CODEX ALIMENTARIUS COMMISSION E

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World Health Organization

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Agenda Item 5 **CX/NFSDU 15/37/5**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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REVIEW OF THE *STANDARD FOR FOLLOW-UP FORMULA* (CODEX STAN 156-1987)

Prepared by the Electronic Working Group led by New Zealand with the assistance of France and Indonesia[1]

(At Step 3)

Governments and interested international organizations are invited to submit comments on the proposed draft revision for sections 2 – 3.3 of the Standard for Follow-up Formula, as presented in Appendix 2 at Step 3, as well as on Recommendations 1 -22 and should do so in writing in conformity with the Uniform Procedure for the Elaboration of Codex Standards and Related Texts (see *Procedural Manual of the Codex Alimentarius Commission*) **to**: German Secretariat of CCNFSDU, email ccnfsdu@bmel.bund.de with copy to Secretariat, Codex Alimentarius Commission, Joint WHO/FAO Food Standards Programme, FAO, Rome, Italy, email codex@fao.org **by 16 October 2015.**

Format for submitting comments: In order to facilitate the compilation of comments and prepare a more useful comments document, Members and Observers, which are not yet doing so, are requested to provide their comments in the format outlined in the Annex to this document.

1. INTRODUCTION

1.1 Previous consideration by CCNFSDU

At the 36th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU36), the Committee agreed to retain a *Standard for Follow-up Formula* (CODEX STAN 156-1987) and continue with an electronic working group (eWG) working in English, with the following Terms of Reference:

Terms of Reference for the electronic working group:

On the basis of the data collected so far and taking into account the discussion at the CCNFSDU36 including pertinent CRDs:

- Review the Section 2 (Description) of the current *Standard for Follow-up Formula* and propose drafting changes if necessary;
- Review the compositional requirements of the current *Standard for Follow-up Formula*, 6-36 months with a point of differentiation at 12 months (Sections 3.1-3.3) and propose revised requirements.

Physical working group:

At the 36th Session it was also agreed that a physical working group (pWG) would be established chaired by NZ, co-chaired by France and Indonesia working in English, French and Spanish, taking into consideration the findings of the eWG 2015 to develop draft revised Sections 2 to 3.3 of the Standard for consideration by the CCNFSDU. It is planned that the physical working group will meet directly before the next session of CCNFSDU.

Please note that for the purposes of this Paper the Chairs have referred to product targeted to infants aged 6-12 months as *follow-up formula for older infants*, and product for young children aged 12 to 36 months as *follow-up formula for young children*. The use of these terms does not prejudice the ability of the standard to prescribe different names to describe product targeted to these different age groups.

[1] Members of the electronic working group: Argentina, Australia, Brazil, Canada, Chile, China, Columbia, Costa Rica, European Union, India, Iran, Malaysia, Mexico, Morocco, Netherlands, Norway, Philippines, Russia, Singapore, South Africa, Switzerland, the United States of America, the Early Nutrition Academy (ENA), Federation of European Specialty Food Ingredients Industries (ELC), European Network of Childbirth Associations (ENCA), the European Vegetable Protein Federation (EUVEPRO), Helen Keller International (HKI), Institute of Food Technologies (IFT), International Baby Food Action Network (IBFAN), International Association of Consumer Food Organizations (IACFO), International Dairy Federation (IDF), and International Special Dietary Foods Industries (ISDI).

1.2 Conduct of the Electronic Working Group (eWG)

The eWG has considered two Consultation Papers circulated in March and June respectively. As per the Terms of Reference (ToR), the first Consultation Paper undertook to review Section 2 (Description) of the *Standard for Follow-up Formula*. eWG members were asked to consider the current definitions and comment on whether each definition should be retained as is, retained but amended, or removed from the Standard. Members were asked to provide justification for their answers as well as provide alternative wording if an amendment was recommended. The first Consultation Paper also reviewed the compositional requirements of follow-up formula for the 6-12 month age group using the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981) and findings of preceding eWG reports as a basis for this review. Finally, the first Consultation Paper considered what approach(es) should be used to determine the compositional requirements for the 12 to 36 month age group. Thirty-two submissions were received from the first round of consultation (21 Codex Member Countries (CM), one Codex Member Organisation (CMO), and ten Codex Observers (CO)).

The second Consultation Paper collated the responses from the eWG to the first Consultation Paper and refined the review of compositional requirements for follow-up formula for older infants (6-12 months). It also took in to consideration comments received on the process for determining the compositional requirements for young children aged 12 – 36 months. The second Consultation Paper continued the review of Section 2 (Description) and proposed draft wording for consideration by the eWG. Thirty-two submissions were received in response to the second Consultation Paper (21 CM, one CMO, and 10 CO).

The Chairs of the eWG have used feedback from the March and June eWG consultations to prepare this Agenda Paper. All participating members are acknowledged above.

2. EXECUTIVE SUMMARY

The eWG has undertaken two rounds of consultation to help address its ToR and believes that the Committee is now in a position to make informed decisions regarding the review of the *Standard for Follow up Formula* (6-36 months).

In relation to the review of Section 2 (Description) of the Standard there was constructive discussion within the eWG and progress was made to allow for the Chairs to propose recommendations for revised definitions for Section 2. The key themes of discussion were:

- support for consistency in terms of definitions, terminology and layout, with the *Standard for Infant Formula Standard and Formulas for Special Medical Purposes Intended for Infants (from hereon referred to as the Infant Formula Standard)*;
- support for consistency (in terminology) with other appropriate recently revised Codex standards; and
- relocation of some terms that are not considered definitions.

The eWG canvassed members' views on the recommendation of the WHO that the Committee include text in the revised Standard which adequately reflects WHA resolution 39.28. The majority of eWG members suggested that reference to relevant WHA resolutions be incorporated into the Scope of the *Standard for Follow-up Formula,* but review of the Scope and Labelling requirements did not form part of the Terms of Reference for the eWG and therefore discussions on this issue should be deferred until a time when this is specifically addressed.

