



P1025 AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE REVISION INC SUBMISSION

27 September 2013

OVERVIEW OF THE INC

This submission has been prepared by the Infant Nutrition Council (INC). The INC represents the majority of companies marketing infant formula and companies who manufacture infant formula 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
- Bayer Australia Ltd
- Fonterra Co-operative Group Ltd
- H. J. Heinz Company Australia Ltd & H. J. Heinz Company NZ Ltd
- Nestlé Australia Ltd & Nestlé New Zealand Limited
- Nutricia Pty Ltd

Associate Members:

- A2 Infant Nutrition Ltd
- Ardagh Group NZ Ltd
- Biolife New Zealand Ltd
- Cambricare New Zealand Ltd
- Dairy Goat Co-operative (N.Z.) Ltd
- Douglas Nutrition Ltd

- e-babycare NZ limited
- Fresco Nutrition Ltd
- GMP Pharmaceuticals Ltd
- Murray Goulburn Co-operative Co Ltd
- New Image Group
- New Zealand GoldMax Health Limited
- New Zealand Dairy Products Ltd
- New Zealand New Milk Ltd
- Silver Fern Branding Ltd
- Sutton Group (NZ)
- Synlait Milk Ltd (NZ)
- Tatura Milk Industries
- Unitech Industries
- Westland Co-operative Dairy Company Limited

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.

EXECUTIVE SUMMARY

INC appreciates that this revision of the Food Standards Code is intended to modernise how the Code is presented, for that presentation to be clearer and for there to be a greater reliance on definitions already present in food acts in New Zealand, the Australian States and the Australian Territories. INC understands that the scope of the revision is such that it should not change the effect of provisions that impose requirements or obligations.

Overall, INC considers the revision to generally have minimal impact on what is currently Standard 2.9.1 Infant Formula Products with 5 key exceptions. As well, collocating many of the definitions used in the Code at the beginning of the Code is very helpful and strongly supported. The structure of the Code, as single unified document is helpful, especially from a searchability perspective. In general, separating the larger tables and schedules to a separate document is supported but again with some qualification.

In terms of key issue areas, the following identifies these:

- 1) Meaning of 'used as a food additive'. INC considers the definition has changed significantly the effect of 'additive' and has narrowed its application. As well, the terminology is not consistent between the revised Code, and Schedules 14, 15 and 16.
- 2) Definition of ingredient. The definition as revised is so broad as to be unworkable insofar as the term now captures any environmental substance at all whether added or not simply by 'coming into contact' with a process. It would also significantly change the labelling of many of the substances currently used as processing aids since it would be in conflict with section 1.59 which exempts the need for the statement of ingredients to list substances used as processing aids.
- 3) L-amino acids. Subsection 2.89(3) proposes that L-amino acids may be added 'only in an amount necessary to meet the minimum amino acid requirements.' This changes significantly the current provision that L-amino acids must be added 'only in an amount necessary to improve protein quality'. Not only does it remove the important linkage between L-amino acids and protein quality but more importantly, it potentially requires such precision of addition as to be unworkable for industry and unenforceable for regulators. As a result INC considers this revision is beyond the scope of the Proposal.
- 4) Definition of infant formula product. Unless amended, the revision also changes the current definition significantly. The current definition provides that infant formula is understood to be nutritionally adequate to serve by itself as either the sole or principal liquid source of nourishment for infants depending on the age of the infant.
- 5) Separation of schedules. While overall INC supports having tables and certain other information separate to the main body of the standards in the Code, some of the information is so minimal as to be an irritation by being separate. Very small tables and other information would be far easier to use if they were reinserted in the Code. The calculation of energy in S30.1 is a good example. Comprising less than 10 lines of text, it would be far more useful sitting with the relevant section, section 2.83. INC opposes the inclusion of this and several other sections in Schedule 30.

In summary, INC is supportive of the revision of the Food Standards Code but the issues noted above must be resolved for the Code to continue to operate and for the Proposal not to result in significant change to the application of the Code.

