Ministry for Primary Industries
Manatū Ahu Matua

28 September 2017

Project Officer Proposal P1028
Food Standards Australia New Zealand
PO Box 10559
The Terrace
WELLINGTON 6036

Dear Sir/Madam

Proposal P1028 – Consultation paper – Proposal P1028 -
Regulation of Infant formula – Infant formula products for special dietary use

Thank you for the opportunity to comment on this proposal. The Ministry for Primary Industries (MPI) has the following comments to make.

General comments
MPI supports retaining Infant Formula Products for Special Dietary Use (IFPSDU) within the Infant Formula Products standard (Standard 2.9.1), as proposed by FSANZ. We do not support regulating these products within Standard 2.9.5, as IFPSDU are infant formula, and should comply with the compositional and labelling requirements for general infant formula within Standard 2.9.1, except where deviations are needed, consistent with the purpose of the product. We therefore support the overall purpose that is the subject of this consultation, that is, to identify how IFPSDU products should be regulated, within the overarching Infant Formula Products standard. We fully appreciate that the products are often made in overseas markets, in small volumes, and that the standard should provide for maximum flexibility to ensure the availability of suitable products, while maintaining public health and safety. This approach is also consistent with Codex.

If there are aspects of the Foods for Special Medical Purpose standard (Standard 2.9.5) that are considered applicable to the regulation of IFPSDU (such as supply or access), these should be addressed within the IFPSDU part of Standard 2.9.1 of the Food Standards Code.

MPI is also of the view that whatever the final regulatory framework is for IFPSDU, it should not be a barrier to those highly specialised products, such as those IFPSMPs which are predominantly imported into New Zealand (and Australia). In this regard, a standard which is flexible and which will allow for the continued importation of these products is critical to ensure continued supply and access to specialised products by those consumers requiring them.

Biosecurity Science, Food Science and Risk Assessment Directorate
Regulation and Assurance
Pastoral House, 25 The Terrace, PO Box 2526
Wellington 6140, New Zealand
Telephone: 0800 00 83 33, Facsimile: +64-4-894 0300
www.mpi.govt.nz

Contaminant MLs
Section 5.2 addresses contaminant MLs. We have provided comments as set out below, as no question related directly to contaminant MLs.

Aluminium – MPI supports the FSANZ proposed approach, that is, to retain an ML for aluminium (and to transfer the provision to s19). We note that as a regulatory intervention method it would seem that reviewing aluminium containing additive use in foods for infants would provide an influence on limiting and decreasing aluminium exposure in infants.

Arsenic - MPI supports the proposal to not set an ML specifically for arsenic in infant formula at this time but to review in a future proposal an ML in relation to rice ingredients should the need exist.

Melamine - MPI considers that FSANZ should consider setting an ML for melamine in infant formula, including in IFPSDUs. As FSANZ notes, Codex has set limits for melamine in infant formula. Melamine can be detected in powdered dairy products, as a result of filters that have a melamine component. The Codex levels are readily achievable and would not lead to an adverse health impact. Whilst a similar outcome would be achieved by maintaining melamine as ALARA, what an ML would provide is a clear threshold for identifying when adulteration may have occurred in the product as opposed to migration during manufacturing. We therefore support further consideration of an ML for melamine, consistent with Codex.

Lead - MPI supports the reduction in the lead ML to harmonise with that set by Codex.

Consideration of European MLs
MPI notes the FSANZ preliminary view on each of the additional contaminants regulated in the EU. MPI's comments are as follow:

Aflatoxins – We note FSANZ's preliminary view that introducing new MLs for aflatoxin in infant formula is not necessary. MPI supports this view.

Ochratoxin A – We note FSANZ's preliminary view that introducing new MLs for ochratoxin A in infant formula is not necessary. MPI supports this view.

Polycyclic aromatic hydrocarbons PAHs - We note FSANZ's preliminary view that introducing new MLs for PAHs in infant formula is not necessary. MPI supports this view.

Cadmium - We note FSANZ's preliminary view that introducing new MLs for cadmium in infant formula is not necessary. MPI supports this view. Dairy and plant based milks as ingredients in IFPSDU are not expected to be appreciable sources of cadmium.

Q1 Are there any other overseas regulations relevant to IFPSDU?
We have nothing to add at this point in time.