The eWG has had extensive discussions on the review the compositional requirements of the current *Standard for Follow-up Formula* for the six to 12 month age group. The approach taken by the eWG was to align where possible the recommendations for the essential composition of follow-up formula for older infants with the *Infant Formula Standard*. The composition of infant formula is designed to be adequate for infants in the first six months of life as the sole source of nutrition. It is generally assumed that from six months onward the contribution of energy and nutrient intakes from complementary foods will compensate for the higher dietary requirements of older infants.

The eWG reviewed the scientific evidence which underpins the essential composition of infant and follow-up formula from a variety of sources[1-3]. For some nutrients the majority of the eWG have recommended an approach which deviates from the requirements in the Infant Formula Standard. The rationale for deviation is either a result of cases where the scientific evidence has progressed since the development of the *Infant Formula Standard*, or where there is evidence of nutrient requirements differing between the two age groups.

In relation to the compositional requirements of the 12 – 36 month age group there is still a need for the Committee to agree a preferred approach and then finalise the composition. In deciding on a preferred approach the eWG has identified a number of key themes that should be taken into account. These are:

Flexibility: to address nutrients of concern which vary regionally, flexibility in the nutrients that should be mandated, and flexibility to enable fortified milk drinks to be covered within the standard.

Less Prescription: including general support that follow-up formula for young children does not need to contain the full range of nutrients that are mandated for addition to product for older infants.

Consistency: with follow-up formula for older infants (where possible).

Key nutrients: as per the findings of the 2014 and 2015 eWGs, globally iron and the quality of dietary fat were consistently found to be inadequate in sub-groups of the population. Other nutrients which were most frequently found to be limited in the diets of older infants and young children included α-linolenic acid (ALA), docosahexanoic acid (DHA), vitamin A and D, calcium, zinc and iodine; however these differed regionally. In addition to this, possible excessive intakes of protein and sodium were reported in some countries.

Nutritional integrity: maintaining the integrity of the product. For example;

- restrictions on the addition of sugars,
- ensuring nutritional equivalence to products that follow-up formula for young children might be replacing,
- establishing upper limits (max or GUL) to ensure safety.

The Chairs of the eWG have proposed an option for consideration by the Committee for progressing the review of the *Standard for Follow-up Formula* for young children. This recommends the composition be based on a list of core nutrients for mandatory addition, and then allows for expansion of this list at a national level, depending on the particular requirements of and role of product within the individual country/region. For the substances permitted for voluntary addition to follow-up formula for young children, the level of addition must meet the requirements for addition as specified for follow-up formula for older infants.

3. BACKGROUND

CCNFSDU34 agreed to propose new work to undertake a full review of the *Standard for Follow-up Formula* (CODEX STAN 156-1987). An eWG was established in 2013 with an initial focus on the review of the essential composition of follow-up formula, and consideration of the need for compositional differences for older infants compared to young children. In 2013, data on the role of follow-up formula in the diets of older infants and young children was also collected by the eWG.

CCNFSDU35 decided to continue work on reviewing the *Standard for Follow-up Formula* through an eWG. The eWG was tasked with reviewing the nutritional requirements of older infants and young children and to compare these to the compositional requirements of the existing infant and follow-up formula standards, taking into consideration dietary intakes and the role of product in the diet.

Discussions at CCNFSDU36 highlighted that there was consensus within the Committee that follow-up formula is not considered nutritionally necessary. There was however majority support and acknowledgement that although products are not necessary in nutritional terms, they should be regulated to ensure the safety, quality and integrity of these products which are traded internationally. The Committee agreed to continue work on the revision of the standard.

In 2014 the eWG was tasked with reviewing the nutritional requirements of older infants and young children taking into account recent scientific developments and global data. Through this review it was identified that significant scientific advances in defining the nutritional requirements of this age group had occurred since the development of the original standard. Notable advances include the revised estimates of reference body weights of older infants and young children which have resulted in lower estimates for protein requirements. In addition to this there has been increased recognition of the importance of the essential fatty acids in the diets of this age group.

In the eWG it was noted that at the time of the revision of the Infant Formula Standard (2007) many of the identified advances in nutrient requirements were addressed. Although the compositional requirements of the Infant Formula Standard are generally appropriate for older infants, minimum levels of iron in the Infant Formula Standard would not address the increased requirements for iron for older infants.

Although there was considerable support for consistency as much as possible between the Infant Formula Standard and the Follow-up Formula Standard (particularly in relation to product for older infants), there remains a challenge in developing regulation that recognises the most up-to-date science.

The 2014 eWG assessment of global dietary intake and nutritional status data highlighted several nutrients of global concern for where there is evidence to suggest that older infants and young children may have difficulty in achieving adequate intakes. Globally, iron and the quality of dietary fat in the diet were consistently found to be inadequate in sub-groups of the population. Other nutrients which were most frequently found to be limited in the diets of older infants and young children included alpha-linolenic acid (ALA), docosahexanoic acid (DHA), vitamins A and D, calcium, zinc and iodine; however there were regional differences in these nutrients.

In recognition of the variation in the role that follow-up formula plays in the diet of young children, the 2014 eWG identified a need to consider a regulatory approach which provides flexibility in its composition to contribute nutrients at risk of inadequacy, as well as supporting the specific needs of different countries.

4. FOLLOW-UP FORMULA IN THE CONTEXT OF RELEVANT WHA RESOLUTIONS

At CCNFSDU36 the Representative of WHO indicated that WHO was pleased to note the eWG's recognition of follow-up formula as not a necessary product. The Representative of WHO requested the Committee include text in the revised Standard which adequately reflects WHA resolution 39.28 (REP15/NFSDU para 97). WHA resolution 39.28 relates to the non-necessity of follow-up formula and states that *'the practice being introduced in some countries of providing infants with specially formulated milks (so called "follow-up milks") is not necessary'* (WHA 1986).

The Chairs of the eWG note that consideration of WHA resolution 39.28 was also important in the development of the original *Standard for Follow-up Formula*. These discussions are captured in the Report of CCNFSDU15(ALINORM 87/26 paras 59-63), as well as in the Report of CAC17 (Seventeenth Session 1987, paras 436-439).

