexity associated with level of micro-organism listed – is this to the level of family, genus, species or strain?

[2] p4 SD3

INC is aware that there are cultures and processes involving micro-organisms that may not have been captured by the EFSA list and that, as with packaging materials, a positive list approach appears to be an historical approach rather than looking for effective and more efficient approaches to regulatory management.

INC wonders how the list would be updated to reflect developments and assessments overseas to ensure currency and maximise efficiency (not repeating the work undertaken elsewhere). We also see that it is proposed the only form of pre-market assessment for micro-organisms to be "a full risk assessment is completed by FSANZ to determine their safety"[3]. We suggest there may well be lower risk micro-organisms or micro-organisms assessed by overseas agencies (outside of L+ lactic acid producing bacteria) that could well qualify for consideration under the Pre-Market Assessment by Notification Pathway.

EFC2 – FSANZ proposes that animal and crop commodities ('primary foods') excluding fungi, algae and seaweeds be permitted to be sold without pre-market assessment provided they are not prohibited under Standard 1.4.4. Such foods are also proposed to be eligible if they are "physically fractionated, fermented and/or physically processed. From an infant formula perspective, INC is supportive of this criterion, but notes that re-wording is needed to clarify the situation in relation to the eligibility of fungi, algae and seaweeds if they are physically fractionated, fermented and/or physically processed.

We note that commonly used infant formula dairy-based ingredients that have a long history of safe consumption go through a number of processes outlined in EFC2. From a dairy ingredient perspective, the boundaries between EFC2, EFC3 and EFC4 are not clear. Almost all dairy products are produced using the criteria listed in processing techniques[4] so it is not clear where a dairy ingredient stops being "simply processed" and becomes an extract or a substance. INC understands that Dairy Australia is also raising this as an issue. These criteria require further consideration to ensure they provide improved clarity and regulatory certainty.

EFC3 – The proposal is that extracts are eligible if they are prepared from foods described in EFC2 so long as the extract, when added to a processed food, does not exceed the level naturally occurring in the source commodity or substance. This EFC will have the effect of consigning almost all substances from EFC3 to pre-market assessment since few companies would invest in extraction if the substance extracted was limited to return in the processed food at the same level. It does not appear to be a graduated risk approach but simply reverts to the status quo. This basically makes EFC3 largely redundant insofar as it reflects no change in the addition to foods, above the original concentration. There is limited value in developing new extracts and processes if use of the extracts and processes are 'status quo'.

A concern for infant formula manufacture, and this applies to both EFC3 and EFC4, is that innovation in infant formula generally emerges from the efforts of manufacturers to mimic breast milk as closely as possible. The source commodity of a substance is not therefore the benchmark but rather breastmilk. From this perspective, a differentiation of EFC3 and EFC4 for infant formula could be that an extract, when added to infant formula, does not exceed the level naturally occurring in breastmilk rather than the source commodity or substance.

Further, for dairy ingredients, this criterion and EFC4 needs to be shaped to ensure it is possible to use existing dairy ingredients that may be used in infant formula as a point of comparison for addition of more concentrated ingredients. This is important so that pre-market assessment should not be required for concentrated dairy ingredients that

[3] p3 SD2
[4] p8 SD3 Table 3

deliver key components at levels that could feasibly be achieved through addition of other dairy ingredients commonly used in infant formula at a higher addition rate. For example, WPC can be used at a lower addition rate as an alternative to whey powder as a protein source.

EFC4 – This proposes that substances obtained from animal or plant commodities are eligible only if they are added back to the same food class at the same concentration as the range in the relevant food class. As with EFC3, it does not appear to be a graduated risk approach but simply reverts to the status quo.

INC notes that EFC3 and 4 are much narrower than the Policy Guideline envisages and that they appear to reflect a much more risk averse approach.

Question 8: 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.
Response: INC is not aware of foods that may meet the EFC when clearly described that should otherwise be subject to pre-market assessment.

Question 9: Are there foods that would not meet the EFC, but you consider should be eligible? If so, please describe the properties of these foods.
Response: INC is not aware of foods that may meet the EFC when clearly described that should otherwise be subject to pre-market assessment.

As noted above, these criteria need to be shaped to ensure it is possible to use existing dairy ingredients that may be used in infant formula as a point of comparison for addition of alternative ingredients.

Question 10: 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.
Response: This could be a differentiating aspect of the Framework for infant formula products by requiring that, for example, safety assessment documentation relating to Pre-Market Assessment by Notification and Pre-Market Approval Pathways should include a focus on data that is relevant to infants as the target population group, e.g. breast milk levels, use of existing ingredients in infant formula formulated to current Standard 2.9.1 regulatory minimums and maximums.