INC requests that the next round of consultation on the revision of the Food Standards Code be presented in 'track change' so that members can focus on areas of change rather than repeat the very intensive analysis that has been required in this first consultation phase.

INFANT NUTRITION COUNCIL : IMPACT OF P1025 – REVISION OF THE FOOD STANDARDS CODE

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.

1.06 Definitions

INC identified a number of definitions as relevant to infant formula manufacturers. These comprised three groups: those defined in section 1.06, those defined elsewhere in the Code (other than in Chapter 2, Part 9, Division 1) and those defined in Chapter 2, Part 9, Division 1. While section 1.06 provides either definitions or sign-posts to definitions, it is not complete. In excess of another 50 definitions are contained within the Code that are neither contained nor sign-posted in this section. INC is strongly of the view that all the definitions should be in one place, either in full or sign-posted. The definitions in full in section 1.06 or the sign-posts to definitions elsewhere in the Code in the section have no impact. Other definitions are commented on below.

1.16 Basic concepts—*food product*

This section is new and establishes the concept of food product as being the product 'sold to a consumer'. The intention appears to be to clarify the stage of production of food to which a provision applies. Previously and still in sections 1.23(5), 1.101(9), 1.113, 1.114, 1.115(3), 1.124(5) and 2.111(1)(a), 'final food product' is referred to. The New Zealand *Food Act 1981* does not define 'food product' so there is now a disjoint between the Code and the *Food Act 1981*. It is also the case that in places, the term 'final food' is critical for manufacturers and at times this term has not been used in favour of 'food product'.

Of more concern is the application of many of the labelling provisions to 'food product' only. While INC is a strong advocate of less and better regulation, in this case the unintended consequence is to exempt foods that are not for sale to the consumer from labelling. For manufacturers, there is a need for labelling of inputs for both traceability and contractual purposes. It is therefore suggested that this definition not be used and that either 'food' or 'final food' be used. Alternatively, if the term 'food product' is retained, it is suggested that every occurrence be carefully reconsidered in light of manufacturer needs as well as application for 'sale to a consumer'.

1.17 Basic concepts—*ingredient and compound ingredient*

This section is based on clause 1(1) in Standard 1.2.4 but there is very little in common with the current definitions of 'ingredient' and 'compound ingredient' and the proposed new definitions. The new definitions are excessively broad and will have significant labelling and composition implications.

The first issue is with subparagraph 1.17(1)(a)(ii) which states that irrespective of any traces left in a food, a food added to another is an ingredient. This means that all processing aids become ingredients when that is not the current situation. The examples are quite alarming, such that any substance that completely breaks down during processing, even if no trace exists in the final food such as a gas that completely evaporates, becomes an ingredient. As noted, this has significant implications for a substantial part of the food supply.

The second issue concerns paragraph 1.17(1)(b) which provides that any food that ‘comes in contact with a second food after processing such that traces are left in the second food, the food becomes an ingredient. This is so broad as to have implications for substances that are endemic in the environment becoming ‘ingredients’ and has potentially significant implications for food manufacture. This concept needs to be reconsidered and recast before the revised Code proceeds.

1.18 Basic concepts—*component*

This section is based on the definition of component in clause 2 of Standard 1.1.1. However, the revision appears to be much broader than the current definition. The interpretation of the current definition is that an ingoing substance such as a food additive, or a component of a food for which a claim is made, is a component of the food. The revised definition suggests that any breakdown products become components if they are identifiable. The example is carbon dioxide and salt as breakdown substances of sodium bicarbonate. The problem becomes one of separating breakdown substances from other ‘environmental’ substances such as substances in the air – oxygen and CO₂. In fact they become indistinguishable.

1.19 Basic concept—used as a *nutritive substance*

INC considers the concept ‘used as a nutritive substance’ to generally reflect the current arrangements. However, INC members continue to consider this definition and its application in the revised Food Standards Code and will advise further during the next round of consultation.