As part of the First Consultation Paper, eWG members were asked whether WHA resolution 39.28 should be addressed in the *Standard for Follow-Up Formula*, and if so, eWG members were asked to propose how this should be achieved.

The majority of eWG members suggested that reference to relevant WHA resolutions be incorporated into the Scope of theStandard, similar to the approach and wording of Section 1.4 of the Standard for Infant Formula. Many of those eWG members who suggested reference to WHA resolutions be contained within the Scope, also suggested that principles contained within the relevant resolutions will also need be considered as part of the review of the labelling provisions for follow-up formula.

Several eWG members commented that the review of the Scope and Labelling requirements did not form part of the ToR for the 2015 eWG and therefore discussions on this issue should be deferred until such time as the group is able to simultaneously review the Scope and Labelling sections of the Standard. The Chairs agree that discussions and a decision about if, and how, applicable WHA resolutions should be incorporated into the *Standard for Follow-up Formula* fall outside the terms of reference for the eWG, and as such should be deferred until a time when this is specifically addressed. The Chairs would however like to acknowledge the information below provided by eWG members. It is proposed that these valuable comments are noted and considered in future discussions around WHA resolutions.

Comments for future discussions and consideration

Several eWG members did not support the incorporation of relevant WHA resolutions into the *Standard for Follow-up Formula*. As WHA resolution 39.28 relates to the 'non-necessity' of follow-up formula, the point was raised that other Codex Standards for products that are not considered nutritionally necessary do not contain any references to their 'lack of necessity' in the diet, and therefore consistency with the approach taken in other relevant Codex Standards should be followed (for example; the *Standard for Processed Cereal Based Foods for Infants and Young Children* (CODEX STAN 74-1981)).

One Member Country reported that WHA resolution 39.28 relates to the practice of providing 'specially formulated milks', not the marketing and labelling of these products. Another Member Country was of the view that WHA resolution related to 'feeding practices', and as such this information would not normally be included in a Standard.

Several eWG members questioned what would be the 'added value' of including the information contained within WHA resolution into the *Standard for Follow-up Formula*. It was suggested that as standards are not drafted to be read by consumers, its inclusion in the Standard would not result in better information for consumers, nor would it give more relevance to the resolution.

One eWG Member suggested that further discussions on the labelling provisions will most likely consider the necessary information about the correct use of the product as well as whether it is considered a breastmilk substitute or not.

Comment was made that the eWG will also need to consider whether the WHO clarification on *Information concerning the use and marketing of follow-up formula*, should be referenced and quoted in the *Standard for Follow-up Formula*. This information states that;

> *If follow-up formula is marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement for breast milk, it is covered by the Code (International Code of Marketing of Breast-milk Substitutes). In addition, where follow-up formula is otherwise represented in a manner which results in such product being perceived or used as a partial or total replacement for breast milk, such product also falls within the scope of the Code.*

Several eWG members also referenced WHA resolution 63.23 (2010), in addition to WHA resolution 39.28 and suggested its relevance to the Standard for Follow-up Formula should also be considered.

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

The eWG was tasked with reviewing Section 2 (Description) of the current *Standard for Follow-up Formula* (CODEX STAN 156-1987) and propose drafting changes if necessary.

The current drafting of Section 2 of the *Standard for Follow-up Formula* (CODEX STAN 156-*1987)* is as below:

2. DESCRIPTION

2.1 Definitions

2.1.1 ***Follow-up formula*** means a food intended for use as a liquid part of the weaning diet for the infant from the 6th month on and for young children.

2.1.2 The term infant means a person of not more than 12 months of age.

2.1.3 The term ***young children*** means persons from the age of more than 12 months up to the age of three years (36 months).

2.1.4 The term ***calorie*** means a kilocalorie (kcal). 1 kilojoule (kJ) is equivalent to 0.239 calories (kcal).

2.2 ***Follow-up formula*** is a food prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin, which have been proved to be suitable for infants from the 6th month on and for young children.

2.3 ***Follow-up formula*** is a food processed by physical means only so as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution.

2.4 ***Follow-up formula,*** when in liquid form, is suitable for use either directly or diluted with water before feeding, as appropriate. In powdered form it requires water for preparation. The product shall be nutritionally adequate to contribute to normal growth and development when used in accordance with its directions for use.

Several key themes emerged from the summary of submissions in relation to Section 2. These are summarised below. As the review progresses and the final structure of the Standard is determined, the Chairs acknowledge that it will be necessary to continue to review the definitions contained within the Standard to ensure that they remain relevant and provide sufficient clarity.

Key themes relating to the review of Section 2:

- There was widespread support amongst eWG members for ensuring consistency in terms of definitions, terminology and layout, with the Infant Formula Standard.
- There was also widespread support for consistency (in terminology) with other appropriate recently revised Codex standards.
- Amending the format and terminology within Section 2 may assist with avoiding confusion between what might be considered a product definition compared to a product description. For example, points 2.2, 2.3, and 2.4 of the current Standard were not considered by some to be additional definitions for 'follow-up formula', but might be considered product descriptions.
- Some of the definitions/descriptions currently contained within Section 2, might be best located elsewhere in the Standard. It was considered that some text currently appearing under Section 2 o could be moved to Section 3 (Essential Composition) and Section 9.5 (Information for use) to align with the equivalent statements and approach taken in the Infant Formula Standard.

Based on the collective comments of the eWG, the Chairs propose the following structure and definitions for Section 2 for consideration and discussion by the Committee:

2. DESCRIPTION

2.1 Product Definition

2.1.1 **Follow-up formula** means a food intended for use as ~~a liquid part of the weaning diet for the infant from the 6th month on and for young children.~~

[a) the liquid part of the diet for older infants when complementary feeding is introduced; and

b) a liquid part of the progressively diversified diet of young children.]

2.1.2 **[Follow-up formula** is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold].

OR

[Follow-up formula is so processed ~~by physical means only~~ and ~~so~~ packaged as to prevent spoilage and contamination under all normal conditions of handling, storage [,] ~~and~~ distribution [and sale] ~~in the country where the product is sold~~].

