Dairy Goat Co-operative

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20th October 2021

To FSANZ: submissions@foodstandards.gov.au.

SUBMISSION

FSANZ Proposal P1028

Consultation Paper 3 2021: Regulatory Framework and Definitions

Submitter:

Dairy Goat Co-operative (N.Z.) Ltd
[redacted]

Information regarding the submitter:

Dairy Goat Co-operative (N.Z.) Ltd, (abbreviated as 'DGC'), is a New Zealand manufacturer, developer and exporter of premium consumer packaged nutritional powders primarily for infants and young children. It is a leading New Zealand exporter, and services over 30 international markets via its marketing partner and joint venture relationships. The markets are located primarily in Asia, Europe and Oceania.

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Contents

Introduction

We appreciate the opportunity provided by this Consultation Paper to make comments on the proposals put forward. DGC is an associate member of the Infant Nutrition Council (INC) and has participated in the preparation of the INC submission to this consultation paper. This submission focuses on the issues of key importance and relevance to DGC as listed in contents above. We have also provided responses to the questions for submitters in the consultation paper.

Please note that abbreviations used are as per CP3. Any abbreviations additional to those in CP3 are used in conjunction with full term when first used in this submission.

Key Issues

Novel foods and Nutritive Substances

DGC supports:

- **No review of novel foods and nutritive substances specific to IFPs under P1028**
- **A change to the definition of novel foods as soon as possible to provide increased clarity in the interim until P1024 is progressed and concluded.**

DGC supports FSANZ's proposal not to proceed with a review of novel foods and nutritive substances specific to IFP under P1028. Our view is that a broader review is needed of these aspects of the Food Standards Code. This is the purpose of P1024 and we would be very pleased to see work on this proposal progress. Once this broader review is undertaken, and a future framework established for general foods, IFP can be considered in the context of this framework and whether or not additional provisions are appropriate with respect to infant formula products.

So saying, given the time that has elapsed since the initiation of P1024 and the current ambiguities arising from the definition of novel foods, DGC recommends that the definition of novel foods is amended as soon as possible to make it clear that the population for which the novel food is intended must be taken into consideration. For example, this could be achieved by addition of text shown in red in 1.5.1-2 (1):

> Novel food means a non-traditional food for the intended [consumer] population that requires an assessment of the public health and safety considerations having regard to:..."

In the CP3 consultation paper FSANZ notes that a number of, "substances having uncertain regulatory status," were identified from a survey of IFPs on the market in ANZ. None of these substances were considered to pose a degree of risk such that FSANZ felt compelled to include a separate review of novel foods and nutritive substances applicable to IFP under P1028. It has very recently come to our notice (since our submission to P1028 CP2) that pea protein and rice protein is being used in standard IFPs in this market with no pre-market pre-assessment by FSANZ. This prompted us to take a careful look at the definition of novel foods. Both peas and rice would certainly be considered to be traditional foods (i.e. not novel) for the general population but not for infants prior to the introduction of complementary foods. Given the concern raised by FSANZ in CP2 regarding the trend towards wider use of plant proteins we think it would provide greater clarity if the definition of novel foods was amended such that the intended population for food concerned is taken into account.

We believe that the implementation of this change, together with the following suggestions in our submission to CP2, would provide greater protections for infants in the interim until P1024 is progressed and concluded:

1. Adding text to Division 2 of Standard 2.9.1 which replicates the following principles included in 3.1.1 of CX 72-1981:

   3.1.1 Infant formula is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients *which have been proven to be suitable for infant feeding.* The nutritional safety and adequacy of infant formula *shall be scientifically demonstrated* to support growth and development of infants….

   Please refer to our comments on the definition of IFP below. The amendment of this definition provides an opportunity to capture the principles highlighted in italics.

2. Consideration of implementing a prescribed permitted protein list for non-mammalian milk protein and non-intact protein sources (excluding hydrolysed milk proteins).

Regarding nutritive substances, we reiterate the feedback provided in our submission to CP2. We would very much prefer for voluntary permissions to add certain substances or ingredients to be managed as optional ingredients, as per the Codex approach, rather than the current approach of, "used as a nutritive substance."