1.27 Meaning of *label*, *labelling* and *bear a label*

This section is based on subclause 1(2) of Standard 1.2.2 but goes well beyond that subclause. There is no issue with application of the term ‘label’ or ‘bear a label’ both of which are used extensively in the current Code.

The key issue is with the term ‘labelling’. This is defined in the revision as:

“*labelling*, in relation to a food product being sold, means all of the labels for the food product together.”

Labelling is a commonly used conjugation of the verb ‘to label’. For the Code, however, it is defined as a noun meaning ‘all the labels on food product’. This is confusing enough but its use in the revised Code is sometimes as the verb with the usual meaning and sometimes as the defined term and sometimes it is unclear what its use is. For example, the title of Part 3 ‘Labelling and other information requirements’ appears to be the verb but could be either. However, its use later in this section (paragraph 1.27(2)(b) reads ‘a requirement for the labelling of a food product to include specified content is a requirement for at least one of the labels to have that content’ can only refer to the verb because otherwise there would be no need to refer to ‘at least one of the labels’.

Some selected examples are in subsection 1.33(1) and in sections 1.40, 1.45 1.53 and subsection 1.74(a). As well, the phrase used throughout the revision: ‘for the labelling provisions’ seems to only make sense if this is the verb and not the noun. It is suggested that the term ‘labelling’ not be defined and instead a term such as ‘all labels’ or similar be defined.

Division 2—Food additives

1.122 Interpretation

The meaning of ‘used as a food additive’ removes reference to ‘technological function’ and refers to ‘technological purpose’. INC considers that ‘function’ and ‘purpose’ are not directly interchangeable such that the purpose is the reason something is done while function is the action of the thing or in this case, substance. An example of the difference is provided with a

food additive that is an emulsifier. The purpose of the emulsifier is to provide for a more homogeneous product but its function is to facilitate emulsification of one substance into another. Of greater concern is the narrowing of the definition such that a substance used as a food additive must be extracted, refined, or synthesised and not normally be sold as a food product or used as an ingredient by consumers. In an environment where 'natural' substances are increasingly sought, the definition appears to preclude the use of these substances as additives. An example of foods that are sold as food products but are additives are lecithin (sold to be sprinkled over other foods or used in baking) and vitamin C powders, the latter raising issues about substances added to supplemented foods.

Division 4—Processing aids

Subdivision A—Interpretation

1.131 Meaning of *used as a processing aid*

The meaning of 'used as processing aid' is generally aligned with the current understanding of the term. The key concern is the potential need to label the processing aid where this definition interfaces with the definition of ingredient. This would result in a significant change to the application of the Code. There is also inconsistency in the use of the term 'additive' which is proposed to be a substance used as a food additive' but in paragraph 1.131(3)(b) is referred to simply as 'additive'.

Part 9—Special purpose foods

Division 1—Infant formula products

Subdivision A—Preliminary

2.81 Outline of Division

INC notes that the outline of the Division amends the purpose statement contained in Standard 2.9.1. INC considers there are no impacts of the amendments made.

2.82 Definitions

INC notes that several of the definitions contained in clause 1 of Standard 2.9.1 are amended and one definition is moved.

infant formula product – the final phrase is amended to read “which is nutritionally adequate to serve by itself as the sole or principal liquid source of nourishment for infants.” The issue is whether 'sole or principal' could be read as synonyms when the intention is that they be read as alternates. Infant formula product must be able to provide the sole source of nourishment for the infant to 4-6 months. Beyond this it can, by itself, be a principal source of liquid nourishment along with other sources of nourishment. On this basis, the definition would be clearer if it read:

infant formula product means a product based on milk or other edible food constituents of animal or plant origin which is nutritionally adequate to serve by itself as either the sole or principal liquid source of nourishment for infants depending on the age of the infant.

infant formula – there are no impacts of the amendments.

follow-on formula – there are no impacts of the amendments.

lactose free formula – INC notes this definition has been deleted in favour of a compositional provision only. INC supports this deletion.

