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

INC Response to CCNSFDU37 Agenda Item 5
Review of the *Standard for Follow-Up Formula* (CODEX STAN 156-1987) at Step 4

Comments provided in advance of CCNSFDU37
October 2015

SUMMARY

The key area of comment by INC on CCNSFDU Agenda Item 5 concerns Section 6 Essential Composition of Follow-up Formula for Older Infants (6-12 months) and, within that section, on the nutrients identified as problematic by the eWG. One comment on conversion factors is made at the outset noting there remain areas of inconsistency and recommending that all figures in CODEX STAN 156-1987 are presented to two significant places.

In relation to macronutrients, on protein, INC remains strongly in favour of a minimum of 1.65 g/100kcal noting the strong scientific evidence that supports this position, citing new research in the area and noting the benefits that might accrue to older infants. INC critiques the reasons for a higher minimum noting the national surveys that have shown protein intakes exceed minimum requirements. INC concurs with the recommendation that the maximum protein level be set at 3.5 g/100kcal for scientific, health and very practical trade reasons. INC supports retention of both footnotes 5 and 6 and the reference to goats' milk in Footnote 5.On lipids, INC remains of the view that the addition of DHA, ARA and EPA should be optional and comments on related aspects. On Carbohydrates, INC supports the minimum and maximum levels for carbohydrates which align with the levels in the Infant Formula Standard but does not support Footnote 9 as presented and identifies the issues associated with it.

Concerning vitamins, the levels proposed for Vitamin A creates issues associated with a significant narrowing of the range. The manufacturing challenges of this are associated with addressing the decline in levels during product shelf life but ensuring that levels are not lower than necessary when the product reaches the target population. On Vitamin D, while INC could support a minimum level of 1.0 µg/100kcal, INC is strongly of the view that an wider range than is currently intended by the proposed maximum is necessary and supports a maximum of 4.5 µg/100kcal.At this level there is no risk of exceeding the tolerable upper level revised in 2010 by IOM of 40 µg/day for infants aged 6-12 months (IOM 2010).

In relation to minerals and trace elements, INC supports the proposed minimum and maximum levels for iron. INC sets out a range of issues with the calcium and phosphorous levels and is of the view that a higher calcium minimum is important. INC is strongly of the view that GULs are not necessary for either minerals but especially not for phosphorous, the levels of which are controlled by the calcium:phosphorous ratio. On selenium, INC accepts the increased minimum to 2 µg/100 kcal but cautions that this level should be monitored by national authorities for impact over time. On zinc, INC supports the current minimum of 0.5 mg/100 kcal but remains firmly of the view that the GUL should be set at 1.5 mg/100 kcal.

Where optional ingredients are concerned (Section 7), INC is pleased to see provisions retained and particularly the provision that makes it clear that the optional ingredients listed are not an exhaustive list.

Finally, in relation to Section 8, Essential Composition for Follow-up Formula for Young Children (12-36 months), the most concerning aspects are the limited range of mandatory additions being too narrow to provide a smooth transition from follow-up formula for older infants to follow-up formula for young children; the scope of the Standard in relation to fortified milk-based drinks; the approach proposed (a limited list of mandatory additions and a wide list of optional additions) is not consistent with the Codex principles of developing common standards to facilitate trade; and for levels of optional additions of (non-mandatory) vitamins and minerals to default to the requirements proposed for follow-up formula for older infants due to their different nutritional requirements.

COMMENTS

Agenda Paper Section 5. DESCRIPTION OF FOLLOW-UP FORMULA (SECTION 2)

INC acknowledges the rationale around the restructuring of the Description in CODEX STAN 156-1987 and supports the collocation of product definitions in one section and other definitions in an adjoining section.

Agenda Paper Section 6. ESSENTIAL COMPOSITION OF FOLLOW-UP FORMULA FOR OLDER INFANTS (6-12 MONTHS)

INC notes the application of assumptions around mean intake, body weight and representative caloric intake and of principles for establishing compositional requirements. The following comments focus mainly on the essential composition for follow-up formula for the nutrients identified as problematic by the eWG:

- Macronutrients: protein, lipids and carbohydrates
- Vitamins: vitamin A, vitamin D,
- Minerals and trace elements: iron, calcium, phosphorous, selenium, and zinc.