2.2 Other Definitions

2.2.1 The term **infant** means a person of not more than 12 months of age.

2.2.2 [**Older infants** means persons from the age of 6 months and not more than 12 months of age.]

2.2.3 The term **young child** means persons from the age of more than 12 months up to the age of three years (36 months).

Please note that the above proposed structure and approach for Section 2 would see current definitions 2.2 and 2.4 moved to other sections of the Standard; definition 2.2 moved to Section 3 – Essential Composition, and definition 2.4 moved to Section 9.5 – Information for Use.

As a review of Section 3 – Essential Composition, currently formed part of the ToR for the eWG, the group considered the drafting of the statement that is currently definition 2.2 and reads as follows:

> ***Follow-up formula*** *is a food prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin, which have been proved to be suitable for infants from the 6th month on and for young children.*

As a result of the collective comments of the eWG, the Chairs propose the following amended drafting for consideration:

Follow-up formula *is a [food] OR [product]* ~~*prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin,*~~ *[based on] OR [consisting of] milk of cows or other animals or a mixture thereof [,] and/or other ingredients which have been [proved] OR [proven] to be [safe and] suitable [and nutritionally adequate] [to support growth and development] for [the intended age range] OR [older infants and young children].* ~~*infants from the 6th month on and for young children.*~~

The following statements have also been proposed (in addition to that above) for consideration by the Committee, if the inclusion of the concept of 'supporting growth and development' is deemed necessary.

[The nutritional safety and adequacy of follow-up formula shall be scientifically demonstrated to support growth and development of older infants and young children.]

OR

[Consumption of the formula should appropriately contribute to normal growth and development of the intended age range].

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

6.1 Overview

The second term of reference for the eWG was to: review the compositional requirements of the *Standard for Follow-up Formula* (6-36 months) with a point of differentiation at 12 months (Sections 3.1-3.3) and propose revised requirements. The findings of the 2014 eWG as presented in CX/NFSDU 14/36/7 and REP15/NFSDU (para 91) were that there was general agreement:

- that there should be a recognised point of differentiation at 12 months of age due to different nutritional requirements and the different role of follow-up formula in the diets of older infants compared to that of young children; and
- that the *Standard for Infant Formula* (CODEX STAN 72-1981) should be the basis for composition of follow-up formula particularly for older infants.

There is strong support from the eWG that the guiding principles for establishing compositional requirements for follow-up formula for older infants should be consistent with the compositional requirements for infant formula unless differences are scientifically justified.

The general principles used to establish minimum and maximum levels in the development of the Infant Formula Standard are outlined in the Annex II of the Standard (CODEX STAN 72-1981, Annex II). In these general principles it is stated that when establishing minimum or maximum amounts of nutrients based on consideration of reference values, the following assumptions were taken into account:

a. The mean intake of prepared formula for infants from birth to six months of age is 750 mL per day, and

b. A representative body weight for an infant over this period is 5 kg, and

c. A representative caloric intake of an infant over this period is 500 kcal per day (or 100 kcal/kg/day).

In considering the essential composition of follow-up formula for older infants (6 to 12 months) the eWG reviewed the scientific basis for establishing the essential compositional requirements from a variety of sources including:

- the report of an international expert group (IEG) coordinated by ESPGHAN[1] which informed *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981),
- the European Food Safety Authority (EFSA) scientific opinion on the essential composition of infant and follow-on formulae (for infants aged 6-12 months)[2] which informed the draft revised EU legislation for the essential composition of infant and follow-on formulae
- the recommendations of recent IEG coordinated by ENA[3]
- recent scientific studies

The approach taken by the eWG was to align where possible with the Infant Formula Standard. The composition of infant formula is designed to be adequate for infants in the first six months of life as a sole source of nutrition. It is generally assumed that from six months onward the contribution of energy and nutrient intakes from complementary foods will compensate for the higher dietary requirements of older infants.

For some nutrients the majority of the eWG have recommended an approach which deviates from the requirements in the Infant Formula Standard. The rationale for deviation is either a result of cases where the scientific evidence has progressed since the development of the Infant Formula Standard, or where there is evidence of nutrient requirements differing between the two age groups.

There was consensus amongst the eWG that the following compositional requirements should align with the requirements within the Infant Formula Standard:

- Energy
- Micronutrients: vitamin B_{12}, pantothenic acid and magnesium

As such it is recommended that the Committee adopt the essential composition requirements specified in the Infant Formula Standard for Energy, vitamin B_{12}, pantothenic acid and magnesium.

There was almost full eWG support that the following nutrients should align with the requirements within the Standard for Infant Formula: vitamin E, vitamin K, thiamin, riboflavin, niacin, biotin, vitamin C, sodium, chloride and potassium. As there was very strong support to align with the Standard for Infant Formula for these nutrients and no clear scientific rationale to deviate, it is recommended that the Committee adopt the essential requirements specified in the Standard for Infant Formula for the composition of follow-up formula for older infants for these nutrients. Further information on the scientific rationale and eWG views on the compositional requirements for these nutrients are provided in Appendix 1.

Further consideration by the Committee and pWG is required for the essential composition (including associated footnotes) of follow-up formula for the following nutrients:

- Macronutrients: protein, lipids and carbohydrates
- Vitamins: vitamin A, vitamin D, vitamin B_6, folic acid
- Minerals and trace elements: iron, calcium, phosphorous, manganese, iodine, selenium, copper and zinc.

For these nutrients further information on the eWG's views as to how these nutrients should be included in the essential composition for follow-up formula for older infants is presented in detail below. This paper provides recommendations for discussion in the physical working group regarding these nutrients.