Approach to regulation of IFPSDU

DGC supports the proposed approach to:

- **Continue to regulate IFSPDU that may be used as the sole source of nutrition for young infants under standard 2.9.1.**
- **Regulate other infant products for special dietary or medical purposes that have a supplementary nutritional role (e.g. human milk fortifiers) under standard 2.9.5**

Definitions

For IFP, IF and FOF:

- **DGC does not support the changes proposed by FSANZ to the IFP and IF definitions. Alternative amendments are put forward for consideration.**
- **DGC recommends that the current FOF definition being retained as is.**

DGC comments on other relevant definitions are fully aligned with INC comments:

- **Soy-based formula: self-explanatory; no definition needed.**
- **Pre-term formula: retain definition**
- **Medium chain triglycerides (MCT): replace with definition for MCT oils**
- **Addition of definitions for conditions such as gastrointestinal reflux: not recommended.**

Definition of infant formula product

IFP is currently defined in the Food Standards Code as, "A product based on milk or other edible constituents of animal or plant origin which is nutritionally adequate to serve by itself as the sole or principal liquid source of nourishment for infants, depending on the age of the infant."

FSANZ have identified that the description of ingredients included does not cover the scope of ingredients used in IFP and proposes to shorten the definition to, "A product ~~based on milk or other edible constituents of animal or plant origin which~~ that is nutritionally adequate to serve by itself as the sole or principal liquid source of nourishment for infants, depending on the age of the infant."

Rather than deleting this description of ingredients, DGC advocates that the definition is amended to better align with the ingredient description in included in 3.1.1 of CX 72-1981. It would then read:

> "A product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be suitable for infant feeding ~~or other edible constituents of animal or plant origin which~~ that is nutritionally adequate to serve by itself as the sole or principal liquid source of nourishment for infants, depending on the age of the infant."

This definition covers the scope of ingredients used in IFP including IFPSDU. In addition it captures the important principle that ingredients used have to be proven to be suitable for feeding infants.

Alternatively this definition could be expanded to:

> "A product based on milk ~~[~~of cows or other animals or a mixture thereof] and/or other ingredients which have been proven to be suitable for infant feeding ~~or other edible constituents of animal or plant origin which~~ that ~~is~~ has been scientifically demonstrated to be nutritionally adequate to serve by itself as the sole or principal liquid source of nourishment for infants, depending on the age of the infant."

This alternative captures the additional principle in CX 72-1981 that the nutritional adequacy of the formula should be scientifically demonstrated. We note that FSANZ is proposing to enshrine in regulation the principle that IFSPDU are formulated in accordance with scientific evidence relating to their intended purpose and that this would become the basis of classification of a product as either a general IFP or and IFPSDU. Our view is that the principle of scientific demonstration of nutritional adequacy applies to all IFP and that IFSPDU are differentiated from IFP by being suitable for the dietary management of infants with specific disorders, diseases or medical conditions. This is discussed further below under **Provisions for IFPSDU-purpose, use and sale: Scientific Evidence of Purpose.**

If this principle of scientific demonstration is included in the definition of IFP we recommend that it sits there as a simple statement that is expected to be followed without further detail regarding how it is to be met (as per CXS-72-1981).

Definition of infant formula

The definition of Infant formula in the Food Standards Code is as follows:

> "An infant formula product that:
>
> (a) is represented as a breast milk substitute for infants; and
> (b) satisfies by itself the nutritional requirements of infants under 4 to 6 months."

FSANZ proposes to amend this definition to the following:

> "An infant formula product that:

[redacted]

(a) is represented as a breast milk substitute for infants; and
(b) satisfies by itself the nutritional requirements of infants under the age ~~4 to~~ of 6 months."

With an adjacent note that infant means a person under the age of 12 months.

In our view this proposed change does not allow for, "a more certain determination of nutritional adequacy from which to set compositional criteria," as per comment made in CP3. Our preference is for the definition to acknowledge that IF serve as a sole source of nutrition until the introduction of complementary foods and then may continue to be used as the principle source of nutrition. We propose the definition of IF is amended as follows:

"An infant formula product that:

(a) is represented as a breast milk substitute for infants; and

(b) satisfies by itself the nutritional requirements of infants ~~under 4 to 6 months~~ for the first months of life until the introduction of complementary feeding as recommended by health authorities and is subsequently [*or* continues to be] suitable as the principal liquid source of nourishment."