Conversion Factors
INC acknowledges the action taken by the eWG on conversion factors as this area is particularly critical to consistency, interpretation and, at the end of the day, to manufacturing specifications. However, we note there remain areas of inconsistency (e.g. Carbohydrate max 14.0 not 14; Vitamin E GUL 5 rather than 5.0; and Vitamin K min 4 rather than 4.0) and recommend that all figures are presented to two significant places.

Macronutrients

Protein
Minimum: In relation to protein, INC remains strongly in favour of a minimum of 1.65 g/100kcal.

The minimum protein requirement is set to cover maintenance and growth. Recent estimates of protein requirements are lower than previous estimates, primarily as a result of changes in the reference body weights that were previously used (WHO/FAO/UNU 2007). EFSA adopted the same approach in its 2013 published “Scientific Opinion on nutrient requirements and dietary intakes of infants and young children in the European Union”.

The scientific basis for the proposed minimum of 1.65 g/100 kcal was noted in the Agenda Paper (p9) as confirmed by the Early Nutrition Academy (ENA) Guideline and is based on the

WHO/FAO/UNU revised guidelines on protein requirements (2007) and a good protein quality providing an adequate content of bioavailable essential amino acids. Recognised as safe, this lower minimum level will retain the benefits of follow-up formula while allowing other protein sources to be introduced into the diversified diet but still maintaining protein intakes that are similar to minimum protein requirements.

The safety and suitability of a formula with a protein content of 1.65g/100kcal has been confirmed in more recent randomised clinical trials. Ziegler et al demonstrated that the growth of infants fed a high quality protein formula with 1.61 g/100kcal of protein was equivalent to infants fed a control formula (Ziegler 2015). A similar formula was tested in a specific population of infants born to overweight mothers. It confirms that a protein content of 1.65 g/100kcal is safe and results in weight gains closer to those of breast-fed infants, even in this sub-population (Inostroza, 2014).

The support for a higher minimum of 1.8 g/100kcal rests on two factors:

- a suggested need for protein in formula to exceed that provided by human milk (in order to compensate for differences in dietary digestibility, bioavailability and efficiency of utilization between breast milk and formula)
- meeting the nutritional needs of infants in low income countries where protein intakes can be limited and protein quality of the complementary diet is inadequate to support needs.

The need for protein to exceed that provided by human milk, does not identify the level in human milk other than to acknowledge the EFSA opinion that "the composition of the protein fraction in breast milk changes over time and no data are available on the true digestibility". INC does not consider this to be compelling justification for retaining a high minimum level but rather supports protein levels across a range from a minimum that addresses variability.

In relation to the second reason for maintaining a minimum of 1.8 g/100kcal, INC is concerned that meeting the nutritional needs of infants in low income countries not commit Codex to setting higher minimum protein levels. The lower minimum of 1.65 g/100kcal will allow for the introduction of other protein sources from the diversified diet whilst maintaining protein intakes that are similar to protein requirements. Several representative national surveys have shown protein intakes exceed minimum requirements (Thailand, Australia, Mexico and Malaysia – CX/NSFDU 14/36/7 2014).

Maximum: INC concurs with the recommendation that the maximum protein level be set at 3.5 /100kcal for scientific, health and very practical trade reasons noting that in many countries the minimum limit for protein is currently 3.0 g/100kcal. Taking countries from a minimum of 3.0 g/100kcal to a maximum at that same level, could have unexpected consequences and an overlap provides a more balanced approach. INC notes that the paper touches on the transitional issue of this change. INC supports the ISDI position in this area, which elaborates on this rationale.

INC considers a transitional arrangement to be necessary to manage the changeover and recommends that very clear provisions are made for this purpose that discourage member countries from wanting to be 'first to implement'. Synchronised implementation is vital.

Footnote 5

INC is of the view that the text in square brackets in this Footnote, "and goats' ", must be included to provide the coverage to goats' milk. The second sentence will need to be amended to reflect this change.

Footnote 6

INC is strongly of the view that this Footnote is required and should remain in the Standard.

Footnote 6 remains important for any formula based on cow or goats milk with a protein level below 1.8 g, formula based on hydrolysed protein containing less than 2.25 g/100 kcal protein and formula based on milk protein of other species. If the protein concerned (origin and quantity/100kcal) has been clinically assessed as suitable for infant formula, it may be used in formulas for older infants without further clinical assessment.