There are no other amendments to the remaining definitions:

pre-term formula

soy-based formula

medium chain triglycerides

protein substitute.

2.83 Interpretation

Interpretation of compositional requirements

The amendments forming subsection (1) are made to clause 2 of Standard 2.9.1. The amendments streamline the text.

Calculation of energy, protein and potential renal solute load

The calculations for energy, protein and potential renal solute load have been moved to the Schedules and specifically sections S30.01, S30.02 and S30.03 in Schedule 30. Subsection (2) therefore contains simply cross references. Schedule 30 is commented on separately later in this submission. However, INC is of the view that sections S30.01, S30.02 and S30.03 should all revert to inclusion in the body of the Code where their usability would be enhanced.

Subdivision B—General compositional requirements for infant formula products

This subdivision is an amended version of Subdivision 3 of Standard 2.9.1. The first clause in this subdivision was clause **6 Restrictions and prohibitions**. Subclause (1) stated that:

- “A vitamin, mineral, food additive or nutritive substance must not be added to infant formula product unless –
- (a) expressly permitted by this Code; or
 - (b) it is naturally present in an ingredient of the infant formula product.”

This has been deleted and (a) now appears in the definition of ‘used as a nutritive substance’ and (b) appears in paragraph 1.21(5). INC supports this change.

Subclause (2) stated that infant formula product must contain no detectable gluten. This provision is intended to be covered in section 2.87 which provides for restrictions on other substances and states that:

- “Infant formula product must not contain:
- (a) detectable gluten; or...”

INC agrees with this amendment.

2.84 Use of substances as nutritive substances

This section is the result of amendments proposed to clause 7 in Standard 2.9.1. The table to clause 7 is now located in S30.04 of the Schedules and is commented on later in this submission.

Subclause 7(1) is now preceded by a subheading which reads “What substances may be used as nutritive substances” while subclause 7(2) is preceded by a subheading which reads “When labelling may refer to presence of substances used as nutritive substances”. These subheadings are useful sign-posts to the content of the section.

Subsection 7(1)(b) refers to the amount of the substance in column 3 of the table “(taking into account both the naturally-occurring and added substance)”. Currently, the relevant paragraph refers to the total amount of added and any naturally occurring amount of the substance. There is no difference in intent but the amended text is clearer. INC therefore supports the proposed change.

Similarly subsection (2) is a clearer statement of what is currently subclause 7(2) and INC supports this change.

2.85 Addition of lactic acid producing microorganisms

This section is the result of amendments to clause 9 of Standard 2.9.1. The key change is to refer to 'lactic acid producing microorganisms' rather than 'lactic acid cultures'. The terminology has no impact on the provisions.

2.86 Permitted quantities of added inulin-derived substances and galato-oligosaccharides

This section is a redraft of clause 9A in Standard 2.9.1. It combines the start of subclause 9A(1) and all of subclause 9A(2) into a single, more definitive introductory statement such that 'may contain ... no more than' is now 'must contain ... no more than'. INC believes this is a clearer statement and supports the change.

2.87 Restriction on levels of other substances in infant formula product

This section combines what is currently subclause 6(2) concerning gluten with the provisions in clauses 8 and 10 concerning restrictions on the level of nucleotide 5'-monophosphates and aluminium respectively. Collocating these restrictions is helpful and clearer. There is no impact of these amendments.

Subdivision C—Infant formula and follow-on formula

This Subdivision reflects amendments to what is currently Division 2 in Standard 2.9.1.

2.88 Infant formula and follow-on formula—composition

Clause 1 of the current Division provides for the minimum and maximum levels of energy content, protein and fat for infant formula and follow-on formula. Subsection 2.88(1) deals with the minimum and maximum levels of energy content, protein and fat for infant formula only while subsection 2.88(2) deals with the maximum levels for same substances for follow-on formula. The separation has no impact and improves useability.