This approach of referring to recommendation by health authorities allows for NZ and Australia to have different recommendations regarding complementary feeding and for recommendations on the appropriate age of introduction for complementary feeding to be updated to align with latest science without necessitating a change to the IF definition. Alternatively, "as recommended by health authorities," could be replaced with, "around 6 months of age," which provides an indication of age of introduction but still allows flexibility to accommodate changing recommendations.

The proposed wording above for part (b) of the IF definition aligns with wording used in part (b) of the definition of FOF which we recommend is retained as is:

"Follow-on formula means an infant formula product that:

(a) is represented as either a breast-milk substitute or replacement for infant formula; and
(b) is suitable to constitute the principal liquid source of nourishment in a progressively diversified diet for infants from the age of 6 months."

[redacted]

Regulatory Framework for IFPSDU

DGC does not support all IFSPDU being classified as IFPSMP as proposed by FSANZ. We support a framework where IFPSMP are a sub-set of IFPSDU for which there is greater flexibility on formulations and labelling as proposed by INC.

Restrictions on trade are not supported for all IFPSDU. These should only be applicable to IFPSMP sub-category as proposed by INC (i.e. to highly specialised products not suitable for use by healthy infants).

DGC supports that the suitability of IFPSDU for intended purposes should be underpinned by generally accepted scientific evidence but does not support the development of guidelines put forward in this consultation paper.

We do not support accommodating use of IFPSDU/IFPSMP beyond infancy in regulation. We consider that use beyond infancy should be left to the discretion of medical practitioners.

We consider that products containing no or low levels of lactose should be able to include a statement on their labels advising of the malabsorptive conditions for which they are suitable.

DGC supports the labelling proposals developed by INC which differentiate between IFPSDU and proposed sub-category of IFPSMP for highly specialised IFPSDU

FSANZ proposes to simplify the current regulatory framework by dispensing with the current three current sub-categories:

Products formulated for premature or low-birth weight babies
Products for metabolic, immunological, renal, hepatic and malabsorptive conditions
Products for specific dietary use based on a protein substitute

And replacing these with one category of IFPSMP subject to the stringent requirements currently imposed on FSMPs including restriction on sale. FSMPs are subject to restriction of sale due to manage the risks associated with their minimal prescribed composition and the potential for manufacturers and importers to take advantage of the low compositional requirements specified within standard 2.9.5. We are strongly opposed to this proposed approach which categorises all IFPSDU as posing a high risk with regard to potential for unsupervised and inappropriate use. This does not reflect the reality where most IFPSDU do not pose a risk if fed to healthy infants.

We support simplification of the current framework but not to the degree proposed by FSANZ. Our recommendation is to treat IFPSMP as a subset of IFPSDU as shown below (and in alignment with proposal of INC):

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Division 4

Infant Formula Products for special dietary uses including those for special medical purposes

Infant formula products for special dietary uses

- Serve as a substitute for human milk, and replacement for infant formula and/or follow-on formula
- Have composition that meets IFP requirements except for minor adaptions to assist with the dietary management of infants with a disorder, disease or condition based on appropriate scientific evidence and
- Are intended for use under medical supervision but may be used safely by healthy infants

Infant Formula Products for Special Medical Purposes are IFSPDU that are not suitable for use by healthy infants

- Highly specialised products with significant deviations from compositional requirements for IFP
- Subject to restrictions on trade as must only be used under strict medical supervision

Our proposal is that:

- less specialised/low-risk IFSPDU
  - can only deviate from the compositional requirements for IFP in the Food Standards Code as needed for the dietary management of the condition for which they are formulated.
  - have only limited differences applied with regard to labelling requirements compared to standard IFP.
- Highly specialised IFPSMU:
  - have much greater flexibility with respect to composition. In particular, alternative compositional requirements for IFP (as specified in Codex standards, EU or US regulations) may be complied with rather than those in the Food Standards Code.
  - Have much greater flexibility with respect to labelling.

  More flexibility is needed for these highly specialised products in order to secure security of supply for the limited number of infants that require them.

As indicated in CP3, some less specialised IFPSDU comply with the compositional requirements of general IFP. As such, there is no basis for their availability to be constrained.

IFP with partially hydrolysed proteins are an example. In CP2 FSANZ proposed that partially hydrolysed proteins be included in the Food Standards code as a prescribed permitted protein source for IFP.

Further, the proposal to apply restrictions of trade to these products does not take into account the prevalence of less serious conditions, such as reflux and colic, where IFSPDU can assist in dietary management.