Lipids

INC remains of the view that the addition of DHA, ARA and EPA should be optional but that if DHA is added, then the level of EPA should not be greater than DHA. A footnote to this effect would be important. The footnote should also make it clear that if DHA is added there is no requirement to add ARA.

Carbohydrates

INC supports the minimum and maximum levels for carbohydrates which align with the levels in the Infant Formula Standard.

INC does not support Footnote 9 as presented and had supported a replacement Footnote 9 that read:

""Lactose should be the preferred carbohydrate but glucose polymers are an acceptable alternative which may be used without restriction. Only pre-cooked and/or gelatinised starches may be added [that are gluten free by nature]. The addition of other sugars should be avoided. If needed, sucrose, fructose or honey (the last listed treated to destroy spores of *C. botulinum*) may be added providing the sum of these does not exceed 20% of the total carbohydrates."

In relation to the text proposed, INC supports both the square bracketed texts. However, the second square bracketed text requires amending to include reference to glucose. INC omitted glucose in error in its comments on the second Consultation Paper in 2015 and cannot identify any rationale for excluding glucose from addition and inclusion. Indeed, the exclusion of glucose from addition promotes fructose and sucrose as superior carbohydrates when this is not the case.

Vitamins

Vitamin A

INC notes that retaining a vitamin A minimum level that aligns with CODEX STAN 156-1987 (75 µRE/100kcal) and a maximum level that aligns with Infant Formula Standard (180 µRE/100kcal down from CODEX STAN 156-1987 maximum of 225 µRE/100kcal) significantly narrows the range for manufacturing by almost a third.

Manufacturing with vitamin A is challenging because of the decline in levels during product shelf life. While INC notes that consumption of formula at the follow-up formula maximum would provide vitamin A in excess of the tolerable upper level (UL) established by WHO/FAO (600 µg retinol and EFSA (800 µg retinol), it will be important not to reduce the permitted range to the extent proposed and risk lower than necessary levels of vitamin A reaching the target population. Manufacturing generally works on the basis of a maximum around three times the minimum for vitamin A. An alternate range that addresses the technical issue associated with the shelf life degradation of the vitamin, the challenge for manufacturing to deliver the optimum amount for infants and the importance of the product in the hands of the consumer not exceeding the tolerable upper limit needs further consideration. It is almost certain that the maximum of 225 µRE/100kcal is never delivered to the consumer.

Vitamin D
Minimum: INC could support a minimum level of 1.0 µg/100kcal.

Maximum: INC notes that an upper limit of 3.0 µg/100kcal widens the range for the addition of vitamin D to address the sub-optimal vitamin D status in many regions (Saraf et al, 2015, Koletzko et al, 2012) and as outlined by the IEG. INC supports this wider range but is strongly of the view that an even wider range is necessary to address the issue with a maximum set at 4.5 µg/100kcal. Importantly, there is no risk of exceeding the tolerable upper level revised in 2010 by IOM of 40 µg/day for infants aged 6-12 months (IOM 2010). Consumption of 450ml of follow-up formula (average daily follow-up formula intakes cited in CX(NFSDU 14/36/7) containing 4.5 µg/100kcal would deliver approximately 13.6 µg/day of vitamin D (assuming an energy density of 67 kcal/100ml), which is far below the tolerable upper level.

Minerals and trace elements

Iron
Minimum: INC supports the proposed minimum level for the reasons set out in the paper.

Maximum: INC notes the proposal to retain a maximum level of 2.0 mg/kcal of iron.

Calcium and Phosphorous
Minimum: INC supports retaining the higher minimum level for calcium of 90 mg/100kcal for the reasons set out in the paper. These arguments far outweigh retaining the minimum level set in the Infant Formula Standard. Follow-up formula is the main source of calcium in the older infants' diet. As well, older infants consume lower amounts of formula than younger infants and the calcium level in follow-up formula should be comparably higher than in infant formula.

In relation to the phosphorous minimum, INC remains strongly of the view that the higher minimum of 60 mg/100kcal is needed because follow-up formula is the main source of phosphorous in the young children's diet. The arguments for a higher calcium level apply also to phosphorous – young children consume lower amounts of formula than infants and the phosphorous calcium level in follow-up formula should be comparably higher than in infant formula. Careful consideration is necessary before more than halving this minimum level.

