DAIRY COMPANIES ASSOCIATION OF NEW ZEALAND

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DAIRY COMPANIES ASSOCIATION OF NEW ZEALAND

SUBMISSION TO: FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

ON

Proposal P1028 Review of Infant Formula: Consultation Paper No.2 2021

2nd September 2021

1. Summary

1.1 The Dairy Companies Association of New Zealand (DCANZ) appreciates the opportunity to consider and provide comment on the issues and preliminary proposals raised in this Proposal P1028, second consultation paper in 2021, in light of its relevance and importance to our member companies. DCANZ member companies collectively account for more than 98% of the milk processed in New Zealand and the vast majority of New Zealand's dairy exports (including infant formula products).

1.2 Breast feeding is acknowledged as the normal and preferred way to feed infants. However, when breastmilk is not available for an infant, the only suitable and safe alternative is a scientifically developed infant formula.

1.3 To ensure the best possible nutrition for non-breastfed infants, policy and regulatory instruments must ensure a balance between restrictions on use and formulation in order to protect public health and providing flexibility and incentive for innovation to enable continuous improvement of infant formulas.

1.4 This DCANZ submission on Proposal P1028 submission is focused on Infant Formula issues only at this time.

1.5 DCANZ is generally supportive of the points raised in the Infant Formula Council's (INC) submission on this P1028 Consultation Paper.

The contact for this submission is:

[redacted]

2. General Comment

DCANZ would like to highlight points made within the INC Submissions Executive Summary, with the addition of comment specific to DCANZ, as follows:

Protein

2.1 DCANZ supports a protein range of 0.43 –0.72 g/100kJ for infant formula (based on the equivalence factor of 1 kcal = 4.18 kJ), noting that this range should not be applied only to cows' milk-based formulas. Rather we agree with INC that this range should be applied to all milk-based infant formula.

2.2 We are supportive of the technical correction of the FSANZ protein minimum, as it allows harmonisation with Codex and EU recipes, particularly for low protein products. We also support the maximum being stated to 2 significant figures.

2.3 DCANZ supports the INC suggestion that consideration be given to the potential for use of plant proteins other than soy for the future. "FSANZ may wish to consider adding a footnote similar to footnote 5 in Codex STAN 72-1981 which highlights that other minimum values may need to apply for formulas based on other non-milk proteins. Such a footnote signals that the appropriate protein minimum needs consideration for plant proteins other than soy."

2.4 In principle, DCANZ supports INC position of not supporting FSANZ's proposed approach to prescribe permitted protein sources. DCANZ has a general concern regarding positive lists as they tend to inhibit innovation and inhibit alignment with emerging nutritional science.

2.5 Whilst INC notes that new sources of protein are already required to be approved through the pre-market assessment process INC also acknowledges that greater clarity around what is considered 'novel/nutritive substance' is needed. It is our understanding that Proposal P1024 was to address this issue and DCANZ encourages resurrection of this Review.

2.6 All 'new' protein sources (not previously used for infant formula products) need to be carefully assessed prior to use in infant formula products but such assessment should be graduated based on the potential risks posed. Milk protein sources, for example a different degree of concentration for whey protein concentrate or use of specific whey protein fractions, are generally at the lower end of such a graduated risk profile. DCANZ is opposed to a prescribed permitted protein list for specific mammalian milk protein sources. However, DCANZ could support a permitted prescribed protein approach for non-mammalian milk protein (e.g., new plant protein) for use in infant formula, at least until P1024 is progressed. This would provide further clarity that such protein sources require a pre-market assessment by FSANZ.

Nitrogen Conversion Factor (NCF)

2.7 The NCF used, determines the amount of protein source required to achieve the regulated protein minimum. New Zealand infant formula manufacturers have been operating using the two alternative NCF's of 6.38 and 6.25 for milk-based formulas, since the 2007 revision of the Codex STAN 72-1981 which adopted the use of the factor 6.25 for infant formula products.

2.8 The FSANZ consultation document proposes two options: 1) Adoption of 6.25 and alignment with the Codex STAN 72-1981 NCF footnote for all infant formula products or 2) Adoption of all three NCFs (5.71, 6.25, 6.38). Currently DCANZ prefers option 1), with modification to reflect the full Codex IF Standard footnote, in alignment with INC position.

2.9 DCANZ appreciate that FSANZ has attempted to find a flexible approach in accommodating previous industry and stakeholder feedback in Option 2. This approach allows choice for industry to harmonise with international standards which use a NCF of 6.25 for infant formula, or to utilise science-based conversion factors i.e., 5.71 for soy based infant formula, or 6.38 for dairy-based infant formula, the latter also reflecting FSANZ status quo for dairy based infant formula.

2.10 DCANZ can support the flexibility outlined for the use of 5.71 or 6.25 for soy based infant formula (with appropriate modification of the minimum protein level, and labelling consideration), and flexibility in the use of a NCF of 6.38 or 6.25 for any dairy formula including whey-based formula. DCANZ does not support whey-based infant formula being distinguished from other dairy infant formula in the choice of NCFs as the Option 2 proposal currently outlines.