Here are some excerpts from Zeevenhooven et al, 2021:

> Functional gastrointestinal disorders (FGIDs) in infants and toddlers are common worldwide and cover a variety of disorders associated with chronic, recurrent symptoms attributable to the gastrointestinal tract, but not explained by structural or biochemical abnormalities.
>
> Reported prevalence rates of FGIDs in neonates and toddlers vary between 27.1% and 38.0%, with the most prevalent disorders being infant regurgitation and functional constipation (1-25.9% and 1-31%, respectively). Infants and toddlers with an FGID display a reduced quality of life and visit medical professionals more often compared to healthy controls. Moreover, the impact on the families of affected children is considerable. Recurrent unexplained symptoms in young children can cause concerns for caretakers, especially because young children are unable to adequately describe emotions or pain. *Whether these parental concerns result in health care utilization or not depends on the coping style of parents, their perception of their child's symptoms and previous experiences they have had.*

The text in italics above is very pertinent and highlights the importance of less specialised/low risk IFSPDU being accessible to caregivers.

It is also noted in CP3 that highly specialised products, “are only relevant to a small percentage of the general population and ...are also more expensive that general infant formula, thus are usually accessed through the New Zealand PHARMAC and APBS from pharmacies.” In practice, the availability of these products is determined by the market demand for the applications for which these products are formulated. Applying restrictions on trade for less specialised products could have unintended consequences, for example restricting caregivers’ ability to source them when needed and higher pricing due to reduction in competitive outlets.

Provisions for use of IFPSDU –purpose use and sale

Scientific Evidence of Purpose

FSANZ proposes to enshrine in legislation the principle that IFPSDU/IFPSMP are formulated in accordance with scientific evidence that demonstrates the efficacy of the product in accordance with its intended purpose. This is noted in CP3 as being particularly relevant to products for less serious conditions such as reflux, colic, hungry babies.

FSANZ further proposes that this would become the basis for classification of a product either as a general IFP or an IFSPDU/IFPSMU.

As stated above, DGC supports the principle in CXS 72-1981 that infant formula is a product that has been scientifically demonstrated to be nutritionally adequate to serve by itself as the sole or principal liquid source of nourishment for infants, depending on the age of the infant. We consider that the principle of scientific demonstration of nutritional adequacy is applicable to all IFP and recommend that if this principle is to be captured in 2.9.1 it would be most appropriate to include it in the definition of IFP.

In our view the basis of classification of IFP as IFPSDU is suitability for the dietary management of infants with specific disorders, diseases or medical conditions as declared in a statement on the label in accordance with the labelling requirements for IFPSDU. In this context there are standard IFP products that have been developed for use by healthy infants that, in the course of research to evaluate nutritional adequacy, have also been scientifically demonstrated to be suitable for use for the dietary management of specific conditions, for example with regard to atopic dermatitis (or could potentially be in the future due to ongoing research activities). Such products only become IFPSDU if they include a statement on the label regarding suitability for use for the condition concerned.

We concur that IFSPDU/IFPSMU formulations need to have a scientific basis (as should all IFP), but stress that the wording used to regulate this needs very careful consideration. These products are not therapeutic. Their role is dietary management. They provide either the sole or principal source of nutrition to infants to support growth and development. As such, the use of the word, “efficacy,” is inappropriate. DGC’s view is that products for special dietary use or special medical purpose should be formulated based on generally accepted scientific evidence and/or be scientifically demonstrated as beneficial in the dietary management of the condition for which they are intended.

We recommend that FSANZ focuses on encouraging increased transparency regarding the scientific evidence or data formula companies hold in relation to their formula products rather than developing guidelines or expecting enforcement agencies to assess the quality or strength of evidence held. **Please see our response to question 13** where we outline the challenges relating to developing guidelines and recommend against duplicating assessments already being done in practice.