GUL: INC could support the GUL for calcium of 180 mg/kcal for the reasons set out in the paper but believes this is unnecessary. More concerning however, for INC is a GUL for phosphorous which is entirely unnecessary because of the constraints placed on the calcium:phosphorous ratio. We consider it is also a distraction when the calcium:phosphorous ratio is the more critical aspect for phosphorous levels

Further consideration will need to be given to the calcium (and phosphorous) range if the limits applied to nutrients for 6-12 months become default limits for optional vitamins and minerals for 12-36 months. This is because the current minimum recommendations for calcium levels in 12-36 months formula at 200mg/100kcal exceed the proposed GUL for 6-12 months.

Selenium
Minimum: INC notes the minimum level of selenium is set to increase from 1 µg/100kcal to 2 µg/100kcal based on US and EFSA recommendations. In the absence of evidence suggesting the minimum of 1 µg/100kcal be retained, INC accepts the increased minimum but cautions that this level should be monitored by national authorities for impact over time.

Zinc
Minimum: INC supported the current minimum of 0.5 mg/100kcal.

Maximum/GUL: The choices provided in the July consultation paper from the eWG were a maximum or a GUL of 1.25 or 1.5 mg/100kcal. INC supported a GUL of 1.5 mg/100kcal on the basis that this provided alignment with CODEX STAN 72-1981 (Rev 2007) and with the ENA Guideline for follow-up formula. We note the opposing views from EFSA and the risk of consumption leading to excessive intakes but there are also manufacturing challenges associated with the much narrow range and on this basis INC remains firmly of the view that the GUL should be set at 1.5 mg/100kcal. There are also impacts on the Chair's proposal for this limit if they become the default limits for 12-36 months where addition is voluntary. For example, the IEG (2015) are recommending a GUL of 1.8mg/100g for 12-36 month age group. Application of a GUL of 1.5 for the 6-12 month age group would be better aligned with this proposed GUL for 12-36 month age group.

Agenda Paper Section 7. OPTIONAL INGREDIENTS FOR OLDER INFANTS (6-12 MONTHS)

INC is pleased to see the provisions around optional ingredients retained and continues to support their inclusion in the Standard. INC supports the first options for text provided in each case for 3.3.2.1 and 3.3.2.2.

INC is pleased to see 3.3.2.3 includes the statement that "…this is not intended to be an exhaustive list, but provides a guide for national authorities as to appropriate levels when these substances are added". INC stresses the importance of retaining this statement as an acknowledgement that the list of optional ingredients included is not exhaustive.

An additional provision was sought that needs reconsideration relating to amendments to the relevant comparable sections in the Infant Formula Standard such that an addition to the optional ingredients there would trigger a comparable amendment to the provisions in CODEX STAN 156-1987.

Agenda Paper Section 8. ESSENTIAL COMPOSITION OF FOLLOW-UP FORMULA FOR YOUNG CHILDREN (12-36 MONTHS)

INC appreciates the need for the next area of review, products for 12-36 months, to be undertaken within an agreed framework. However, we suggest that the limited range of mandatory additions is too narrow to provide a smooth transition from follow-up formula for older infants to follow-up formula for young children. The interface between the two compositional ranges needs to reflect a progression or transition for growing infants, a transition that will adjust over time but which nonetheless needs to be managed at the outset.

INC also notes that the broader question relating to the scope of the nutrient composition for follow-up formula for 12-36 months needs to be addressed, that is, whether fortified milk-based drinks are also included in the scope of CODEX STAN 156-1987. Previously it was understood the intent of the Standard was to also include those products principally based on cow's milk with the addition of the key nutrients. However, the incorporation of ALA/LA parameters, depending on level, mandates the use of vegetable oils in such products. This therefore needs further consideration.

INC is concerned that the approach proposed of a limited list of mandatory requirements and a wide list of optional additions may not be consistent with the Codex principles of developing common standards to facilitate trade. The proposed approach is unlikely to result in globally harmonised requirements. It risks the introduction of substantial variations to the products within the category and risks consumer confusion when faced with a wide variety of products.

INC also has reservations regarding the Chairs' proposal for levels of voluntary addition of other (non-mandatory) vitamins and minerals to default to the requirements proposed for follow-up formula for older infants due to their different nutritional requirements. Comments have been included in the text above under the response to Section 6 in relation to calcium, phosphorus and zinc to highlight the types of issues that will arise using this approach.