Q2 What are the advantages and/or disadvantages of these options, in particular creating an 'infant formula product for special medical purposes' subcategory? If you support creation of a separate category for IFPSMP, should pre-term products be included?

MPI supports a sub-category approach. To our understanding, this approach has worked well in the current Food Standards Code. FSANZ has provided a detailed analysis of possible options to regulate IFPSDU. MPI is however of the view that the possible new regulatory classification of IFPSDU as presented by FSANZ in Figure 1 should be modified and reduced from four to three subcategories.

MPI proposes three subcategories under IFPSDU. We do not support inclusion of a subcategory based on protein substitutes and question the validity of these products falling under the definition of IFPSDU. We consider that partially hydrolysed protein products should be regulated as a general infant formula as is the case in the EU, and those products which are extensively hydrolysed, elemental formulas or L-amino acid based could be relocated to the IFPSMP subcategory.

Further to this, we are of the view that products for colic and constipation should also fall within the general provisions for IFPs and should not be considered IFPSDU as these are often managed through other means rather than through a specialised formula product.

We therefore recommend the following three subcategories of IFPSDU:

- Subcategory 1: Products for premature or low birthweight (excluding HMF)
- Subcategory 2: Products for Special Dietary Uses (for infants) (ie, that are neither an IFPSMP nor formula for premature or low birthweight infants – see proposed definition under question 3).
- Subcategory 3: Infant Formula Products for Special Medical Purposes (see proposed definition under question 4)

Whilst we support the inclusion of a subcategory for products for premature or low birthweight infants, as these products are specially formulated and regular infant formula is not suitable, we do not support the inclusion of Human Milk Fortifiers within this subcategory. Human Milk Fortifiers are for the fortification of breastmilk and therefore do not sit within a standard that regulates infant formula products.

With regards to Subcategory 2, MPI would like to give further consideration to the classification/name of this subcategory of IFPSDU, and what types of IFPSDU it may cover. Our initial thinking is that this subcategory of products are for infants who have a *limited or impaired capacity to take, digest, absorb, metabolise or excrete food* (see our proposed definition of IFPSDU below), but whom do not necessarily have a diagnosed disease, disorder or medical condition, or are born premature. By way of example, such products may only be required for a limited period of time and may include thickened formulas for infants with gastro-oesophageal reflux or low lactose/lactose free formulas. We do not believe this subcategory should however include formulas for colic, constipation or formulas for infants at a higher risk of developing an allergy (or as noted above, partially hydrolysed protein products) as we are of the view that these products should be covered by general infant formula provisions (for both composition and labelling). These provisions already allow for the addition of lactic acid producing microorganisms and inulin-type fructans and galacto-oligosaccharides.

We recommend that FSANZ engage a paediatric specialist advisory group to assist in informing the formula types that might be included within each subcategory. The same group could advise on composition and nutritional parameters.

Q3 Do you support inclusion of a category definition for IFPSDU in the Code? Why or why not? Is the proposed definition of IFPSDU appropriate; if not, what should it say?

MPI supports a category definition for IFPSDU. We are of the view that this will assist in determination of what IFP's should be regulated within the general provisions and which products are considered to be for special dietary uses. The definition proposed by FSANZ is as follows:

Infant Formula Products for Special Dietary Use means an Infant Formula Product that is specifically formulated:

(a) for an infant with a specific disorder, disease or medical condition;
(b) to satisfy, either partially or fully, the special nutritional requirements of that infant; and
(c) to be used under medical supervision.

MPI would like to propose an alternative definition for IFPSDU and suggests that this overarching definition should instead refer to product that has been specifically formulated for infants who have; *'limited or impaired capacity to take, digest, absorb, metabolise or excrete food including another type of infant formula'* rather than for infants with a diagnosed disorder, disease or medical condition. MPI considers that '*limited or impaired capacity to take, digest, absorb, metabolise or excrete food*' applies to all sub-categories of IFPSDU. The reference to disorders, disease or medical conditions should instead form part of the definition of infant formula products for special medical purposes.

MPI proposed definition for IFPSDU:
Infant Formula Products for Special Dietary Use means an Infant Formula Product that is specifically formulated for infants:

a) who have limited or impaired capacity to take, digest, absorb, metabolise or excrete food including another type of infant formula';
b) to satisfy, either partially or fully, the special nutritional requirements of that infant; and
c) *to be used under medical supervision.*

Q4 If you support including a subcategory definition for IFPSMP in the Code, is the proposed definition of IFPSMP appropriate; if not, what should it say?

