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To FSANZ: submissions@foodstandards.gov.au.

SUBMISSION

FSANZ Proposal P1028
Infant Formula

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Level at which submission authorised: authorised by GM Strategy and Commercial

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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 approximately 20 international markets via its marketing partner and joint venture relationships. The markets are located primarily in Asia, Europe and Oceania.

Introduction

DGC believes that breastfeeding is the normal and best way to feed infants with numerous benefits for both mothers and infants. However, when an infant is not given breast milk the only suitable and safe alternative is an infant formula. DGC strives to contribute to the provision of best possible nutrition for non-breast fed infants through its product development, research, manufacturing practices, quality assurance programs and input into policy and regulatory developments.

DGC appreciates the opportunity to consider the issues and preliminary views proposed in the consultation paper for Proposal P1028, and to provide feedback to Food Standards Australia New Zealand (FSANZ) relating to the Consultation paper on the Regulation of Infant Formula. In order to ensure continuous improvement of infant formula and avoid unnecessary regulatory burden, it is critical that policy and regulatory instruments implemented strike an appropriate balance between restrictive requirements applied in order to protect public health and flexibility for innovation. DGC favours use of a scientific, evidence-based approach in conjunction with risk analysis to inform and achieve this balance.

DGC is an associate member of the Infant Nutrition Council (INC) with representatives on the INC Scientific and Regulatory Committee. DGC has actively participated in the preparation of the INC submission which it supports. Additionally, DGC is a member of the Dairy Companies Association of New Zealand (DCANZ), and supports the points made in the DCANZ submission.

Given the very comprehensive submission prepared by INC, the scope of DGC's submission is restricted to areas of particular interest or concern to DGC only. *Some of these are covered in the Commercial in Confidence information provided as a separate annex to this submission.*

Specific Comments

1. **Alignment with Codex STAN 72-1981 and International Harmonisation**

As an overarching principle DGC supports harmonisation of national standards with relevant Codex standards as a means of reducing non-tariff trade barriers, unless there is strong scientific justification for a different approach. Much closer alignment of FSC 2.9.1 with Codex STAN 72-1981 Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants will greatly assist with harmonisation of FSANZ requirements with those applied by many other national jurisdictions particularly in the Asia/Pacific region which is so economically significant to Australia and New Zealand.

DGC notes that the EU has recently updated the regulatory requirements that cover infant formula composition in the EU (EU Directive 2016/127 was promulgated in February this year and comes into force in February 2020[1]). It is recommended that the assessments conducted by EFSA prior to this update should also be considered in relation to this review particularly with respect to application of higher minimum requirements for vitamin D and iodine. The new ranges applied for these nutrients in 2.9.1 should provide flexibility to allow product formulation in compliance with these higher minimum levels.

However, DGC does not support EU's move to mandate the addition of DHA. DGC concurs with FSANZ preliminary view regarding DHA and notes that the mandating of DHA has been contentious in the EU with some leading experts opposed to DHA addition without any requirement for AA addition. Koletzko et al, 2015[2], state, "We consider it premature to accept the use of formula for infants from birth with the addition of 20-50mg/100kcal to infant formula [as applied in new EU Directive 2016/127)] without addition of ARA[3] in the absence of confirmed data on the suitability and safety from a thorough clinical evaluation of this novel approach." AA is the more expensive of these two long chain polyunsaturated fatty acids so any consideration of mandating for both would require very careful consideration of the potential benefits versus cost. DGC supports in principle the retention of a voluntary permission for DHA in FSC 2.9.1., but with further review and consideration of ratio of omega-6 to omega-3 (C>=20) series fatty acids requirements (or alternatively AA to DHA ratios) applied when DHA is added.

[1] Except for hydrolysed formula which have an additional year until Feb 2021 to comply.

[2] Koletzko et al, 2015. Should infant formula provide both Omega-3 DHA and Omega-6 Arachidonic acid? Ann Nutr Metab 2015; 66:137-138 DOI: 10.1159/000

[3] Abbreviation used in this reference for arachidonic acid (abbreviated as AA in FSANZ SD1 to this consultation).

2. **Calculation of protein: nitrogen conversion factors**

DGC supports use of the nitrogen conversion factors (NCF) of 5.71 for soy and 6.38 for milk protein as the scientifically correct factors for these protein sources. So saying, DGC can accept the use of 6.25 as the NCF for infant formula based on milk protein in alignment with Codex STAN 72-1981 but considers that use of 6.25 for soy protein is inappropriate given that this overestimates the protein content by 9%. We suggest that use of either 6.38 or 6.25 for milk proteins is permitted given the difference of 2% between these two factors has very little impact on infant formula composition stated per 100ml as demonstrated in the INC submission.