Recommendation 1

That CCNFSDU agree to revise the essential composition for follow-up formula for older infants to align with the requirements specified in the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981) for the following nutrients:

- Energy
- Vitamins: vitamin E, vitamin K, thiamin, riboflavin, niacin, vitamin B_{12}, pantothenic acid, vitamin C and biotin.
- Minerals: magnesium, sodium, chloride, potassium

Other issues related to the essential composition of follow-up formula

Acknowledging the support for aligning with the Infant Formula Standard, the eWG have noted some inconsistencies within the Infant Formula standard which should be addressed in the revision of the Follow-up Formula standard. The first of which is the inconsistent conversion factors to calculate the requirements when presented as kJ. At times rounding inconsistencies have occurred in the derivation of values per kJ in the Infant Formula Standard when using the international standard unit (ISU) conversion factors[4]. The conversion factors for kilojoules and kilocalories are: 1 kJ = 0.239 kcal; and 1 kcal = 4.184 kJ. A table correcting these differences is provided in Appendix 1. It is recommended that the Committee give consideration to the conversion factors used when revising the essential composition of the *Standard for Follow-up Formula*.

In addition to this there are inconsistencies between the units presented in the Infant Formula Standard and the permitted forms of nutrients listed in the *Advisory List of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CAC/GL 10-1979). For example, vitamin D is listed only as cholecalciferol (D3) however two forms of vitamin D are permitted to be added to infant and follow-up formula.

Recommendation 2

That CCNFSDU consider amending the conversion factors in line with the International Standard Unit conversion factors and conventional rounding.

6.2 Macronutrients

6.2.1 Protein

All eWG members supported lowering the protein requirements of the *Standard for Follow-up Formula*. The eWG acknowledged the 2007 WHO/FAO/UNU revised guidelines on protein requirements[5] were lower than previous estimates of protein requirements for this age group and that high protein composition of formula was not adequate for normal growth and development.

Despite all eWG members supporting a reduction in the minimum and maximum compositional requirements for follow-up formula for this age group, there were diverging opinions as to the specific requirements that should be established.

Minimum

The majority of eWG members supported adopting the minimum protein compositional requirements of the Infant Formula Standard, which also align with the recommendations of EFSA[2] (11 CM, 1CMO, 3 CO). It was highlighted by many eWG members that there was no scientific rationale to alter the requirements to those established for infant formula, as 1.8 g/100 kcal is nutritionally adequate to support growth and development.

Some eWG members considered that the minimum protein content should be further lowered to 1.65 g/100 kcal based on the IEG report coordinated by ENA (6 CM, 2 CO). The rationale provided by the IEG relate specifically to the revised protein requirements established by WHO/FAO/UNU[5] and EFSA[6], and the minimum quantity of protein in formula to safely cover these needs[3]. In addition to this it was stated that there was suggestive evidence which supported this value. For example, evidence of lower protein content of human milk fed to older infants, and trials which suggest that excessive protein intakes in early childhood may lead to differences in growth and obesity outcomes later in life.

The EFSA opinion reviewed the protein content of human milk, protein requirements and studies evaluating the adequacy of protein in formula. The EFSA opinion recommendations are principally based on the evidence provided by randomised controlled trials illustrating the adequacy of protein formulations of infant and follow-on formulas[2].

The EFSA Scientific Opinion stated the following regarding protein intake estimates based on human milk: "*Estimating true protein intakes from breast milk is difficult because of the non-protein nitrogen (NPN) fraction, which represents about 25 % of total nitrogen and is made up of urea (up to 50 % of NPN), free amino acids and other nitrogenous compounds. How and how much of NPN is utilised by the body is not entirely understood[5]. Moreover, the composition of the protein fraction of breast milk changes with time, and no data are available on the true digestibility of the different fractions. Therefore, in previous opinions[6] the Panel decided to derive an adequate requirement and subsequently a population reference intake for protein for infants based on a factorial approach as the sum of the requirement for maintenance and the requirement for growth adjusted for efficiency of dietary protein utilisation."*

Regarding the availability of studies conducted evaluating the adequacy of protein content of formulas, EFSA have provided the following opinion: *Several studies which investigated the safety and suitability of IF based on intact cows' milk protein with protein contents of 1.8-1.9 g/100 kcal have been reviewed by the Panel previously[7]. These studies have generally shown that protein concentrations in formula of 1.8-1.9 g/100 kcal when derived from intact milk protein are adequate to promote normal growth when these formulae are fed ad libitum. In a study of infants consuming a low protein IF with 1.77 g protein per 100 kcal and subsequently FOF providing 2.2 g protein per 100 kcal for the first year of life and who were followed up until 24 months of age, no statistically significant differences between the group consuming low-protein formula and the breast-fed reference group with respect to weight-for-length and body mass index (BMI) were found at 24 months of follow-up[8]. Another study investigated the effect on infant growth of an IF with a protein content of 1.9 g/100 kcal compared with an IF with a protein content of 2.2 g/100 kcal which was consumed for four months[9]. There were no statistically significant differences between the two formula groups with respect to weight gain, length gain and head circumference at the end of the study at four months of age.* No eWG member has provided alternative studies in support of establishing a different compositional requirement.

For those in support of establishing a minimum value of 1.8 g/100 kcal it was noted that WHO/FAO state that the protein composition of formula will need to exceed that provided by human milk and protein requirements in order to compensate for differences in dietary protein digestibility, bioavailability and efficiency of utilization between human milk and formula to meet the protein requirements of formula-fed infants[5]. Some eWG members also stressed the importance of ensuring that composition was sufficient to meet the nutritional needs of infants, an issue which was of particular importance in low income countries where protein intakes can be limited, and protein quality of the complementary diet inadequate to support needs.

Based on the collective comments of the eWG it is recommended that the minimum composition of follow-up formula should be lowered to the level permitted in the Infant Formula Standard (1.8 g/100 kcal).

Maximum

The establishment of a maximum protein level for follow-up formula is complicated by the fact that there is no scientific data available which can enable the establishment of precise cut-off values for the maximum protein content of formula for the first year of life. The eWG had a variety of views as to the level which should be established and it is acknowledged that all proposed values are based on expert judgement of what would constitute an upper bound of the adequate range of intake.