MPI supports a category definition for IFPSMP to differentiate these highly specialised products (some of which may pose a risk to healthy infants if consumed) from other IFPSDUs, but we do not support the definition proposed by FSANZ. The proposed definition is as follows:

Infant formula product for special medical purposes means an infant formula product for special dietary use that is specifically formulated for infants:

(a) who have
(i) medically determined nutrient requirements, or
(ii) limited or impaired capacity to take, digest, absorb, metabolise or excrete food including another type of infant formula product

MPI is of the view that the defining feature which would classify an IFP as being for a special medical purpose is a product that is specifically formulated for infants with a *diagnosed* disorder, disease or medical condition for the dietary management and distinctive nutritional requirements of such infants as a result of the disorder, disease or medical condition. Such products would include those IFPSMPs that are for the dietary management of maple syrup urine disease, or phenylketonuria by way of example.

MPI proposes the following definition of IFPSMP for consideration. This proposal is in part based on Section B of the Codex Infant Formula Standard (specifically provision 1.1):

Infant formula product for special medical purposes means an infant formula product for special dietary use that is specifically formulated for infants who have a diagnosed disorder, disease or medical condition, to meet the special nutritional requirements arising from the disorder, disease or medical condition for whose dietary management the product has been formulated.

Q5 Are there any issues with the current definition for protein substitutes?
The current definition, proposed to be retained by FSANZ is:

protein substitute means:
- *(a) L-amino acids; or*
- *(b) the hydrolysate of one or more of the proteins on which infant formula product is normally based; or*
- *(c) a combination of L-amino acids and the hydrolysate of one or more of the proteins on which infant formula product is normally based.*

MPI does not support retaining a definition for protein substitute within the Food Standards Code. This is based on the premise that internationally there does not appear to be any such definition used. Neither the Codex Infant Formula Standard, nor the EU regulations include a definition for protein substitute. Further to this, MPI is of the view that infant formula products based on partially hydrolysed protein should not be considered an IFPSDU and should instead be regulated by the general provisions for IFPs.

Q6 Is there a benefit to defining one or more of the following in the Code:
– Hypo-allergenic formula
– Partially hydrolysed formula
– Extensively hydrolysed formula
– Amino acid-based infant formula?
If yes, what are the benefits of including these definitions? And what should be the key elements of each definition?

No. MPI does not support including definitions for the categories proposed above. As is the approach taken at Codex and within EU regulations, no such definitions are used. Furthermore, MPI is of the view that both 'hypo-allergenic formulas' and 'partially hydrolysed formulas' should not be considered IFPSDU, and should be regulated by the general provisions for IFPs. As presented within Section 2.2.1 of the Consultation Paper, *'In Europe, formula based on protein hydrolysates as a source of protein are regulated as a general infant formula by Commission Directive 2006/141/EC and Regulation (EU) 2016/127. Commission Directive 2006/141/EC notes that infant formulae based on protein hydrolysates are distinct from semi-elemental diet products based on high degree hydrolysates used for the dietary management of diagnosed medical conditions',* MPI supports adopting a similar approach within Standard 2.9.1.

Q7 Are there any issues with the current definition for pre-term products?
MPI is not aware of any issues and supports retaining the current definition.

Q8 What, if any, are the benefits of including age and weight parameters in the regulatory definition for pre-term products?

As pre-term formulas are specially formulated and used under medical supervision, MPI is of the view that it is not necessary to include age and weight parameters in the regulatory definition. As such, it would seem reasonable to continue with the current definition of pre-term formula.

Q9 What is the general composition of human milk fortifiers for premature or low birthweight infants? What are the uses of these products other than premature or low birthweight infants?

MPI does not have this information. As per our response to Question 2, MPI is of the view that Human Milk Fortifiers are for the fortification of breastmilk and therefore do not sit within a standard that regulates infant formula products.

Q10 Is there a need to prescribe a name for IFPSDU – what are the implications for subcategories?

MPI does not support prescribing the name IFPSDU given that there is no consistency internationally with respect to the wording of this overarching category.

Q11 Is there a need to prescribe names for any the IFPSDU subcategories? If yes, what benefit would this provide?

