Infant Nutrition Council
Industry supporting both Breastfeeding & Infant Formula
AUSTRALIA & NEW ZEALAND

IMPACT OF P1025 – REVISION OF THE FOOD STANDARDS CODE – SECOND CALL FOR SUBMISSIONS

OVERVIEW OF THE INC

INC is the association for the infant formula industry in Australia and New Zealand and represents manufacturers, marketers and brand owners who between them are responsible for more than 95% of the volume of infant formula manufactured, sold and exported in Australia and New Zealand.

INC aims to:

1. Improve infant nutrition by supporting the public health goals for the protection and promotion of breastfeeding and, when needed, infant formula as the only suitable alternative; and
2. Represent the infant formula industry in Australia and New Zealand.

The INC is a responsible body that voluntarily restricts its marketing practices to support government policies for the protection and promotion of breastfeeding. The companies represented by INC are:

Members:

- Abbott Nutrition
- Aspen Nutritionals Austrlia
- Fonterra Co-operative Group Ltd
- H. J. Heinz Company Australia Ltd & H. J. Heinz Company NZ Ltd
- Nestlé Australia Ltd & Nestlé New Zealand Limited
- Danone Nutricia Pty Ltd
- Synlait Ltd

Associate Members:

- A2 Infant Nutrition Ltd
- Ardagh Group NZ Ltd
- Australian Dairy Park
- Bayer Australia Ltd
- Biolife New Zealand Pty Ltd
- Burra Foods
- Cambricare New Zealand Ltd
- Dairy Goat Co-operative (NZ) Ltd
- Douglas Nutrition Ltd
- E-Babycare NZ Ltd
- Everhealth
- Fresco Nutrition Ltd
- GMP Pharmaceuticals Pty Ltd
- Graincorp
- Green Monkey
- Milk World Natural Dairy NZ Ltd
- Murray Goulburn Co-operative Co Ltd (Aust)
- New Image International Ltd
- New Zealand Goldmax Health Pty Ltd
- New Zealand New Milk Ltd
- Nutricare Group Ltd
- Nuztri
- Peak NZ Pty Ltd
- Sutton Group (NZ)
- Synlait Milk Ltd (NZ)
- Tatura Milk Industries
- Unitech Industries Ltd
- Westland Cooperative Dairy Co Ltd

The INC believes that breastfeeding is the normal way to feed infants as it has numerous benefits for both mothers and babies. When an infant is not given breast milk the only suitable and safe alternative is a scientifically developed infant formula product. For these infants, infant formula is the sole source of nutrition for around the first 6 months. It is important that scientific advances in infant nutrition are captured and incorporated into these products to ensure the best possible outcome for infants that are unable to have the benefit of breast milk.

The following assesses a selection of sections in the revision of the main body of the Food Standards Code then all of the sections that reflect a revision of what is currently Standard 2.9.1 in the Code. The headings and numbering system is taken from the proposed revised Code.

CHAPTER 1

Standard 1.1.1 Structure of the Code and general provisions

1.1.1—6 How average quantity is to be calculated

Subsection 1.1.1—6(3)(c) adds a phrase to the methods for the calculation of average quantity that reads “relevant to that manufacturer or producer and the food”. The current provision does not limit the data to ‘relevant to that manufacturer or producer and the food’. The phrase narrows the generally accepted data unnecessarily and further complicates an otherwise clearly understood concept of ‘generally accepted data’.

INC recommends that section 1.1.1—6(3)(c) read “the calculation from generally accepted data” and that it not be limited to data relevant to that manufacturer or producer and the food

Standard 1.1.2 Definitions used throughout the Code

1.1.2—4 Definition of *characterising component* and *characterising ingredient*

INC considers that changing the term ‘is usually associated with’ to ‘is likely to be associated with’ changes significantly the application of the definitions and would likely have a negative impact on industry. The term "usual" focuses on the common or ordinary which is past or current behaviour. In this context, the characterising ingredient would be a component of food that is commonly or ordinarily associated with the name of food. On the other hand, the use of the words "likely to be" broadens the definitions by introducing an element of future behaviour and changing the meaning to provide for something that "is" to something that "could be".