Alignment of the maximum protein composition of 3.0 g/100 kcal in the Infant Formula Standard was the preferred maximum of the eWG (8 CM, 1 CO). However, there was also support for reducing the maximum to 2.5 g/100 kcal (5 CM, 1CMO), or to 3.5 g/100 kcal (5 CM, 1CO). Some eWG members noted that alignment with the Infant Formula Standard would result in a reduction in protein content in follow-up formula which does not align with the current compositional range for protein in the *Standard for Follow-up Formula* (current range: 3.0 -5.5 g/100 kcal). It was noted that this could cause significant issues for trade as current formulations of follow-up formula will not comply with the protein requirements. Furthermore this will have issues as national jurisdictions begin to adopt the revised *Standard for Follow-up Formula*. The Committee

will need to consider how to accommodate an approach which would result in such a shift in composition, and if this was the preferred approach whether a transition period for implementation would be required.

Due to the lack of strong scientific justification in establishing a maximum limit and potential impact on trade, it is recommended that a maximum level of 3.5 g/100 kcal is established to enable the transition to lower protein content of follow-up formula globally.

Footnote 2

[2]For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of different conversion factor for a particular product. The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. The value of 6.38 is generally established as a specific factor appropriate for conversion of nitrogen to protein in other milk products, and the value of 5.71 as a specific factor for conversion of nitrogen to protein in other soy products.

Inclusion of footnote 2 in the format presented in the Infant Formula Standard was recommended by the majority of the eWG (12 CM, 6 CO). One Codex Member Organisation suggested that the footnote could be simplified to state: "for the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25" if this was to be simultaneously modified in the Infant Formula Standard.

Three Codex Observers did not support this approach. These members noted that isolated soy protein is the most commonly used soy protein source in formula, in addition to soy protein concentrate and soy protein flour which are sometimes used. They noted that the *Standard for Soy Protein Products* (CODEX STAN 175-1989) lists the appropriate nitrogen to protein conversion factors as 6.25 for these ingredients. As this view was not supported by the majority of the eWG it is proposed to include Footnote 2 as stated in the Infant Formula Standard.

Footnote 3

[3] For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex I); nevertheless for calculation purposes, the concentrations of tyrosine and phenylalanine may be added together. The concentrations of methionine and cysteine may be added together if the ratio is less than 2:1; in the case that the ratio is between 2:1 and 3:1 the suitability of the formula has to be demonstrated by clinical testing.

All eWG members supported inclusion of footnote 3 with regards to the reference to the amino acid composition of breast milk as defined in Annex I of the Infant Formula Standard as the reference protein. Some eWG members noted that the Annex may need to be reviewed.

The majority of eWG members supported adapting the footnote slightly. eWG members noted that there should be no restrictions regarding amino acid ratios as complementary foods will contribute to amino acid intakes and the metabolism of older infants is more mature with respect to the capacity to convert methionine to cysteine and phenylalanine to tyrosine. The majority of eWG members supported removing the reference to ratios but ensuring that for calculation purposes the sum of tyrosine and phenylalanine and the sum of methionine and cysteine may be used. It is recommended that footnote 3 is adapted to reflect this.

Footnote 4

[4] Isolated amino acids may be added to Infant Formula only to improve its nutritional value for infants. Essential and semi-essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only L-forms of amino acids shall be used.

All eWG members supported adopting footnote 4 of the Infant Formula Standard with modification to reflect that this is applicable to follow-up formula.

Footnote 5

[5] The minimum value applies to cows' milk protein. For infant formula based on non-cows' milk protein other minimum values may need to be applied. For infant formula based on soy protein isolate, a minimum value of 2.25 g/100 kcal (0.5 g/100 kJ) applies.

The majority of eWG members noted that separate protein compositional requirements should be established for soy protein isolate formulas and supported the inclusion of footnote 5. This approach is consistent with the recommendations of EFSA[10] and IEG[3]. It was suggested that the footnote should be amended to improve the clarity to reflect that the minimum value applies to cows' **and/or other animals'** milk

protein, and should be amended accordingly. However many eWG members noted that this would not be suitable as it implied that milk protein of any other animal is considered similar to cows' milk protein. It was noted that clinical testing would be required to support minimum protein values for other types of animal milk. It is noted that clinical trials of goats milk based formulas have been conducted and independently evaluated by EFSA as safe and adequate for infants[11], and it may be more accurate to include reference to goats' milk. It is therefore recommended to adopt the footnote as presented in the Infant Formula Standard with consideration of whether the minimum value is also applicable to goats' milk protein.

Footnote 6

[6] Infant formula based on non-hydrolysed milk protein containing less than 2 g protein/100 kcal and infant formula based on hydrolysed protein containing less than 2.25 g protein/100 kcal should be clinically evaluated.

Several eWG members did not support the inclusion of footnote 6 as currently presented in the Infant Formula Standard. Some eWG members noted that there is no rationale for providing formula based on protein hydrolysates after the introduction of complementary foods. In addition to this it was noted that there is no need to state that formula based on non-hydrolysed milk protein needed to be clinically evaluated as there was already strong evidence to support its adequacy and safety. Some eWG members noted that if formula is clinically evaluated as suitable for young infants this should preclude further evaluation for the older infant age range. Taking into consideration the collective eWG comments it is recommended that footnote 6 is not included.

Recommendation 3

That CCNFSDU agree to revise the protein minimum and maximum level and associated footnotes, as follows:

Protein[2), 3), 4)]

Unit	**Minimum**	**Maximum**	**GUL**
g /100 kcal	[1.8][5)]	[3.5]	-
g /100 kJ	[0.43][5)]	[0.84]	-

[2)] For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product**.** The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. The value of 6.38 is generally established as a specific factor appropriate for conversion of nitrogen to protein in other milk products, and the value of 5.71 as a specific factor for conversion of nitrogen to protein in other soy products.

[3)] For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex I of the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981)); nevertheless for calculation purposes the sum of tyrosine and phenylalanine and the sum of methionine and cysteine may be used.

[4)] Isolated amino acids may be added to ~~Infant F~~ follow-up formula only to improve its nutritional value for infants. Essential and semi-essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only L-forms of amino acids shall be used.