Until such time as the subcategories of IFPSDU are finalised, MPI is of the view that it is premature to consider the detail of the product names. We support the Codex approach where the product name is stated, but flexibility is provided.

Section B of the Codex Infant Formula Standard states that "the name of the product shall be 'Formula for Special Medical Purposes Intended for Infants' or any appropriate designation indicating the true nature of the product, in accordance with national usage". A similar approach could be taken for IFPSDU within Standard 2.9.1.

Q12 Are any specific compositional requirements (energy/macronutrient etc) needed in the Code for formula intended for premature or low birthweight infants, or for those suffering metabolic etc. conditions? If so, what are they?

No comment. As noted above, we suggest that FSANZ consults a paediatric specialist advisory group, unless sufficient information is provided in response to this consultation paper.

Q13 Are any specific compositional changes needed in the Code for protein substitutes? If so, what are they and what is your justification for them?

We do not support continuation of this subcategory.

Q14 Are any specific compositional requirements (energy/macronutrient etc) needed in the Code if a new subcategory of formula for special medical purposes were created? If so, what are they?

As per Section B of the Codex Infant Formula Standard and the approach taken in the EU, MPI is of the view that the standard should clearly articulate that the composition of all IFPSDU (not just IFPSMP) should be based on the general infant formula compositional requirements except for the compositional provisions which must be modified to meet the special nutritional requirements arising from the special dietary need for such products.

Q15 What benefit, if any, would the inclusion of a specific requirement for any IFPSDU to be demonstrated by generally accepted scientific data as: safe, beneficial and effective in meeting the specific nutritional requirements of intended infant subpopulation?

We note the FSANZ summary of the US and EU approach to this question in section 3.1.4, and note that in the incoming EU Directive (EU) 2016/128 it states; *'it is not appropriate to lay down detailed compositional rules for such food products. It is however important to set principles and requirements specific to them in order to ensure that they are safe, beneficial and effective for the persons for whom they are intended on the basis of generally accepted scientific data'.* That being said, for FSMP developed for infants, the nutritional requirements should be based on that of infant and follow-on formula *'to take in to account the specificities of the nutritional requirements of infants'* and modified as necessary to *'satisfy the nutritional requirements of infants when this is necessary for the intended use of the product'.*

We strongly support the inclusion of a similar statement which says that where any modifications are necessary these are demonstrated by generally accepted scientific data as: safe, beneficial and effective in meeting the specific nutritional requirements of intended infant subpopulation. This approach is similar to the EU approach, but not as strict as the US approach (where approval is required by the US FDA). As these products can deviate from the micronutrient and nutritive substance permissions, to meet the special nutritional requirements of the product based on its purpose and role as a IFPSDU, it is important that the supplier of the product holds the information (or has access to) the data that supports the deviation.

While this may already be a requirement under the Food Acts applying in both New Zealand and Australia, it is more explicit if contained in the Food Standards Code. As it is already a requirement, this is not adding to the regulatory burden on suppliers and manufacturers. If this is not an explicit requirement, the standard is more difficult to enforce.

Q16 Are there any issues with the current requirements for micronutrients and nutritive substances in IFPSDU products?

MPI is unaware of any issues at this point in time.

Q17 Do you have any information to support the inclusion of a minimum and maximum amount of chromium in IFPSDU? If yes, should this be considered only in relation to certain categories of IFPSDU?

MPI has no information to provide. If information is not provided in response to submissions, we would be interested in the views of a paediatric specialist advisory group.

Q18 Do you have any information to support the inclusion of a minimum and maximum amount of molybdenum in IFPSDU? If yes, should this be considered only in relation to certain categories of IFPSDU?

MPI has no information to provide. If information is not provided in response to submissions, we would be interested in the views of a paediatric specialist advisory group.

Food Additives – general comments:

We support alignment with Codex and EU food additive provisions as far as practical, provided there is a JECFA or other safety assessment relevant to the age group (i.e applying to less than 12 weeks of age). We

support the comments made by FSANZ in section 4.2.1 of the Consultation Paper (para 3), "that the final hierarchical system of food categories for IFPSDU will depend on the number and arrangement of IFPSDU subcategories in the Standard".