3. **Amino acid content**

DGC agrees with the FSANZ's preliminary view to align the minimum requirements for isoleucine, lysine, threonine, tryptophan and valine with Codex STAN 72-1981. But, in addition, DGC considers that it is important that minimums applied for the sulphur containing amino acids methionine and cysteine are also aligned, including the flexibility to sum the levels of these amino acids for compliance purposes as set out in footnote 3) in this Codex standard.

4. **Trans Fatty Acids**

DGC contends that the current Trans Fatty Acids (TFA) limit in Standard 2.9.1, set at 4% of total fatty acids is already well aligned with the maximum of 3% applied in the CODEX STAN 72-1981 when the different definitions applied to TFA by the Food Standards Code and Codex are taken into account. The INC submission provides more details on the differences in these definitions. Given these differences it is not appropriate to apply the TFA limit applied in CODEX STAN 72-1981 in FSANZ Standard 2.9.1. Further, if this proposed change were to be implemented, this would further limit the amounts of milkfat that can be incorporated into infant formula products as an unintended consequence.

5. **Phospholipids**

DGC considers that there is no strong justification to set an upper level for phospholipids. There are no specific safety concerns or evidence of adverse effects in infants and nor is there any evidence of market failure in ANZ where no phospholipids limit are currently applied.

If an upper limit is applied this should be aligned with Codex STAN 72-1981 which applies a limit of 2g/L as does the new EU Directive (EC 2016/127) covering infant and follow-on formula.

6. **Vitamin D**

DGC supports the FSANZ proposal to retain the current minimum level for vitamin D but recommends that the maximum for vitamin D is increased to align with the maximum of 0.72ug/100kJ as adopted by the EU in EC Directive 2016/127. The EU has implemented a higher minimum and maximum for vitamin D compared to Codex STAN 72-1981 based on the scientific evaluation conducted by EFSA. There is currently only a narrow common range between Codex STAN 72-1981 and the EU regulations which is too tight to allow product formulation and manufacture in compliance with both sets of requirements. DGC therefore recommends alignment with the EU maximum requirement to promote broad international harmonisation. If the Standard 2.9.1 requirement for a maximum for vitamin D stays aligned with Codex STAN 72-1981 this could have significant implications for products imported from the EU, including infant formula products for special dietary use.

7. **Folic acid**

DGC notes that the new EU Directive specifies requirements as ug-DFE[4]. The minimum level applied of 15 ug DFE is the same as the minimum folic acid level specified in Codex STAN 72-1981. DGC advocates alignment with the folic acid minimum and GUL specified in Codex STAN 72-1981, and retaining use of ug folic acid rather than ug DFE, as the best approach to achieve international harmonisation for this nutrient. .

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8. **Iodine**

The levels of iodine in milk are influenced by on-farm practices and as such are subject to significant variation. The minimum for iodine applied by Codex STAN 72-1981 is twice the minimum currently set in 2.9.1. The new EU Directive has set minimum iodine content 3 times the current FSANZ minimum but with a lower upper limit setting a tight range that will be challenging to comply with. DGC therefore supports FSANZ preliminary view to increase the minimum and upper limit for iodine to those set by Codex STAN 72-1981 and to apply a GUL rather than a maximum consistent with this Codex standard.

9. **L-carnitine**

We wish to express concern regarding the feasibility of achieving the proposed L-Carnitine maximum of 0.8mg/100kJ due to natural milk levels. This proposal is not aligned with Codex which does not include a maximum level.

10. **Choline**

DGC supports the proposal to mandate a minimum choline level of 1.7mg/100KJ, and setting an upper limit of 12mg/100kJ. It is however important that this upper limit is specified as a GUL in alignment with Codex, and not as a maximum.

11. **Nutritive Substances and Novel Foods**

DGC considers Standard 2.9.1 should be included within the scope of Proposal P1024 and its framework going forward with additional considerations relevant to the infant population. DGC therefore requests that the DGC submission on P1024 is read in conjunction with this submission on P1028.

12. **Food Additives and Carry-over**

DGC supports permission for all food additives outlined in Codex STAN 72-1981 Section 4, as well as CAC/GL 10-1979, whether intentionally added during the production of the finished product or carried over into infant formula from raw materials or ingredients. This is important to avoid trade barriers where additives are permitted to be carried over from raw ingredients under Codex, but not permitted for use in infant formula products in the Food Standards Code. Even more importantly, without this carry-over provision the quality of some key ingredients, for example ingredients susceptible to oxidation like polyunsaturated fats could be compromised resulting in a reduction of product quality.