2.89 Infant formula and follow-on formula—protein

Subsection 2.89(1) contains a cross reference to a table in section S30.05 of Schedule 30 which is commented on separately later in this submission. The provision is clearer in that it provides that the L-amino acids must be present at 'a level no less than the corresponding minimum level' in the table. Currently the provision is that the L-amino acids must be 'at the minimum level' which could be interpreted as meaning either no more than the minimum level or, because of the inclusion of the term 'minimum', it means 'no less than the minimum level'. The amendment removes doubt.

Subsection 2.89(2) reflects technical amendments only.

Subsection 2.89(3) states that L-amino acids may be added 'only in an amount necessary to meet the minimum amino acid requirements.' Currently, subclause 22(3) provides that L-amino acids must be added 'only in an amount necessary to improve protein quality'. The change is significant. It removes any linkage between L-amino acids and protein quality but more importantly, it significantly constrains any flexibility available to industry and presents enforceability issues for the added amount to be excessively precise. INC does not support this change and believes it is beyond the scope of the revision proposal.

2.90 Infant formula and follow-on formula—fat

This section comprises amendments to the current clause 23. The table to the clause is moved to S30.07 of Schedule 30 which is commented on later in this submission. However, INC believes the reference in sub-paragraph 2.90(1)(a)(ii) should be to S30.06 in Schedule 30, not S30.07.

2.91 Infant formula and follow-on formula—vitamins, minerals and electrolytes

This section comprises amendments to the current clause 24. The table to the clause is moved to S30.08 of Schedule 30 which is commented on later in this submission.

Subsection 2.91(2) is recast from paragraph 24(1)(a) and now appears as a separate table (in S30.06) of permitted forms of the vitamins, minerals and electrolytes. However, in stating that “Any vitamins, minerals or electrolytes that are used as nutritive substances ...” ignores the prospect that they might be used for purposes other than nutritive or that they might have multiple uses – that they might be used as an additive or processing aid. For example, vitamin E might be used as an antioxidant (an additive) and as a nutrient. Subsection 2.91(2) might therefore also apply to vitamins, minerals or electrolytes used as nutritive substances or food additives or processing aids.

INC notes that this is intended to be addressed by the note to the table to subsection 121(4) (Requirements relating to food product on sale). This states “There is an overlap between these categories. For example, some substances may be used as a food additive or as a nutritive substance. For such substances, there will be different provisions permitting use of the substance for different purposes.” INC considers this to be a fundamental part of the concept and that this should be clearly reflected in section 2.91 and any other affected sections of the Food Standards Code

The residual amendments have no impact.

Subdivision D—Infant formula products for special dietary use

This subdivision reflects amendments to what is currently Division 3 in Standard 2.9.1.

2.92 Products formulated for premature or low birthweight infants

Subsection (1) is intended to provide that the requirements of the Division do not apply if it would prevent the sale of the special infant formula. This ensures the flexibility for scientifically and medically substantiated substances to be added to these products to meet the needs of the specific infant group. This is particularly important since all or almost all these products are formulated and produced overseas and are imported to Australia and New Zealand for administration by health professionals.

The amendments to subsection (2) do not have an impact.

2.93 Products for metabolic, immunological, renal, hepatic and malabsorptive conditions

Subsection (1) is intended to provide that the requirements of the Division do not apply if it would prevent the sale of the special infant formula. As above, this ensures the flexibility for scientifically and medically substantiated substances to be added to these products to meet the needs of the specific infant group. Also as above, this is particularly important since all or almost all these products are formulated and produced overseas and are imported to Australia and New Zealand for administration by health professionals. INC considers, however, that it is not clear that, for example, in relation to lactose-free product, all the compositional requirements other than that relating to lactose must be complied with. INC believes that this has the potential to be interpreted more broadly and that what is intended is that those aspects of composition specific to the condition can be varied but all other compositional requirements must otherwise be met.

The amendments to subsection (2) do not have an impact.

Subsections (3) to (6) provide the compositional and labelling provisions for lactose free and low lactose infant formula. There is no impact from the amendments.