We comment that if there is a change in the way the category for IFPSDU is defined, and some products move to the general category (for example), there will need to be a revision of the specific requirements that exist for IFPSDU. If (hypothetically) products based on protein substitutes moved to the parent category, this may mean that any specific additive provisions in IFPSDU for these products move to the parent category.

MPI suggests food additive provisions should in the first instance be considered for all infant formula in the higher hierarchical category of 13.1. Further provisions (eg different additives and/or different levels of use) that apply to other classes of formula can be made either to one or more subcategories (soy-based, hydrolysed protein, amino acid-based) or by stating specified conditions of use eg for ready to consume liquid formula.

MPI notes that just because a particular formula is produced as IFPSDU does not in itself indicate a need for a particular technological function or particular food additive. Technological functions are required due ingredients used, the type of processing and its physical form (ie dry powder or ready to use liquid) which is largely independent of whether a formula is intended for special dietary use or not.

Comment on the current Food Category system - Schedule 15, food Category 13.1

MPI considers that the sub-categories could be clearer. For example:
a) 13.1.2 currently refers to Liquid infant formula products. As this is a subcategory of 13.1, it would appear to not relate to either 13.1.1 Soy-based Infant Formula or 13.1.3 Infant Formula products for specific dietary use based on a protein substitute.

b) 13.1.3 refers to Infant Formula products for specific dietary use based on a protein substitute. By implication, this has no further provisions for liquid versions (noting that carrageenan is specifically listed, at a higher level).

A possible complicating feature of infant formula categories is that the food additive MPLs are applied in 'ready to consume form' with units of mg/L. This is sensible, and presumably occurs via the application of standard 1.3.1, section 1.3.1—4(4). Food category 13.1 could be improved by including a footnote that clearly defines those provisions that apply to the ready to drink products, the dry powders, or concentrated liquid products (to which further water is still required to be added).

Q19 Could one category of IFPSDU be used for all additional food additives, or should additional or modified subcategories be devised (noting the possible four subcategories in section 2.2).

For the purposes of allocating food additives permissions, one category for infant formula products would allow for a consistent range and use levels of food additives across infant formula and IFPSDU independently of ingredients used or purpose of the particular product, with conditions of use stated as appropriate. There also needs to be clarity about ready to drink (liquid products) versus dry mix formulas, which have very different technological needs for food additives.

Therefore, MPI believes that revised food additive provisions including those related to alignment with EU and Codex, should in the first instance be considered for all infant formulae in the higher hierarchical category of 13.1. Further provisions (eg different additives and or different levels of use) that apply to other types of formula can be made either as one or more subcategories (soy-based, hydrolysed protein, amino acid-based) or by use of specified conditions of use eg for ready to consume liquid formula.

Q20 Do you support the proposed amendments listed in Table 7 for IFPSDU at the amounts shown?
In principle, we support alignment with Codex and EU food additive provisions as far as practical.

At the 49th Session of the Codex Committee on Food Additives (CCFA), the JECFA secretariat provided information JECFA had compiled, on an overview of all additives listed in the Standard for Infant Formula and Formulas for Special Medical Purposes (CODEX STAN 72–1981) and of the provisions in the GSFA for food categories (FC) 13.1.1 and 13.1.3. This was provided as CRD15rev at the 49th meeting of the Codex Committee on Food Additives, and can be found at the following link:

http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-711-49%252FCRD%252Ffa%2B49%2BCRD15x_rev.pdf

The JECFA paper shows that a number of currently permitted food additives have not been evaluated for use in infant formula. CCFA noted that the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) could take into account the information in their on-going work on technological justification for certain food additives and also in terms of the future work on alignment of food additives in standards developed by CCNSFDU with provisions in the GSFA.

The relevance of this is that several additives referred to in Table 7 (and question 20) do not have complete safety assessments by JECFA, in infants (i.e less than 12 weeks of age). In the Table 7 list, these are: sodium phosphates (INS 339 i, ii and iii), potassium phosphates (INS 340 i, ii and iii), locust bean gum (INS 410), and guar gum (INS 412).

It is therefore not as straightforward as aligning with Codex, and in our view, further consideration is required. It needs to be demonstrated that the additives are safe in infant formula, and IFPSDU products.

Where the EU have a permission, but Codex do not, the safety assessment will need to be carefully checked. We would expect that the EU permissions will eventually become part of the GSFA, if they meet the criteria. We therefore think that the Codex GSFA should be the primary reference point.