Lactose-free and low-lactose formulas

In our view formulas containing low or no lactose are not ideal for long term use by healthy infants and therefore should ideally be considered as IFPSDU not standard IFP, including soy and other plant-based formula devoid of lactose. We note that the NZ health authorities advise that:

- Soy based formula are not suitable for infants under 6 months.
- They may be introduced after 6 months as an alternative to milk-based formulas for infants with cow’s milk allergy or lactose intolerance if advised by an allergy specialist, paediatrician or dietitian (NZ Health Promotion Agency information sheet NPA265, 2020)

However, as per our comments above, there are some product formulations that can be presented either as standard IFP or as IFPSDU, the differentiating factor being the inclusion (or not) of a statement on the label regarding suitability for a specific condition. We consider that it is appropriate for products that contain no/low lactose to be able to include a statement on their labels regarding the malabsorptive conditions for which they are suitable. This would allow a more consistent approach for IFPSDU than requiring "Lactose-free," or, "Low-lactose," to be part of the name of products as is currently the case. We support the requirement for including the galactose content of these products in the nutrition information panel.

Responses to Questions for Submitters included in the consultation paper

General questions

- How effective do you believe the current regulatory measures for IFPSDU are? How could they be made more effective? If you think the requirements should be changed to better manage risk, please explain how and why. Please provide supporting detail and data, where available.

  DGC is not aware of any significant issues with the current regulatory measures for IFPSDU, but supports a reduction in the number of IFPSDU categories to eliminate the overlaps between the existing categories. We support INC's proposal of having just one sub-category for IFPSDU products for more serious disorders (proposed to be called IFPSMP). These are the products that must be used under medical supervision as they are not safe for consumption by healthy infants. In our view only this sub-category warrants application of trade restrictions which tend to happen as a matter of course due to the small volumes involved for their highly specialised applications.

- Do you consider that the options proposed in this paper will ensure that IFPSMP are safe, suitable and meet the nutritional requirements of the infants for whom they are intended? If not, please explain why and provide supporting data and detail, where available.

  The proposal to create a single category of IFPSDU, at the highest risk management level, does not impact on the product safety or suitability to meet the nutritional requirements of the infants for whom they are intended.

  We are not aware of any evidence of market failure, or health risk or safety reason for categorising all IFPSDU at so high a risk as to warrant more limited access. There is also no justification for products that are safe for use by healthy infants to be exempted from a range of IFP labelling requirements.

  Please refer to our comments regarding scientific evidence of purpose above and in response to question 13 below. We have reservations about FSANZ proposals to:

[redacted]

- Enshrine the in regulation the principle that IFPSDU are formulated in accordance with scientific evidence that demonstrates efficacy of the product in accordance with its intended purpose.
- Develop guidelines re strength of scientific evidence

We support the principle of scientific demonstration of nutritional adequacy, but consider this is applicable to all IFP not just IFPSDU. The term, "efficacy," is not appropriate to use in the context of IFPSDU products which are used for dietary management and are not therapeutic in nature. DGC recommends a greater focus on encouraging transparency of scientific information rather than utilising resources to develop guidelines which could be misaligned internationally and quickly become outdated.

- How effective do you believe the options proposed for IFPSMP will be? How could they be made more effective? Do they place an unreasonable cost burden on industry to achieve and/or maintain compliance? Please provide supporting detail and data, where available.

As stated above, we support the INC proposal for a 2 tier approach that recognises that there are two distinct types of IFSPDU:

- Those with only minor (if any) deviations from the compositional requirements for standard IFP which may be safely consumed by healthy infants, and
- Highly specialised products (tentatively designated as IFPSMP) which are not suitable for healthy infants.

INC has carefully considered the flexibility that is appropriate for both IFSPDU, and their proposed sub-category of IFPSMP, with regard to both composition and labelling. We refer you to the INC submission and consider that these proposals will provide a more effective approach than that outlined with in the consultation paper.

DGC does not support trade restrictions being applied to all IFPSDU. In our view trade restrictions should only be applied to the highly specialised products which are not suitable for use by healthy infants.

Careful consideration needs to be given to the handling of scientific demonstration of nutritional adequacy such that unwarranted additional costs are not imposed on industry (refer to response to Question 13 below).

We consider that it is appropriate for products that contain no/low lactose to be able to include a statement on their labels regarding the malabsorptive conditions for which they are suitable. These products, in our view, should ideally be categorised as IFPSDU as they are not ideal for long term consumption by healthy infants. This approach would provide greater consistency with the labelling provisions proposed by INC for IFSPDU than requiring "Lactose-free," or, "Low-lactose," to be part of the name of products as is currently the case.

If there are other issues that FSANZ should consider including within the scope of this Paper, FSANZ requests details and the reasons why FSANZ should consider them to be provided.