2.94 Products for special dietary use based on a protein substitute

Subsection (1) is moved from clause 32 and has no impact. Subsection (2) is a composite from a couple of clauses and a table, converting the table into text. The amendments have

no impact. Subsection (3) is new but provides for complete coverage and subsection (4) is from clause 34 and has no impact.

Subdivision E –labelling and packaging requirements

2.95 Representations about food as infant formula product

There is no impact from the amendments.

2.96 Prescribed names

There is no impact from the amendments.

2.97 Requirement for measuring scoop

There is no impact from the amendments.

2.98 Requirement for warning statements and directions

Some duplication has been removed with the amendments made to this provision. The key concern is in relation to paragraph 2.98(1)(d) concerning the information under the heading 'important notice'. The current provision in subclause 14(3) of Standard 2.9.1 provides that the warning statement that must appear on the label can be the text provided "or any word or words having the same or similar effect". As a result, by omitting this provision, labels may need to be changed, a consequence that would put the revision out of the scope of P1025.

2.99 Print size

The print size is to be specified as 'of at least' rather than 'no less than'. There is no impact from this change.

2.100 Declaration of nutrition information

Sub-paragraph 2.100(1)(a)(iii) requires nutrition information for the average amount of each vitamin 'whether added or naturally occurring'. This is a new addition and INC does not consider that it is clearer. For example, calcium is still calcium whether added or naturally occurring and INC does not believe the additional phrase supports a science-based approach on the basis that the digestive system does not distinguish whether the calcium is added or naturally occurring simply that it is present. INC therefore considers it is clearer to refer simply to the average amount. Also in relation to this sub-paragraph, it is not clear whether the phrase 'used as a nutritive substance' refers only to 'any other substance' or whether it refers to all three substances listed: 'each vitamin, mineral or any other substance'. This requires to be clarified.

The balance of the Section removes duplication and some repetition and has no other impact.

2.101 Date marking and storage instructions

There is no impact from the amendments.

2.102 Statements of protein source and dental fluorosis

Although reordered, there is no impact from amendments.

2.103 Prohibited representations

There is no impact from amendments.

Schedules

Schedule 14—Technological purposes performed by food additives

INC notes the same issues apply to this Schedule as were described in relation to section 1.122, that the purpose and function of a food additive are not interchangeable and that

'purpose' is not generally what is being referred to in the tables of this Schedule. In any event, INC considers the title of this Schedule is inconsistent with the definition now applied to food additive and should be titled "Technological purposes performed by substances used as food additives". Similarly, where 'food additives' are referred to in the Schedule, the reference should be consistent with the expression 'used as a food additive'.

There is also a disjunct between the term 'technological purpose' and the column heading 'functional class'. The latter is currently used to refer to the function of the food additive by class. Since the 'function' has been replaced by 'purpose', 'functional class' is a misnomer. Of course, if the revision reverts to the use of the term 'function' then there is no disjunct.

Schedule 15—Substances that may be used as food additives

There are no impacts of the revision of this Table on infant formula products.

Schedule 16—Definitions for certain types of substances that may be used as food additives

There are no impacts of the revision of this Table on infant formula products. However, it is noted that the heading to the table in S16.01 incorrectly refers to the entire table as a numerical listing when the first part of the list is an alphabetical listing.

Schedule 17—Vitamins and minerals

In S17.01 of Schedule 17, and in relation to Vitamin A, the term 'Carotenoid Forms' is changed to 'Carotene Forms'. Reference to 'Carotene forms' is limited to alpha and beta forms and does not represent a group and is therefore the incorrect form to use. INC does not support this change. 'Carotenoid forms' is the correct technical term to use: it represents a group and is the internationally accepted term for the group.

While the term 'Biotin' has been omitted presumably because no permitted form has been specified, for completeness, its appearance in the table removes doubt that it is still permitted to be used. INC supports its continued inclusion for this reason. The same applies to the omission of 'Vitamin K', 'Chromium', 'Copper', 'Manganese' and 'Molybdenum'.