Q21 Can you provide information on suitable international safety assessment, a demonstrated history of safe use in the context of IFPSDU, and a technological justification for:

- **a) Calcium carbonates**
- **b) Calcium citrates**
- **c) Phosphoric acid**
- **d) Sodium alginate**

e) **Xanthan gum**
f) **Locust bean (carob bean) gum**
g) **Pectins**
h) **Sodium carboxymethylcellulose**
i) **Sucrose esters of fatty acids**
j) **Starch sodium octenylsuccinate**

MPI has no specific comment, and will defer to the industry to provide this information. Please refer to our comments above.

Q22 Are there any technologically justified concerns with changing the permissions for citric and fatty acid esters of glycerol (472c) to:
a) MPL of 9000 mg/L for liquid products
b) MPL of 7500 mg/L for powdered products?

MPI has no specific comment, and will defer to the industry to provide this information. However, we note that JECFA stated in CRD15rev that 472c is 'Not of concern at the proposed use levels'.

Q23 What is the technological justification for the use of diacyltartaric and fatty acid esters of glycerol (472e) in IFPSDU? Are there any technologically justified concerns with the removal of this permission?

No comment.

Q24 Do you support retaining a maximum PRSL for any IFPSDU? Please provide your rationale.

No comment.

Q25 To what extent is pre-term infant formula used following hospital discharge and how do caregivers access it (for example, by prescription)?

MPI is unable to comment on to what extent pre-term infant formula is used post discharge from hospital. We do however note that within the New Zealand Pharmaceutical Schedule which lists products that are subsidised and available using a Special Authority number via prescription, there are provisions for post-discharge pre-term infant formula. The Schedule states that a Special Authority for subsidy is only available from a dietitian, relevant specialist or vocationally registered general practitioner. Approvals are valid for 6 months for applications meeting the following criteria:

The infant was born before 33 weeks gestation or weighed less than 1.5 kg at birth; and
Either:
The infant has faltering growth (downward crossing of percentiles); or
The infant is not maintaining, or is considered unlikely to maintain, adequate growth on standard infant formula.

Q26 Would you support the requirement for a statement that the product must be used under medical supervision, where the wording is not prescribed (an approach which harmonises with the overseas and international requirements)? Please describe your reasons why you do/do not support.

Yes, to support harmonisation with overseas and international requirements, and to ensure appropriate use of the products, to protect the public health and safety of all infants.

Q27 Are there any specific FSMP labelling requirements that you consider applicable to a particular type of IFPSDU?

MPI considers that for our proposed subcategories 1 and 3 (products for premature or low birthweight infants, and IFPSMP), labelling requirements should align as much as possible with those included under Standard 2.9.5 (specifically Division 4).

Q28 Are there any specific FSMP labelling requirements that should apply to all IFPSDU?

A statement to the effect that the product is not suitable for general use and should be used under medical supervision. This is to ensure the appropriate use of the product, to protect the public health and safety of all infants.

Q29 What specific labelling requirements for the safe preparation and use of IFPSDUs are being used that contradict the general requirements set out in subsection 2.9.1—19(3) of Standard 2.9.1?

MPI does not have information on whether safe preparation and use labelling elements currently used on IFPSDU contradict the general infant formula requirements.

MPI notes that the current wording of generic labelling requirements in subsection 2.9.1—(19)(3) relating to the preparation and use of infant formula is not prescribed. This current approach accommodates imported IFPSDUs that have to comply with other international regulations however it is possible this may change as a result of comments received to the 2016 FSANZ consultation on issues relating to infant formula (for use from birth to <12 months of age).

Q30 What evidence can you provide to support concerns regarding inappropriate access to any IFPSDU?

MPI does not hold any such evidence.

MPI is of the view that the same restrictions on the persons by whom, and premises at which, our proposed Subcategory 1 and Subcategory 3 products (products for premature or low birthweight (excluding HMF) and Infant Formula Products for Special Medical Purposes (see proposed definition under question 4) respectively) may be sold, should align with Standard 2.9.5 – Foods for Special Medical Purposes. We therefore propose that provision 2.9.5—5 of Division 2 of Standard 2.9.5 should be carried over to Standard 2.9.1 for these subcategories.

Jenny Reid
Manager Food Science and Risk Assessment