INC recommends that in section 1.1.2—4 Definition of *characterising component* and *characterising ingredient,* the wording ‘is likely to be associated with’ is replaced by the currently used term ‘is usually associated with’.

1.1.2—11 Definition of *used as a food additive*, etc

INC notes that the definition of food additive has changed from ‘extracted, refined or synthesised’ to ‘any substance that has been selectively concentrated or refined or synthesised’. This has made a difficult situation less clear and the impact much wider to potentially include ingredients/substances that have never been considered food additives.

There are a broad range of such substances that are selectively concentrated or refined or synthesised in some way and that are added to foods for purposes which might be considered food additive purposes under this new definition but which are not pre-approved.

Use of the term ‘selectively’ is not clear and unnecessarily expands the net of food additives. If this change is implemented, a wide range of substances would become non-compliant and

would all need pre-approval. This would have a very significant impact on the availability of food and an immense cost impact for industry while approvals were sought.

Secondly, as noted in relation to Standard 1.3.1 below, the term 'processed food' has been substituted in a number of places for 'final food' yet they are not synonymous terms.

INC recommends the definition of 'used as a food additive' not proceed as proposed because the impact will remove products from manufacture and involve significant cost to address. INC would favour reverting to the narrower 'has been extracted, refined or synthesised' as a starting point for further analysis in conjunction with industry.

INC recommends that the term 'processed food' be removed from section 1.1.2—11 and the terms 'food' or food for sale' be used as the context demands

INC repeats its view that the terms 'function' and 'purpose' are not interchangeable in law. INC does not disagree that "food additives and processing aids are generally described as substances that have been added *intentionally* to achieve a purpose" (p11 CFS2). That describes *why* they are added. *What* they do is the function. The difference is not "a distinction between objective and subjective intention" but rather a goal and an operation.

INC recommends that the term 'purpose' in reference to processing aids be replaced by the term 'function'.

1.1.2—12 Definition of *used as a nutritive substance*
As in relation to section 1.1.2-11, there are a broad range of such substances that are selectively concentrated or refined or synthesised in some that are added to foods for purposes which might be considered food additive purposes but which are not pre-approved. Use of the term 'selectively' is not clear. If this change is implemented a wide range of substances would become non-compliant and would all need preapproval. This would have a very significant impact on the availability of food and an immense cost impact while approvals were sought.

The current definition in the Food Standards Code refers to the processes of 'extraction and/or refinement, or synthesis'. It would therefore be in keeping with the current definition for the words 'extracted to be added to or substituted for 'concentrated, refined or synthesised' in subsection 1.1.2—12(2)(c). However, the phrase 'to achieve a nutritional purpose' should be removed from this same subsection (at the end of 1.1.2—12(2)(c)) because when the substance is extracted or concentrated, it does not serve a nutritional purpose on its own; it is only when it is added to a food that it serves a nutritional purpose nd this is aspect is covered by 1.1.2—12(1)(a). Another option would be to say at the end of 1.1.2—12(2)(c) '…..to achieve a nutritional purpose when added to a food'.

INC recommends the definition of 'used as a nutritive substance' in section 1.1.2—12 not proceed as proposed because the significant impact of such a change. INC favours reverting to the narrower 'has been extracted, refined or synthesised' term as a starting point for further analysis in conjunction with industry.

1.1.2—13 Definition of *used as a processing aid*
The key problem with this definition relates to the situation where a food or food additive could be construed as being used as a processing aid. Clarity is needed to address a situation that is exacerbated by the proposed definition.

INC recommends that the definition of *used as a processing aid* not proceed until further work has been undertaken to ensure unintended consequences of ingredients and food additives being construed as processing aids is addressed.