[4] Dietary folate equivalent: 1ug DFE = 1ug of folate from food = 0.6ug of folic acid from formula

13. **Proposal for standard scoop size**

DGC does not support the proposal for a standard scoop size. A standard reconstitution ratio can be applied, for example one scoop added to each 50ml water, but it is not possible to use a standard scoop volume due to different weights of powder required (this varies according to product formulation) and due to the different bulk densities of different products which vary with ingredients used as well as with different manufacturing set-ups.

14. **Labelling considerations**

The INC submission provides very comprehensive comments on labelling considerations and our comments here are limited to some considerations and examples that DGC feels may be helpful to further inform discussion. In relation to the following questions raised in the consultation documents:

Q3.1 Should claims about specific ingredients be permitted on packaged infant formula?
Q3.4 Should it be mandatory to declare all or only specified macronutrient subgroups in the nutrition information statement? If so, which macronutrient subgroups and for what reason? For example, any subgroup of protein (whey, casein, alpha-lactalbumin etc.), or specific proteins (only whey and casein).

Yes, DGC considers that claims about specific ingredients/nutrients should be permitted on packaged infant formula. On-pack information is a key source of accurate and credible information on infant formula products. It is important that sufficient information is provided on pack to enable caregivers to make an informed formula choice. A current example of a key point of differentiation between products currently available in ANZ is whether or not the long chain polyunsaturated fatty acids AA and DHA are added and the levels present where added. In our view it is not sufficient to just state the ingredients used to fortify the products with these fatty acids in the ingredient list. It is important that levels present are stated to allow comparison between products and to avoid consumers being potentially misled about the levels present. We also contend that it is helpful to state that these ingredients are added on front of pack.

The EU approach serves as an interesting example. Under EC Directive 2006/141 (in force until 2020) the following statements are permitted:

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The new EC Directive 2016/127, which comes into force in 2020, takes a slightly different approach and states:

Under Article 7 **Specific requirements for nutrient declaration**:

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And Under Article 9 **Statements related to lactose and docosahexanoic acid (DHA):**

3. The
DHA (as
before 22

DGC would like to highlight the following key aspects of the approaches taken in the EU:

a. Nutrient declarations can include amounts of components of protein, carbohydrate or fat, whey protein/casein protein ratio; the amount of any optional ingredient added (like nucleotides) covered in Annex II; and the amount of any ingredient proven to be suitable for use in infant formula as per the criteria set out in Article 3 which covers suitability of ingredients.
b. Nutrient content claims are permitted for DHA under EC 2006/141 which permits voluntary DHA addition. Once DHA addition becomes mandatory in 2020 nutrient content claims for DHA will remain permitted (with a qualifying statement advising it is required in all infant formula) for up to a further five years as a transitional measure.

Q3.6 If nutrition information about macronutrient subgroups is provided, is there potential for caregivers of formula-fed infants to be misled about the nutritional value of formula?

DGC suggests that the approach taken by the EU on inclusion of information on macronutrient sub-groups in the nutrition information panel could be considered as a possible model. There are restrictions about the additional nutrients that can be listed in the nutrition information but with flexibility to allow infant formula producers to include information on nutrients most relevant to the product concerned.

Q3.9 Do stakeholders believe that the names of ingredients should align with nutrient declarations in the nutrition information statement?

It is not practically possible to align ingredient names with nutrient declarations. For example:

a. Fat is typically sourced from a number of different ingredients. In the case of milk-based formula most polyunsaturated fatty acids.

b. Calcium is also present in most dairy ingredients and can be present in permitted forms of vitamins such as calcium ascorbate and calcium pantothenate in addition to permitted forms of calcium added to achieve total calcium content from all calcium containing ingredients stated in the nutrition information panel.

Q3.16 Is nutrition information on infant formula products used by caregivers to inform their purchase decisions?

DGC believes that nutrition information on infant formula products should be recognised by caregivers as a reliable, credible and useful source of information to inform their purchasing decisions. But this can only be the case if the information provided is adequate to allow the key differences between products to be apparent to caregivers.

15. **Implementation and transitional arrangements**

These were not raised by FSANZ in Feb 2016 consultation paper. DGC foresees potential roll-over of changes to be implemented for infant formula to follow-on formula (outside of the scope of this consultation) that will need to be taken into account prior to implementation. It is also critically important that any transitional arrangements allow adequate time for any formulation and/or labelling changes to be undertaken in a composed manner. DGC requests that there is consideration and consultation of these issues prior to gazettal of revised requirements.