[5)] The minimum value applies to cows' [**and goats'**] milk protein. For ~~infant~~ follow-up formula based on non-cows' milk protein other minimum values may need to be applied. For ~~infant~~ follow-up formula based on soy protein isolate, a minimum value of 2.25 g/100 kcal (0.54 g/100 kJ) applies.

[6)] **[**~~Follow-up formula based on non-hydrolysed milk protein containing less than~~ **[**~~2 g protein/100 kcal~~**]** ~~and~~**]** ~~infant~~ **[**~~formula based on hydrolysed protein containing less than~~ **[**~~2.25 g protein/100 kcal~~**]** ~~should be clinically evaluated~~**].**

6.2.2 Lipids

The Infant Formula Standard requires a total fat content of 4.4-6.0 g/100 kcal, the equivalent to about 40-55% of energy content typically found in human milk. EFSA[2]and the IEG[3] also recommend that this composition is required for follow-up formula, as there is no scientific reason to differentiate the fat content of infant and follow-up formula. All eWG members supported the alignment of the total fat content to that prescribed in the Infant Formula Standard. All eWG also supported alignment with footnotes associated with

the “Total Fat” requirements as specified in the Infant Formula Standard for the requirements for lauric, myristic and erucic acid, use of commercially hydrogenated oils, and trans fat limitations.

Some eWG members noted that while the Infant Formula Standard total fat requirements and associated footnotes largely aligned with those set by EFSA, yet there were some differences. These included the lack of specification of requirements for lauric, myristic and erucic acid or phospholipids. EFSA did not consider that there was sufficient evidence to mandate upper or lower bounds for specific types of saturated fatty acids[2]. In the second round of consultation all eWG members were satisfied to take a precautionary approach, in line with the requirements of the Infant Formula Standard.

One eWG member noted that a definition for trans fatty acids is not included in the standard. The Committee is currently awaiting the outcome of the WHO Nutrition Guidance Expert Advisory Group (NUGAG) sub-group on Diet and Health opinion on trans-fatty acids prior to consideration of a definition for trans fatty acids (REP13/NFSDU, para 151-153).

Regarding phospholipids, EFSA considered there to be a lack of convincing evidence for a beneficial effect of LCPUFAs supplied as phospholipids instead of triacylglcerides[2]. However in the second consultation paper the majority of eWG members recommended alignment with the Infant Formula Standard (20 CM, 1 CMO, 6 CO). A higher GUL for phospholipids was also proposed by two eWG members citing the IEG recommendations which state that an increased GUL could be set as the complementary diet can contain much higher amounts of phospholipids[3].

Taking into consideration the support from the eWG it is recommended that the compositional requirements for total fat, including footnotes 7 and 8 from the Infant Formula Standard are adopted for the essential composition of follow-up formula for older infants.

Recommendation 4

That CCNFSDU agree to revise the total fat minimum and maximum level and associated footnotes, as follows:

Total Fat [7), 8)]

Unit	Minimum	Maximum	GUL
g /100 kcal	[4.4]	[6.0]	-
g /100 kJ	[1.1]	[1.4]	-

[7)] Commercially hydrogenated oils and fats shall not be used in follow-up formula

[8)] Lauric acid and myristic acids are constituents of fats, but combined shall not exceed 20% of total fatty acids. The content of trans fatty acids shall not exceed 3% of total fatty acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to 3% of trans fatty acids is intended to allow for the use of milk fat in follow-up formulae. The erucic acid content shall not exceed 1% of total fatty acids. The total content of phospholipids should not exceed 300 mg/100 kcal (72 mg/100 kJ).

6.2.3 Linoleic and α-Linolenic acid

The majority of eWG members supported adopting the compositional requirements for linoleic acid (LA) (18:2n-6) and α-linolenic acid (ALA) (18:3n-3) as specified in Infant Formula Standard (16 CM, 3 CO). The Infant Formula Standard also specifies that the addition of LA and ALA is within a minimum and maximum ratio of 5:1 to 15:1 (16 CM, 3 CO).

Linoleic acid (LA)

The Infant Formula Standard requirements for these essential fatty acids (EFAs) was based on the report of the ESPGHAN IEG stated that a minimum level of 300 mg/100 kcal (2.7% E) is sufficient to cover the minimum linoleic acid requirement. This value was considered to be in line with the adequate intake level proposed by FAO and sufficient to meet the needs of infants[12].

Some eWG members noted that the EFSA requirements differed slightly[1] (3 CM, 1 CMO, 2 CO). The EFSA recommendations for minimum and maximum compositional requirements for LA were based on reported LA content of human milk, however it was noted that the PUFA content of human milk does vary dependent on the maternal diet[2].

The establishment of a maximum limit for LA was deemed necessary by the ESPGHAN IEG to prevent high intakes which *may induce untoward metabolic effects with respect to lipoprotein metabolism, immune function, eicosanoid balance and oxidative stress*[1]. However the ESPGHAN IEG maximum limit of 1200

mg/100 kcal was not adopted by the Committee in the establishment of the Standard of Infant Formula as a history of apparent safe use had been demonstrated in formulas on the market containing 1400 mg/100 kcal.

α-Linolenic acid (ALA)

ALA is an essential fatty acid and is particularly important in its role as a precursor to DHA[1]. All eWG members supported establishing a minimum requirement of 50 mg/100 kcal for follow-up formula for older infants in line with the requirements of the Infant Formula Standard. Almost all eWG members preferred to take the approach of the Infant Formula Standard and to establish a ratio of LA/ALA. The use of a ratio negates the need to establish an additional maximum limit for ALA as it is limited by the upper bound of the ratio and maximum established for LA. The ratio takes into account that high intakes of ALA may increase the risk of lipid perodixation, product rancification, and may adversely affect product stability. A ratio was established to ensure appropriate limitation of ALA to no more than 240 mg/100 kcal. Many in the eWG stated that the inclusion of a ratio has further benefits as it also ensures that LA and ALA composition is in line with the content of these fatty acids in human milk, and ensures an appropriate balance of LA and ALA and their long chain polyunsaturated fatty acid (LCPUFA) metabolites.