Standard 1.3.1—Food additives
INC notes the comment in the second Call for Submissions that states:

> "While the term 'final food' might be understood in the food industry it is not a term with legal certainty. To resolve the uncertainty the first call for submissions proposed use of the term 'food item' to describe a food that is for sale on the basis that it is ready for consumption without further processing. In consultation with stakeholders it was made clear that this term was not acceptable because the notion of food item involved elements beyond the sale itself. While we do not accept that this was a source of legal uncertainty we have modified the language to refer, where appropriate, to food for sale." (p14-15)

We also note the use of term 'processed food' which is undefined and the use of a phrase in relation to 1.1.2-13 Definition of used as a processing aid, as a substance that is 'used during the course of processing'.

INC does not agree that a substance in a processed food is not also used in the course of processing and there is therefore no clarity as to the point in the process that a test for presence or use might be applied. INC does not believe that the clarity currently delivered by the term 'final food' has been achieved by the term 'processed food'.

The term 'final food' is more closely aligned with 'food for sale' and 'retail food' which both have elements of the food presented to the consumer with no further processing. By contrast, the term 'processed food' can be applied to any substance during the processing process. A half completed jam or salami or milk are all processed foods at any stage of manufacture and any ingredients or substances added are added 'in the course of processing'. There is no distinction. The impact is potentially significant for the integrity of the Food Standards Code.

INC recommends the term 'processed food' be removed entirely and replaced by either 'food' or 'food for sale' depending on the context. As a result **INC recommends** replacing 'processed foods' with 'foods' in subsections 1.3.1—4(1) and (3) such that these read:

> "(1) An additive permitted in ~~processed~~ foods or a colouring permitted in ~~processed~~ foods that is permitted to be used as a food additive by Schedule 15 may be present in a food for sale as a result of use in accordance with GMP.
> (3) For a colouring permitted in ~~processed~~ foods to a maximum level that is permitted to be used as a food additive by Schedule 15, the level of all such colours together in a food for sale must be no more than:"

CHAPTER 2

Part 9—Special purpose foods
Standard 2.9.1 Infant formula products
2.9.1—11
In subsection 2.9.1—11(1)(a)(ii) the reference to the table should be to S30—7 not to S30—8.

INC recommends the reference in subsection 2.9.1—11(1)(a)(ii) should be to S30—7.

2.9.1—21 Declaration of nutrition information
Subsection 2.9.1—21(1)(a)(iii) in the revision reads:

> "the average amount of each vitamin or mineral and any other substance used as a nutritive substance permitted by this Standard expressed in weight/100 mL (including any naturally-occurring amount)"

The words 'used as a nutritive substance' have been added when compared to the current provisions in the Food Standards Code. It is not clear whether the phrase 'used as a nutritive substance' only qualifies 'any other substance' or not. If it does, then INC has no issue. If it does not, this could be read as implying that only the average amount of vitamins and minerals, when added as a nutritive substance, need to be declared on the label. Practically, manufacturers would consider the total amount of vitamins and minerals in the product for label declaration whether added as nutritive substances or as food additives. For example, tocopherols used as antioxidants are also a source of vitamin E and ascorbic acid can be used as an antioxidant and also a source of vitamin C. The same approach to 'total amount' is taken when considering compliance against compositional minimum and maximum requirements. In subsection 2.9.1—12(1), vitamins, minerals and electrolytes are, INC believes correctly, not qualified by the words 'used as a nutritive substance'. Notes 2 and 3 under section 1.1.1—10 (Requirements relating to food for sale) might have been expected to have assisted with clarifying subsection 2.9.1—21(1)(a)(iii). However, Note 3 refers to 'total amount added' provisions not 'average amount' provisions when it states:

> "In some cases, a provision refers to the total amount of a substance added to a food. In these cases, the total amount applies irrespective of whether the substance was used as a food additive, used as a processing aid or used as a nutritive substance."

Accordingly, it is possible that adding a comma after the phrase 'each vitamin or mineral' might clarify subsection 2.9.1—21(1)(a)(iii) such that it would read '(iii) the average amount of each vitamin or mineral, and any other substance used as a nutritive substance permitted by this Standard …'.

