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To FSANZ: submissions@foodstandards.gov.au.

SUBMISSION

FSANZ Application A1173 Call for Submissions May 2019

Minimum protein in follow-up formula

Submitter:

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Level at which submission authorised: authorised by General Manager 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 over 20 international markets via its marketing partner and joint venture relationships. The markets are located primarily in Asia, Europe and Oceania.

Introduction

DGC welcomes amendment of the Australia and New Zealand Food Standards Code ('the FSANZ Code') to permit lower protein levels in follow-on formula than the current provisions. This is in line with the international trend to reduce protein levels in these products motivated to shift the physiological outcomes of formula-fed infants closer to those of breast-fed infants.

We appreciate the opportunity provided by this Call for Submissions to make comments on the conclusions reached by FSANZ and the proposed drafting for implementation. DGC is an associate member of the Infant Nutrition Council (INC) and has participated in the preparation of the INC submission. This submission is therefore brief and serves to highlight the aspects of particular concern for DGC.

Key points

1. **Conclusions reached are limited to certain specific proteins only.** FSANZ assessed the application and concluded that the lower protein levels evaluated by the applicant were safe and maintained normal growth and development of older infants. FSANZ concluded that an amendment for the FSANZ Code to permit protein levels from no less than 0.45g/100kcal to no less than 0.38g/100kJ should apply to milk-based follow-on only and not for soy-based formula. DGC supports both these conclusions, based on the supporting evidence presented in the application, but we are very concerned that there were no conclusions drawn for other protein sources.
2. **The non-coverage of all protein sources has potential to create a regulatory gap:** if the conclusions reached by FSANZ are reflected in regulatory requirements this will create a regulatory gap, a void, a legal no man's land, with respect to the protein sources not covered. This would be irresponsible in our view, creating issues for compliance, enforcement and future innovation.
3. **Proposed drafting for implementation confirms regulatory gap.** The INC submission details fully the regulatory gap created by the drafting proposed by FSANZ. This proposed drafting is more aligned to the EU regulatory framework which is very different from the FSANZ framework. The EU regulations prescribe specific protein sources that may be used in infant and follow-on formulas. This approach is not appropriate for the FSANZ regulatory framework which is more aligned to the Codex approach. Similar to Codex, the FSANZ Code permits a wide range of possible protein sources in infant formula products *providing* the end infant formula products made available for consumption are, "nutritionally adequate to serve either as the sole or principal liquid source of nourishment for infants, depending on the age of the infant." This is stated in the definition for infant formula products within the FSANZ Code which serves to emphasize the fundamental requirement embedded in the Food Acts applicable in Australia and New Zealand that foods must be safe and suitable for their intended applications.

Given the current regulatory framework it is imperative that provisions in the FSANZ Code, relating to protein minima for these products, are aligned with their definition, and not limited to a selection of specific protein sources as per the drafting proposed by FSANZ in the Call for Submissions. This drafting creates a regulatory gap as per our concerns outlined above. Protein sources, other than milk-based and soy, need to comply with the maximum protein level specified but are left in a void with no minima specified.

4. **Alignment with Codex:**

DGC seeks international harmonization of requirements and for the FSANZ Code to be aligned as close as possible with Codex requirements for infant formula products. The draft revised Codex requirements for follow-up formula for older infants (held at step 7) sets lower and upper protein limits that cover all permissible sources, not just an exclusive list of specific proteins.

5. **Baby nuts and novs:** The discussion on the so-called, “baby nuts and novs,” is still in progress as part of FSANZ proposal P1028 and subject to further consultation. It is important that any potential changes to the FSANZ Code from the work being undertaken on this proposal is not pre-empted in the drafting for implementation of changes as a result of this application.
6. **Drafting options:** We recommend that serious consideration is given to Option A below put forward by INC as preferred option:

<p>Option A</p> <p><i>Based on current provisions of the Food Standards Code 2.9.1—9:</i></p>
<p>(2) Follow-on formula must have:</p> <p>(b)(i) a protein content of no less than 0.38 g/100 kJ and no more than 1.3 g/100 kJ;</p> <p>(ii) despite subsection 2(b)(i), a protein content of no less than 0.45 g/100 kJ applies unless there is appropriate data to support no less than 0.38 g/100 kJ.</p>

Option A fits with the status quo while making it clear that products with protein levels between the current and the new minimum need appropriate supporting evidence.

Options B and C present alternative ways of addressing the regulatory gap identified.

<p>Option B</p> <p><i>Based on proposed texts in page 15 of the Call for Submissions:</i></p>	<p>Option C</p> <p>Based on current provisions of the Australia New Zealand Food Standards Code:</p>
<p>(b) the following protein content:</p> <p>(i) for a milk-based formula—a protein content of no less than 0.38 g/100 kJ and no more than 1.3 g/100 kJ; and</p> <p>(ii) for a formula based on other edible food constituents of animal or plant origin—a protein content of no less than 0.45 g/100 kJ and no more than 1.3 g/100 kJ;</p>	<p>(b) a protein content of no less than 0.45 g/100 kJ and no more than 1.3 g/100 kJ; whereas for a milk-based formula—a protein content of no less than 0.38 g/100 kJ and no more than 1.3 g/100 kJ.</p>