Schedule 18—Processing aids

In S18.01 of Schedule 18, the item number '6' has been omitted in error. It should be applied to 'Carbon monoxide' and there should then be a total of 31 substances. INC has no other comments to make on this Schedule.

S19.01 Interpretation

As with comments made earlier in this submission, INC strongly supports collocating all definitions or sign posts to definitions at the start of the Code.

S19.02 Calculating levels of contaminants and toxicants

This section comprises the text to various subclauses in clause 1 of Standard 1.4.1. The revision has no impact.

S19.03 Maximum levels of metal contaminants

This section and the following sections S19.04 to S19.07 comprise the tables or text to clauses 2 to 6 in Standard 1.4.1 respectively noting that the entry for mercury in fish which was in the table to clause 2 is now in S19.07. The revisions have no impact.

S19.04 Maximum levels of non-metal contaminants

S19.05 Maximum levels of natural toxicants from the addition of a flavouring substance

It is noted in relation to this section that 'sample unit' is defined at the end of the section when it is used throughout the section from the first line. The term should be defined at the outset either of the Schedules entirely or at the outset of Schedule 19.

S19.06 Maximum levels of natural toxicants

S19.07 Mean Level of mercury in fish

Schedule 27—Microbiological limits for foods

S27.01 Microbiological limits for foods

This section comprises the table in the Schedule to Standard 1.6.1. The revision has no immediate impact. However, the table would be greatly enhanced by the inclusion of more descriptive column headings. INC notes that this Schedule is likely to be impacted as a result of the review of Standard 1.6.1 and that this in turn will require further consideration by INC.

Schedule 30—Special purpose foods

Schedule 30 contains 20 different and separate sections containing tables, calculations or other provisions relevant to special purpose foods. Overall, INC agrees to having tables and certain other information separate to the main body of the standards in the Code. However, some of the information is so minimal as to be an irritation by being separate. There are tables, calculations and formulae retained in the main body of the Code. Very small tables and other information would be far easier to use if they were reinserted in the Code in the same way. The calculation of energy in S30.1 is a good example. There is no formula, there are less than 10 lines of text and it would be far more useful sitting with the relevant section, section 2.83. INC opposes the inclusion of this and several of the following sections from being included in Schedules when their utility would be greatly improved by remaining in the body of the Code.

Of the 20 different sections in Schedule 30, all but two have titles that make it clear what special purpose foods they refer to. The two that are not clear are S30.02 Calculation of fat and S30.03 Calculation of potential renal solute load. Both refer to infant formula products and, for consistency and clarity, if they remain in the schedules, would be better stated as 'S30.02 Infant formula product—calculation of fat' and 'S30.03 Infant formula product—calculation of potential renal solute load'.

S30.01 Infant formula product—calculation of energy

The amendments separate out into paragraphs the current clause such that the ingredients that contribute to energy value (fat, protein and carbohydrate) are listed as (i) to (iii). The section also mandates that energy content be expressed in kilojoules. There is no impact of these amendments as they reflect the provisions of clause 3 of Standard 2.9.1. However, as noted above, INC is strongly of the view that the section would be more useful in the body of the Code/standard.

S30.02 Calculation of protein content

The amendments in this section convert text into a formula. The letters used in the equation are defined in the order they appear in the equation. The calculation appears clearer as a result and there are no negative impacts of the amendments. However, as noted above, INC is strongly of the view that the section would be more useful in the body of the Code/standard.

S30.03 Calculation of potential renal solute load

As with S30.02, the amendments in this section convert text into a formula. The calculation appears clearer as a result and there are no negative impacts of the amendments. The terms, however, are defined in alpha order, that is **CI**, **K**, **N**, **NA** and **P_{avail}**. The usual convention with formulae is to define terms as they appear in the formulae has been done

for the terms in S30.02 and a number of other equations in the Schedules. This would result in the following order: **Na, Cl, K, P_{avail}** and **N**.