INC recommends that subsection 2.9.1—21(1)(a)(iii) be reconsidered in relation to total amounts and average amounts to be expressed.

SCHEDULES

Schedule 14—Technological purposes performed by food additives
Consistent with our comments made under section 1.1.2—11 Definition of *used as a food additive*, etc, that the purpose and function of a food additive are not interchangeable, INC remains of the view that 'purpose' is not generally what is being referred to in the tables of this Schedule.

INC recommends that in Schedule 14 the term 'purpose' in reference to processing aids be replaced by the term 'function'.

Schedule 15— Substances that may be used as food additives
Consistent with our comments made under section 1.1.2—11 Definition of *used as a food additive*, etc, INC considers that all occurrences of 'additives permitted in processed foods' in Schedule 15 be replaced with 'additives permitted in foods'.

INC recommends that all occurrences of 'additives permitted in processed foods' in Schedule 15 be replaced with 'additives permitted in foods'.

Schedule 17—Vitamins and minerals

INC notes that in S17—01 of Schedule 17, and in relation to Vitamin A, the term ‘Provitamin A’ has been introduced to replace ’Carotenoid Forms’. INC supports this change. The formatting of this section of the table is inconsistent with that for Vitamin A in S30--7. INC suggests that the latter formatting be adopted in Schedule 17 also.

INC repeats its concern that the term ’Biotin’ had been omitted. INC appreciates that there is currently no permitted form specified, but we would repeat that for completeness, its appearance in the table would remove doubt that it was still permitted to be used. The same applies to the terms ‘Vitamin K’, ‘Chromium’, ‘Copper’, ‘Manganese’ and ‘Molybdenum’.

INC recommends that, for completeness and to remove doubt that these substances are still permitted to be used, Schedule 17 include the terms ’Biotin’, ‘Vitamin K’, ‘Chromium’, ‘Copper’, ‘Manganese’ and ‘Molybdenum’.

S30—5 Infant formula products—substances permitted as nutritive substances
INC noted in response to the first Call for Submissions that the ‘.0’ had been deleted from some whole numbers and that the inclusion of a decimal place reflected an analytical rationale. Some amendments have been made but there are still some amendments that are needed.

INC recommends the following correction be made:
Inositol change the value from 1 mg to 1.0 mg.

S30—07 Permitted forms of vitamins, minerals and electrolytes in infant formula products, food for infants and food for special medical purposes
INC supports the changes made to Schedule 30—7 with respect to Vitamin A and suggests this format also be used for Schedule 17. INC notes an incorrect spelling of calcium lactate and the omission of Biotin and its permitted form ‘d-Biotin’.

INC recommends that ‘calcium lactateerte’ be corrected to ‘calcium lactate’ and that Biotin and its permitted form, d-Biotin, be reinserted in section S30—07

S30—08 Infant formula products—limits on fatty acids that may be present in infant formula and follow-on formula
INC continues to oppose the change that is deletion of the minimum and maximum % of fatty acids columns and replacement with a column that refers to ‘no less than x% total fatty acids’ or ‘no more than x% total fatty acids’.

INC recommends that the columns in S30—08 that refer to ‘no less than x% total fatty acids’ or ‘no more than x% total fatty acids’ revert to the current much clearer terminology of columns titled minimum and maximum % of fatty acids.

S30—10 Guidelines for infant formula products
INC noted in response to the first Call for Submissions that the ‘.0’ had been deleted from some whole numbers and that the inclusion of a decimal place reflected an analytical rationale. Some amendments have been made but there are still some that are needed. As well, Table 3 requires corrections to be made to abbreviations: G to g, Mg to mg or µg as applicable.

INC recommends the following corrections be made:
Guideline for maximum amount of vitamins and minerals in infant formula products
Vitamin K change the value from 5 µg to 5.0 µg
Chromium change the value from 2 µg to 2.0 µg
Table 3

Corrections to abbreviations: G to g, Mg to mg or µg as applicable.