INC notes that SD2 and SD5 each cover some of the information that documentation might cover the former in relation to Eligible Food Criteria, the latter in relation to the Policy Guideline.

INC suggests that there needs to be a scaling of expectations to ensure that documentation and data for Eligible Food Criteria is appropriate to the risk presented by qualifying food under consideration. For example, in the context of infant formula products qualifying foods with a history of use in the general Australia and New Zealand food supply, but not in Australia and New Zealand infant formula products, should have reduced requirements compared to a qualifying food with no such history of use. INC therefore considers a key initial component is a risk assessment to determine key risks and the information needed to address these identified risks.

INC recommends that the list of required documents is kept to a minimum and that this list is used in conjunction with a checklist of items to be considered for inclusion based on a risk assessment approach. This will ensure resources applied to evaluations are focused on the aspects of most relevance and help to reduce the regulatory burden on food manufacturers. As stated previously, the requirements applied to infant formula products can be differentiated from those applied to general purpose foods to take into account the vulnerability of the end users, but the same principles can be applied.

There is a question about what 'food businesses' are intended to hold documentation and whether retailers would be expected (or start) to want to see documentation held for substances in foods they sell. Retailers would not necessarily be aware of new substances in complex foods.

INC notes that there is an interdependence between ingredient supplier and finished goods manufacturers in relation to the documentation and determination of eligibility when used in infant formula. There may be issues of intellectual property and interpretation of requirements from international suppliers.

The issue goes further if complex foods are imported. Where are the documentation demands then and if not applied to imported food, is this creating an uneven playing field?

Question 11: Are the exclusions to the EFC appropriate in identifying foods that should be subject to pre-market assessment, despite otherwise meeting the EFC?
Response: The first exclusion in the Call for Submissions is described as 'foods with characteristics that will always require pre-market safety assessment eg pharmacological properties'. SD3 describes this further and identifies the problem with defining 'pharmacological'. If 'pharmacological properties' are intended to mean 'therapeutic properties' then INC suggests that foods regulated by the Food Standards Code are not in scope. Rather, medicines as regulated by the Therapeutic Goods Administration would have pharmacological properties especially when linked to the therapeutic indication. It is also the case that 'pharmacological properties' is in part defined by the context and the sector involved. For example, there have been cases in Japan of infants developing rickets through vitamin D deficiency[5]. The 'pharmacological property' of vitamin D is the prevention of rickets while more generally it is a micronutrient for growth.

INC is also concerned about what other characteristics of foods might be applied to exclude a substance from being an eligible food. Two further exclusions are described as the potential for adverse effects for a non-target population sub-group and foods in a market segment prone to misuse by suppliers. These exclusions are too broad and open to variable interpretation by different regulators depending on their risk appetite. The term 'potential for adverse effects' could apply to many common substances. These exclusions would also have the potential to create uncertainty at the least and be excessively narrowing at worst.

Question 12: 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.
Response: See response to Question 11.

Data and dossier requirements (section 4.2.3.3)
Question 13: Do you regard the investigation of an alternative approach to regulating nutritive substances and novel foods in the Code as a viable option?
Response: Yes, INC considers the investigation of an alternative approach to regulating nutritive substances and novel foods in the Code as a viable option and believes that the approach encompassing "gateway tests to determine an appropriate assessment pathway"[6] should be considered for application to Standard 2.9.1.

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.

[5] Miyako et al 2005
[6] p20 CFS

Question 14: 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.
Response: As noted in response to Question 6, INC considers Option 3 is a viable option to further develop. The foregoing suggests that the pathway criteria are critical elements for the Option together with documentation and data requirements appropriate to the risk. INC considers that the application of this Option to infant formula products can be achieved through appropriate consideration of the particular vulnerabilities of the target population group in subsequent consultations.

Question 15: Do you have suggestions for the type of foods that would not meet the EFC, but may be suitable for industry self-assessment?
Response: INC suggests that substances suitable for industry notification under the Pre-Market Assessment by Notification Pathway include those that have been subject to pre-market assessment by overseas reputable or recognised authorities such as Codex (through member contributions and assessments by other international agencies such as EU and USFDA (GRAS substances). INC also suggests that extensions of use and minor deviations from the EFC would also be suitable gateway tests for industry self-assessment.See also the response to Question 7.

Question 16: Please provide details of how a self-assessment pathway may or may not provide benefits to industry.
Response: See the response to Question 6.