Transition arrangements

Regarding the implementation of changes from P1028, DGC reiterates its support for INC's request for a five-year transition period, with additional stock in trade provisions, The significant number, scope and complexity of changes proposed warrants a transition period of this length to permit sufficient time to allow for the necessary planning, reformulation, packaging implementation and gaining any regulatory permissions required for new or amended formulations (e.g. exemptions from New Zealand standards for export products; Pharmac listings).

Further, it is strongly recommended that the current standard and any revised Standard should run in parallel over the transition period.

Interim change to the definition of Novel Foods

DGC supports FSANZ's proposal not to proceed with a review of novel foods and nutritive substances specific to IFP under P1028. So saying, given the time that has elapsed since the initiation of P1024 and the current ambiguities arising from the definition of novel foods, DGC recommends that the definition of novel foods is amended as soon as possible to make it clear that the population for which the novel food is intended must be taken into consideration. For example, this could be achieved by addition of text shown in red in 1.5.1-2 (1):

> Novel food means a non-traditional food for the intended [consumer] population that requires an assessment of the public health and safety considerations having regard to:..."

Given the concern raised by FSANZ in CP2 regarding the trend towards wider use of plant proteins we think it would provide greater clarity if the definition of novel foods was amended such that the intended population for food concerned is taken into account. We ask that consideration is given to how this can be done outside of P1028, for example possibly as a technical amendment. Please see additional comments on this topic in the body of our submission above.

Specific questions

Specific questions have been asked in certain sections of this paper and are listed below. As above, supporting detail in submitted responses will assist FSANZ in ensuring that proposed options are based on the best available evidence.

Questions related to the use of novel foods in infant formula products, food for infants and formulated supplementary food for young children (section 2.2)

1) To manufacturers, please provide information on whether the substances listed in Table 5 are used in infant formula products, food for infants and formulated supplementary food for young children.

   We are not aware of any use of these substances in infant formula products or formulated supplementary foods for young children. We are not involved with infant foods other than formulas so cannot comment on these.

Questions related to definitions for specialised infant formulas (section 4.3)

2) Is a definition of soy-based formula needed for the purpose of food additive permissions and aluminium requirements? If so, is the current definition appropriate? If you consider the current definition is inappropriate, please explain why and provide supporting detail and data, where available.

   A definition for soy-based formula is not needed as, 'soy-based formula' is self-explanatory.

   We also take this opportunity to remind of INC's position regarding aluminium. INC noted in its Submission on Consultation Paper 1 that Standard 2.9.1 should align with Codex which does not include limits on aluminium as a contaminant metal in infant formula (Codex STAN 193-1995).

3) Is a definition of pre-term formula needed for the purpose of food additive permissions and aluminium requirements? If so, is the current definition appropriate? If you consider the current definition is inappropriate, please explain why and provide supporting detail and data, where available.

   We support a definition of pre-term for the purpose of food additive permissions and any compositional and/or contaminant requirements specific to pre-term formulas.

   With regard to aluminium as a contaminant we flag INC's position regarding aluminium included in its Submission on Consultation Paper 1: that Standard 2.9.1 should align with Codex which does not include limits on aluminium as a contaminant metal in infant formula (Codex STAN 193-1995).

4) Are definitions needed for any of the new terms proposed to be introduced as conditions for the use of food additives in CP1, such as gastrointestinal reflux, gastrointestinal disorders, or impairment of the gastrointestinal tract, inborn errors of metabolism etc.?

   Our view is that definitions are not needed as these terms used for these conditions are generally well understood. We also note these terms are not defined in EU regulations.

Questions related to products for metabolic, immunological, renal, hepatic and malabsorptive conditions (section 5.5.2)

5) To health professionals: Is there any evidence that current practice in relation to low lactose products or the manganese content of products for metabolic, immunological, renal, hepatic and malabsorptive conditions pose a health concern or risk? If you consider that there is a health concern or risk, please provide relevant details and data, where available.

   N/A to DGC.

6) To industry submitters: How many and what types of low lactose IFPSDU are on the market? And what is their maximum level of lactose? Please provide supporting detail and data, where available.

   DGC does not produce or distribute low lactose IFPSDU so is not in a position to comment.

Questions related to products for specific dietary use based on a protein substitute (section 5.5.3)

7) To industry submitters: What types of partially hydrolysed IFP are on the market? And what is their maximum level of protein denaturation? Are any on the pharmaceutical benefits schemes in Australia or New Zealand? Please provide supporting detail and data, where available.