Subsection (2) contains a formula for P_{avail} used in subsection (1). This is clearer than was reflected in clause 3 of Standard 2.9.1 and is improved with the identification of **P** as phosphorus. INC is of the view that this section would be more useful in the body of the Code/standard

S30.04 Infant formula products—substances permitted as nutritive substances

This section contains what was the table to clause 7 in Standard 2.9.1. The section and the table are titled ‘Infant formula products—substances permitted as nutritive substances’ and the last two columns are reversed so that Column 3 is now ‘Maximum amount per 100kJ’ and Column 4 is ‘Minimum amount per kJ’. There seems no reason for this reversal. A number of other tables read Minimum then Maximum (such as the tables in S30.08 and in S30.20) and several sections in the balance of the revised Code refer to minimum and maximum in that order such as subsection 1.101(6) and paragraphs 1.102(1)(b), 1.102(3)(b), 1.109(1)(b) and 1.166(1)(f). INC opposes this reversal of the minimum and maximum columns not only on consistency grounds but also because it is inconsistent with international norms.

These substances are now referred to as nutritive substances as a result of the ‘basic concept—used as a nutritive substance’.

S30.05 Infant formula products—L-amino acids that may be present in infant formula and follow-on formula

This section contains the table to clause 22 in Standard 2.9.1. There is a single change to the value of one substance, ‘Histidine’ in the table. In the current Code the minimum amount per 100kJ is 10mg while in S30.05 it is presented as 12 mg. This difference is the result of a change made to the Code in May 2013 following a final assessment of Application A1074 – Minimum L-histidine.

S30.06 Permitted forms of vitamins, minerals and electrolytes in infant formula products, food for infants and food for special medical purposes

This section contains the table that is Schedule 1 to Standard 2.9.1. The title of the section and the table is “L-amino acids that may be present in infant formula and follow-on formula”. This is incorrect. The L-amino acids listed are mandated for inclusion in infant formula and follow-on formula and the title should therefore read:

“L-amino acids that must be present in infant formula and follow-on formula”

The changes in the table are:

- ‘Carotenoid Forms’ to ‘Carotene forms’
- Biotin and its permitted form, d-Biotin, has been omitted, and
- a form of Selenium, ‘sodium selenate’, has been added possibly correcting an error in Schedule 1 which lists the form ‘sodium selenite’ twice.

Biotin needs to be added to the table in S30.06. Reference to ‘Carotene forms’ is limited to alpha and beta forms and does not represent a group and is therefore the incorrect form to use. INC does not support this change. ‘Carotenoid forms’ is the correct technical term to use: it represents a group and is the internationally accepted term for the group.

S30.07 Infant formula products—limits on fats that may be present in infant formula and follow-on formula

This section contains the table to clause 23 in Standard 2.9.1. There is no change in the values or the substances listed. The key change has been to delete the minimum and

maximum % of fatty acids columns and to replace them with a column that refers to 'no less than x% total fatty acids' or 'no more than x% total fatty acids' as the case may be. INC does not support this change. INC considers this makes the table more complex than it needs to be. Reverting to the two columns of the table to clause 23 would continue the clarity provided by that table.

S30.08 Required vitamins, minerals and electrolytes in infant formula and follow-on formula

This section contains the table to subclause 24(1) in Standard 2.9.1. There are no changes to the text in the table.

S30.09 Guidelines for infant formula products

Minor changes are proposed to the Guidelines of a grammatical nature or to cross references. The tables have been given headings. INC notes that the '.0' has been deleted from some whole numbers. The inclusion of a decimal place reflects an analytical rationale and the format should therefore reflect international norms, not legal consistency.

Subsection S30.09(3) provides the form for the nutrition information panel. The subheading to this subsection reads '*Nutrition information table*' as it did in clause 24. However, the 'PANEL' has been added to the title of the table and the subheading should therefore match this and read '*Nutrition information panel*'. There are two changes to the text in the table. The first may be a printing error since it records '□g' for selenium instead of 'µg'. This needs to be corrected. The second change is to refer to 'substance used as a nutritive substance' to replace 'nutritive substance'. This has no impact on the table.