Question 17: 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.
Response: INC is supportive of documentation and data (for the Eligible Food Criteria Pathway), being available to relevant enforcement agencies. INC is also supportive of notification as proposed for the Pre-Market Assessment by Notification Pathway and supports transparency for the general public but suggests that some form of summary information be published rather than a company's complete documentation and data given this material will contain a company's commercial-in-confidence information. Details of what might be published could be informed by other country experiences but, in any case, the details need to be developed for the next consultation.

For the Eligible Food Criteria Pathway, INC supports the approach proposed of food companies holding the appropriate documentation and it being available to enforcement agencies to demonstrate rationale for decisions taken to determine eligibility and compliance with the documentation requirements set out in the Food Standards Code.

Draft Framework – Other Considerations
Impact of the Draft Framework on current standards (section 4.3.1)
Question 18: 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.
Response: At a high level, INC cannot identify any downsides to the application of the Option 3 framework to infant formula products but more development on its application and workability is needed.

Other Matters
Exclusive permission for brand and class of food (section 6.2)
Question 19: Do you support retaining the provision to grant exclusive permission in the Code for foods approved by FSANZ? Please provide reasons for your view.
Response: INC considers that exclusivity for new high risk optional ingredients in infant formula products should remain subject to approval by FSANZ. We understand this provision

to mean exclusivity for a product that has received FSANZ pre-market approval but await further detail of the process that might be developed for exclusivity provisions.

Question 20: 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)?
Response: INC considers that if documentation and data sets for the Pre-Market Assessment by Notification Pathway are not public, then notification delivers some level of exclusivity and has the advantage of speed to market. The exclusivity of the Pre-Market Approval Pathway remains attractive for substances not meeting the gateway test for industry self-assessment. How the system might operate in practice will be an important detail to be reviewed in the next consultation. INC presumes, for example, that exclusivity would not preclude applications by other parties for substances that are similar but not identical or applications for identical substances that reflect different documentation and data for delivery. INC will also be looking for more detail on commencement timing (from when application approved?), notification and duration.

Transition and Implementation
Proposed transitional period (section 7.1)
Question 21: Do you support a cut-off date? Please provide reasons for your view.
Response: INC supports a cut-off date if the framework applied to FSC 2.9.1 and FSC 2.9.1 is brought within the scope of P1024. If FSC 2.9.1 is not included in P1024 there could be a significant regulatory gap for infant formula products.

A cut-off date is a facility that has been employed both in the EU and the US. The advantage is that it objectively identifies new food substances entering the food supply after the cut-off date that would be subject to the proposed new framework.

A transition period after gazettal to allow for completion of in-progress innovation projects that may not be concluded at the date of gazettal may also be required.

Question 22: Do you see a need for grandfathering provisions? Please provide reasons for your view.
Response: Yes. INC considers grandfathering removes doubt about substances currently in infant formula products, particularly those currently defined as 'nutritive substances' and supports a grandfathering provision.

Question 23: Do you see a need for a stock in trade provision? Please provide reasons for your view.
Response: INC considers the usual 12 month stock-in-trade provision is appropriate for infant formula products (and foods in the general food supply) at this time.

Implementation (section 7.2)
Question 24: 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.
Response: INC recognises that regulators are seeking to address the problems with the current regime as soon as possible. In light of this, while INC concurs with the transition period proposed of 6 months, it would be important for extensive guidance and industry workshopping and training to be in place before the commencement of the transition period.

Question 25: Do you have any comments regarding the proposal not to allow a stock-in-trade provision during the transition period?
Response: As per the response to Question 23, INC considers the usual 12 month stock-in-trade provision is appropriate for infant formula products (and foods in the general food supply) at this time.

Question 26: Do you have any suggestions as to which peak bodies should be involved in familiarising industry of the new provisions?
Response: INC considers it is best placed to work closely with Implementation Sub-Committee on Food Regulation on implementation proposals and best placed to work with FSANZ and regulators to familiarise the infant formula products industry of the new provisions.

Question 27: 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?
Response: INC suggests four courses might be pursued to enhance awareness:

- Workshops on the provisions to make clear expectations of documentation and decisions on pathways
- Addressing INC Scientific and Regulatory Committee on the provisions
- Addressing the broader INC membership on the arrangements at a pan industry event such as the INC conference (depending on timing of implementation)
- Written material for the infant formula manufacturers

Question 28: Are there any particular comments you feel are appropriate to ensuring satisfactory post-market surveillance?
Response: INC has no comments on this at this stage in time.

Draft Framework for Alternative approach (Attachment C)
Question 29: 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?
Response: INC has no suggestions at this time and has listed its concerns in relation to food substances being potentially categorised as having pharmacological properties in response to question 11.