   DGC does not produce or distribute partially hydrolysed IFP so is not in a position to comment.

8) To health submitters: You have told us that partially hydrolysed IFP are not efficacious in preventing allergy; are they useful in the dietary management of allergy? Please provide supporting detail and data, where available.

   N/A to DGC.

Questions related to specific compositional requirements (section 5.5.3)

9) Regarding options for the regulation of molybdenum and chromium, which option do you prefer and why? Please provide supporting detail and data, where available.

   This question relates to the minimum and maximum for chromium and molybdenum specified in the Food Standards Code for IFP based on a protein substitute (2.9.1-15(2)(e).

   The choices listed in CP3 are:

   1. Retain status quo for protein substitute formula
   2. Permit voluntary addition within compositional limits to be met naturally and/or through addition for all IFPSMP

3. Permit voluntary addition without any compositional limits for all IFPSMP
4. Delete the requirement altogether which then serves to prohibit addition of molybdenum and chromium which are classified as nutritive substances, and their permitted forms in S29-7 become redundant.

DGC supports option 3.

Option 1 is not supported as the current IFPSDU sub-category of protein substitutes will not be maintained under the proposed revised framework. Options 2 and 4 are not supported as both Codex Stan 72-1981 Section B and EU Regulation 2016/128 permit addition of chromium and molybdenum but do not set a mandatory minimum across all IFPSDU.

10) To industry submitters: What type of products contain MCT oil? For what purpose and at what levels? Please provide supporting detail and data, where available.

DGC does not produce IFPSDU containing MCT oil so is not in a position to comment.

11) To health submitters: Are there any health concerns from current practice using products that contain MCT oil? Please provide supporting detail and data, where available.

N/A to DGC.

Questions related to scientific evidence of purpose for IFPSMP (section 5.6.1)

12) To industry submitters: Do infant formula manufacturers hold scientific evidence that supports the purpose of Division 4 products, including for reflux, colic, diarrhoea, and similar products (i.e. for less serious conditions)?

Yes. While we do not currently produce or distribute IFPSDU products in ANZ our Science team monitors international literature relating to infant nutrition. They confirm that at least some of the companies distributing ISPSDU products in ANZ, including for conditions such as colic and constipation, hold scientific data to support the stated purpose of these IFPSDU products. This scientific data can include verification of compositional modifications and/or clinical studies ranging from observational studies looking at the management of symptoms through to double blind, randomised controlled trials tracking growth, tolerance and/or incidence and severity of symptoms.

The sub-category of IFPSDU proposed by INC for serious conditions (tentatively called IFPSMP) are generally listed on the Australian PBS and New Zealand's Pharmac. In order for these products to be considered for these schemes, companies are required to provide scientific evidence to support their use in the management of a particular medical condition, disease or disorder (or in some cases for more than one application). This scientific evidence is then assessed by the clinical experts within these agencies before the products are made available through these schemes. It is our view that these clinical experts are better qualified to assess the scientific evidence available than ANZ

Food Standard Code enforcement agencies and that duplication of these assessment processes should be avoided.

13) If so, what type of scientific evidence is held by companies and what is its strength of evidence?

The strength of the evidence available in scientific literature varies, but we are aware that some IFSPDU products have been studied via multiple clinical trials.

So saying we think it is very challenging to set regulatory criteria for the strength of scientific evidence appropriate for IFPSDU products. The scientific evidence that is appropriate for different types of IFPSDU varies considerably, for example for IFSPDU for lactose malabsorption it is appropriate that a very low lactose and galactose content is confirmed. For other types of IFSPDU a comprehensive range of clinical trials might be appropriate. The design and conduct of clinical trials is a highly specialised and complex endeavour, especially in the area of infant nutrition with the added requirement of carefully ensuring that breastfeeding is not discouraged or reduced through conduct of such trials. It is not simply a matter of whether a (or multiple) clinical trial has been conducted but the appropriateness of the design, the conduct and review of data of such trials. Other considerations include:

- Size of study required to generate meaningful results
- Choice of reference: should this be a breast-fed group, a group fed an alternative formula, or in the case of some IFPSDU a medicated breast-fed of formula fed group?
- Internationally there is no consistency in the reporting of the outcomes for constipation, colic, diarrhoea, regurgitation, etc. For example, for constipation a common stool chart may be used as a reference, but in some studies stool outcomes are reported by parents, in others by a physician or a study staff member.