2.11 The rationale FSANZ has applied in distinguishing NCFs in whey-based from other dairy formula is not clear. Such an approach was not outlined in the 2019 JEMNU Expert Panel recommendations. We refer to a recent publication by Elgar et al (2020) with a specific focus on a range of commercial whey products using different methods for protein determination. This continues to highlight that an NCF for whey ingredients is similar to other dairy products. DCANZ considers that while Option 2 has the ability to support harmonisation, if this Option 2 is to be further progressed, that either 6.38 or 6.25 should be able to be used for all dairy formula, regardless of if whey-based or other dairy formula.

2.12 Furthermore, DCANZ considers the FSANZ summary of the 2019 JEMNU Report recommendations incomplete. Two options were proposed by JEMNU, with the same NCF for soy regardless of which option was selected. The report recommendations were dependent on the definition of protein for infant formula: defined only as amino acids, or a more holistic view of total protein. DCANZ continues to support a holistic view of total protein, acknowledging that dairy protein has total nutritional benefits not just its protein components individually.

2.13 In summary, DCANZ considers there is insufficient scientific basis to support FSANZ's approach of distinguishing whey based, from other dairy formula in the choice of NCF. If FSANZ was to proceed with Option 2, DCANZ would only be supportive of this approach if whey vs. other dairy formula NCFs were not distinguished. Labelling and minimum protein levels would need to be worked through. Thus, at this stage as currently drafted, DCANZ considers Option 1 more appropriate. In addition, we recommend Option 1 is updated to fully reflect the Codex IF Standard NCF footnote.

Specific Compositional Requirements (as contained within the INC submission)

2.14 "Maintaining the current minimum linoleic acid (LA) level but expressing this on an energy basis as 90 mg/100kJ is supported by INC which allows for the lower end of the LA:α linolenic acid (ALA) ratio of 5:1 to be achieved.

2.15 INC supports docosahexaenoic acid (**DHA**) remaining optional together with the requirement of DHA being no higher than arachidonic acid (**AA**) when added. However, the guidance upper limit (**GUL**) should be increased from 0.5 to 1.0% of fat to 14 mg/100kJ.

2.16 In relation to total phospholipids, we consider a phospholipid maximum to be unnecessarily prescriptive. This is due to a lack of evidence of safety concerns and the absence of market failure with status quo provisions. Nonetheless, we can support Option 1 (restrict the phospholipids content to 2 g/L) to align with Codex with modification to reflect this as a GUL. We similarly prefer alignment with Codex units which expresses total phospholipids on a mg/100kcal basis.

2.17 The maintenance of the current restriction on medium chain triglycerides (**MCT**) is not supported by INC and is not aligned to Codex or EU. If this is to remain, it should be clarified as relating only to refined MCT oil".

2.18 DCANZ supports the issues raised by INC concerning the micronutrients:

- Iron,
- Iodine,
- Selenium,
- Fluoride,
- L-carnitine, Choline and Inositol, and
- Nucleotides.

Additional points not addressed in the consultation paper

2.19 In areas not canvassed by this consultation paper DCANZ agrees with the following INC concerns/points*:*

i. recommendation of the removal of the current limit on potential renal solute load for follow-on formulas at the same time as changes are introduced in relation to infant formula implementing the outcomes of P1028.

2.20 The significant number of inconsistencies in conversion factors used in the Codex Infant Formula Standard to convert from the limits set per 100kcal to per 100kJ. These are reflected in the Food Standards Code due to use of per kJ limits only. This review provides the opportunity to correct the limits intended to align to the Codex Infant Formula Standard such that they consistently align with the primary reference limits set per 100kcal. This will overcome the issues industry has experienced from the existing misalignments.

ii. A recommendation that "the term 'GUL' is used and defined (as described in CP2) within the Australia New Zealand Food Standards Code (the **Food Standards Code**) for the guideline maximum amounts included."

iii. "Use of the term 'optional ingredients', as used in Codex, is much preferred to 'may be used as a nutritive substance'. It is recommended that this is reconsidered as part of this review."

iv. "Anomalies have developed within the Food Standards Code as requirements have developed for different forms of unavailable carbohydrates. Some oligosaccharides are classified as nutritive substances and others are not. Similarly, some are considered to be dietary fibre and others not. It is recommended that these be addressed as part of this Review".

Transition Arrangements

2.21 DCANZ submits that a five-year period (with additional stock in trade provision) should be the minimum time permitted for transition to the proposed revisions to Standard 2.9.1 and associated schedules covered in P1028. This period is appropriate given the significand number, scope and complexity of changes proposed and would permit sufficient time to allow for the necessary planning, reformulation, packaging implementation and New Zealand regulatory requirements such as the need for gazetted exemptions from FSANZ standards for export products.

2.22 We acknowledge that the New Zealand requirement for gazetted exemptions from the New Zealand Food Act 2014 (and therefore relevant sections of the Joint Food Standards Code) is both outside of the jurisdiction of FSANZ, and the scope of the P1028 review. However, one of the impacts of this New Zealand regulatory requirement, is that additional time will be required, and

cost incurred by New Zealand manufacturers, to transition to a revised Infant Formula Standard. Additionally, it means that any concerns regarding variation from Codex (e.g. proposal for GUL for Riboflavin to be lower than that of the Codex Standard) are magnified due to this additional regulatory hurdle for New Zealand infant formula manufacturer/exporters.

2.23 It is also our strong preference that the current Standard and any revised Standard should run in parallel over the transition period.