Question 30: Why is it important for novel foods permitted in the Code to be declared 'not novel' after a certain period of time? Please explain the impacts on your business of novel food permissions remaining in the Code (as novel foods).
Response: INC considers that any novel substances approved for use in infant formula products should remain listed as approved optional ingredients in Standard 2.9.1 in the Food Standards Code.

Qualitative assessment of costs and benefits (SD1)
Question 31: 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.
Response: INC members are best placed to advise costs in their individual submissions.

Question 32: 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.
Response: INC understands research, development and legal costs associated with determining whether a substance is novel or nutritive or neither are commonly incurred in this area. Legal costs of defending the decisions a manufacturer makes are also incurred. INC members are best placed to advise costs in their individual submissions.

Question 33: How (if at all) do the current provisions influence your business's decisions regarding developing and launching new products?
Response: INC members find the current provisions very constraining and costly. If pre-market assessment of all new substances was only by approval, the prospect is innovations in processing and products would not be brought to market in Australia and New Zealand, stifling innovation within Australia and New Zealand. The regime must provide alternative pathways to FSANZ pre-market approval for lower risk ingredients for Infant formula products. As noted above, one element of this is recognition of approvals by credible authoritative regulatory bodies made overseas.

Question 34: 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.
Response: INC understands at times export trade opportunities and import opportunities are missed because of approval lags or absence of approvals. For products entering the Australian market, where there is a duo consolidation of key grocery players, single launch windows for new product acceptance could potentially mean a 12 month delay of product entry to the market.

Question 35: (For food regulators) What types of enforcement costs does your organisation experience as a result of the current nutritive substance and novel food standards? E.g. dealing with enquiries about whether a food is novel or a nutritive substance, notifying food businesses that their food is a nutritive substance or novel food and requires pre-market assessment by FSANZ.
Response: Not Applicable.

Question 36: (For food regulators) How would (if at all would) the types of enforcement costs change if Options 2 or 3 were introduced?
Response: Not Applicable.

Reference

Miyako K, Kinjo S, Kohno H. "Vitamin D deficiency rickets caused by improper lifestyle in Japanese children", *Pediatrics International,* April 2005; 47(2): 142-146

COMMERCIAL IN CONFIDENCE

The following describes examples of how the Option 3 framework might operate if it was in place now drawing on substances currently in infant formula products that could be accommodated in the proposed framework:

Eligible Food Criteria Pathway:

- Example 1 – Low 3 MCPD vegetable oils – a new (changed) ingredient that would not have been considered novel nor a nutritive substance under the current definitions and would meet the EFC. Oils are added at permitted FSC 2.9.1 levels, and changes have been implemented to processing procedures to reduce 3-MCPDs.
- Example 2 – Use of milk protein concentrate (MPC) and whey protein concentrate (WPC) as protein sources – ingredients that would not have been considered novel nor a nutritive substance. Companies currently consider and select what ingredients to use to make up the finished composition set out in the Infant Formula regulation. There are minimum requirements that these ingredients need to meet (e.g. minimum processing, etc) but beyond this, companies make decisions about what ingredients to use to meet the compositional standards for proteins.
- Example 3 –galacto-oligosaccharides – a new ingredient that could not have been considered novel nor a nutritive substance. Such substances are derived from milk, with similar galacto-oligosaccharides found in breast-milk, and could be considered under EFC with a differentiating /additional criteria to general foods in considering the levels of oligosaccharides in human milk (ingredients mimicking those in breastmilk need to consider levels in breastmilk as a primary reference).
- Example 4 - Vegetable oils used in the general food supply in ANZ not currently used infant formula products e.g. olive or avocado oils (local production of both is increasing). These would not be considered novel or nutritive substances under the current definitions and are not precluded from use under existing 2.9.1. So saying, they fall within the policy guidelines for pre-market assessment as set in relation to infant formula. In our view the Eligible Food Criteria Pathway applied to infant formula (supported by appropriate documentation requirements) should not preclude use of these types or ingredients.

Pre-Market Assessment by Notification Pathway:

- Example 1 - L-histidine amino acid minimum change to infant formula – a change in levels to an already permitted substance in Standard 2.9.1, and which has been reviewed for safety by other recognised authoritative regulatory bodies
- Example 2 – ARA: DHA 1:1 ratio – a change in levels of an already permitted substance (ARA) in Standard 2.9.1, and which has been reviewed and approved for safety by other recognised authoritative regulatory bodies
- Example 3 – Lutein – a new substance that has been reviewed and approved for safety by other recognised authoritative regulatory bodies (US GRAs) before consideration for use in the Australian and New Zealand markets.

Pre-Market Approval Pathway – a novel food (based on today's definition) or a new substance (under proposed alternative) that has not been approved anywhere else in the world.