In our experience the guidance available internationally, for example on the conduct of clinical trials, is continually increasing the bar in this regard. ESPGHAN published very good guidance on the Nutritional and Safety Assessment of Breast Milk Substitutes and Other Dietary Products for Infants in the early 2000's (Aggett P.J. et al, 2001 and 2003). For ANZ companies or for trials taking place in ANZ, registering trials on the ANZ Clinical Trial Registry is highly encouraged (https://www.anzctr.org.au/Faq.aspx). This also provides a good resource and more comprehensive support material on the conduct of clinical trials is provided by the US Clinical Trials.gov (see https://clinicaltrials.gov/ct2/manage-recs/resources).

In recent years there has been increasing political pressure on paediatric associations and academic institutions not to interact with, and not to accept support from, commercial providers of breast milk substitutes. This is based on the assumption that such interaction would lead to diminished promotion and support of breastfeeding. The very recent publication by Boyd et al raises a number of concerns in this vein about

infant formula studies. This is a double-edged sword as the more difficult and costly it is to conduct research studies the less that can realistically be done.

At DGC we have a Scientific Advisory Group of pre-eminent international infant nutrition experts to provide guidance on the conduct of our formula research activities, including how to apply best practice and steps that can be taken to eliminate bias. For products that have long been established on the market the initial evidence base is likely to be less robust than for newer products unless the companies concerned continue to invest in research. Our recommendation to FSANZ is to focus on increasing transparency rather than developing guidelines.

Our view is that scientific evidence relating to all IFP should be readily available to paediatricians and other health professionals which allows them to make their own assessment of the strength of evidence and suitability for specific applications. It is medical practitioners that provide advice to caregivers on the most appropriate product(s) for their situation. The Important Notice on all IFP labels must include, "Before you decide to use this product, consult your doctor or health worker for advice." In order to be best placed to do this health professionals need easy access to the science available regarding these products. Further, collaboration between the medical community and industry is vital to drive product innovations and improvements which can significantly improve the quality of life of infants, particularly those with certain diseases and conditions. This view is supported by leading paediatric associations in Europe (Bognar et al, 2020):

> "Public–private research collaborations for improving and evaluating pharmaceuticals, vaccines, medical devices, dietetic products, and other products and services for children are actively encouraged, provided they are guided by the goal of enhancing child health and are performed following established high standards."

Providing information via internet portals specifically catering for health care professionals provides ready access to the scientific evidence available. It should be noted that this information is not static but rather being added to as more information is generated.

For IFPSDU/IFPSMP that are available via Pharmac in NZ, or listed on the Australian PBS, regulators have the added assurance of suitability provided by the pre-listing assessments conducted by clinical experts within these organisations.

In conclusion, we support the principle that IFP, including IFPSDU, are formulated in accordance with generally accepted scientific evidence but recommend against FSANZ developing guidance on the strength of evidence required. We think a better and more pragmatic approach is to encourage infant formula companies to provide ready access for health professionals to the scientific information they have available to allow them to assess suitability for particular applications.

Questions related to extension of use beyond infancy for IFPSMP (section 5.6.2)

14) What is the maximum labelled age on products suitable for use beyond infancy? What are the parameters that indicate when the product is no longer appropriate?

N/A to DGC; DGC does not manufacture or distribute specialised infant formula that are intended for use only under medical supervision.

DGC notes that some health authorities promote the use of standard IFP beyond 12 months of age and this is not accommodated in regulation. We do not consider it necessary to accommodate the use of IFPSDU beyond infancy in regulation, especially as these products are intended to be, or in the case of those products for more high risk situations, must be used under medical supervision. The use of these products beyond infancy can therefore be left to the discretion of medical practitioners.

Question related to labelling of IFPSMP (section 5.7)

15) Do you support FSANZ's preliminary views for IFPSMP labelling? Why or why not? Please provide supporting detail and data for your position, where available.

No DGC does not support the FSANZ preliminary views on the labelling of these products.

INC has looked carefully at the FSANZ proposals for labelling of IFPSDU and the current labelling requirements for these products. DGC supports the INC recommendations on labelling for IFPSDU and their proposed sub-category of IFPSMP. More flexibility is required for this sub-category to assure continuity of supply of these specialised products.

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