The EFSA opinion recommended a maximum ALA level in place of a ratio, as it was not considered necessary to establish a ratio due to the mandatory addition of the long chain polyunsaturated fatty acid (LCPUFA) docosahexanoic acid (DHA)[2]. The need for a specific maximum is linked to the mandatory presence of DHA.

Recommendation 5

That CCNFSDU agree to revise the linoleic and alpha-linolenic minimum and maximum level, as follows:

Linoleic acid

Unit	**Minimum**	**Maximum**	**GUL**
mg /100 kcal	[300]	[1400]	-
mg /100 kJ	[72]	[335]	-

α-Linolenic acid

Unit	**Minimum**	**Maximum**	**GUL**
mg/100 kcal	[50]	N.S.*	-
mg /100 kJ	[12]	N.S.	-

*N.S. = not specified

Ratio linoleic acid/ α-Linolenic acid

Min	**Max**
5:1	15:1

6.2.4 Long chain polyunsaturated fatty acids

Several eWG members noted the recent EFSA Scientific Opinion which has recommended that the addition of DHA should be added to all infant and follow-up formulas in the European Union[2].

The EFSA recommendation for the addition of DHA to all formulas was "*based on its structural role in the nervous tissue and retina, and its involvement in normal brain and visual development, and the need of the developing brain to accumulate large amounts of DHA in the first two years of life, and the consideration that the intake of pre-formed DGA generally results in an erythrocyte DHA status more closely resembling that of a breast-fed infant than is achieved with ALA alone.*" The minimum level was based on the level considered adequate for the majority of infants (100 mg/day), whereas the upper bound level was based on the highest observed DHA concentration in human milk (around 1% total fatty acids). EFSA did not consider it necessary to establish a minimum ARA or EPA content, or specific ratios for these fatty acids. Furthermore the EFSA panel noted that "*there is no convincing evidence that the addition of DHA to infant formula and follow-up formula has benefits beyond infancy on any functional outcomes*." [2] Further to this EFSA stated " *there is also a lack of long-term follow-up data on specific aspects of cognitive and behavioural function from adequately powered RCTs of DHA addition to [infant formula and follow-on formula] to demonstrate any purported biologically plausible effect of DHA on these aspects."* [2]

eWG members in support of requiring follow-up formula to contain minimum amounts of DHA stated that there was convincing evidence of the role of DHA on brain and eye development. As stated by EFSA it was

considered prudent to provide pre-formed DHA as it enables erthyrocyte DHA status to more closely resemble that of breast-fed infants than when formula contains ALA alone[2]. It was also highlighted that DHA and ARA are considered conditionally essential during early development by the FAO due to their role in normal retinal and brain development[12]. The 2014 eWG report was cited as supporting evidence demonstrating the limited intakes of DHA in early infancy[13].

Of those eWG members which recommended that the addition of DHA to follow-up formula for older infants remain optional it was stated that there remained a lack of rigorous studies or scientific consensus as to the need to mandate its addition. It was also considered important to consider the DHA content of other complementary foods in the diet, in addition to the affordability of requiring this addition, and the regional variation in intakes. Many eWG members supported alignment with the Infant Formula Standard.

It was also noted by several eWG members that the addition of DHA, whether as optional or essential ingredient, should be accompanied by the addition of arachidonic acid (ARA).

Despite many eWG members recommending that the addition of DHA should be mandated (6 CM, 2 CO) the majority of the eWG recommended that the addition of DHA should remain optional (13 CM, 4 CO). At this time it is recommended that the Committee continue to consider the addition of LCPUFAs DHA, ARA and EPA as optional additions.

Recommendation 6

That CCNFSDU agree to consider the addition of DHA, ARA and EPA as optional additions to follow-up formula.

6.2.5 Carbohydrates

The Infant Formula Standard carbohydrate compositional requirements are based on the residual energy in formula that contain the permitted minimum and maximum amounts of protein and fat. All eWG members supported adopting the total carbohydrate minimum and maximum requirements specified in the Infant Formula Standard (21 CM, 1 CMO, 6 CO).

Footnote 9

Lactose and glucose polymers should be the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein. Only precooked and/or gelatinised starches gluten-free by nature may be added to Infant Formula up to 30% of total carbohydrates and up to 2 g/100 mL

The eWG had a strong preference that the preferred source of carbohydrate should be lactose, unless a product was "lactose free". Some eWG members highlighted that the EFSA opinion recommended establishing a minimum lactose level of 4.5 g/100 kcal[10]. It was generally considered that the same approach as taken for the Infant Formula Standard should be applied to follow-up formula for older infants. As such it is recommended that the statement relating to lactose and glucose polymers as the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein is adopted.

There was consensus from the eWG that any addition of starches must be gluten free, however, there was divergence in views as to whether the addition of gluten-free starches should be limited to up to 30% of total carbohydrates, or unrestricted within the limits of total carbohydrates. The EFSA report recommended that different requirements should be established for infant and follow-up formulas for the addition of pre-cooked and gelatinised starches free of gluten[2]. EFSA recommended that for infant formula the addition of pre-cooked and gelatinised starches free of gluten should be limited to up to 30% of total carbohydrates, and for follow-up formula should be limited only by the maximum permitted total carbohydrate specifications[2].

All eWG members supported the inclusion of a maximum limit to the addition of sucrose and fructose to follow-up formula for older infants therefore it is recommended to be included in footnote 9. There were diverging views as to whether this limit should also include reference to honey. Many eWG members were strongly opposed to including this addition as honey whether raw or pasteurized was not recommended for consumption by infants aged 0-12 months. Taking this view into account it is recommended that honey is not included as a suitable source of carbohydrate.

Recommendation 7

That CCNFSDU agree to revise the carbohydrate minimum and maximum level, as follows:

Total Carbohydrates [9)]

Unit	Minimum	Maximum	GUL
mg /100 kcal	[9.0]	[14.0]	-
mg /100 kJ	[2.2]	[3.3]	-

[9)] Lactose and glucose polymers should be the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein. [Only precooked and/or gelatinised starches gluten-free by nature may be added.] [If needed, sucrose, fructose may be added provided the sum of these does not exceed ≤20% of total carbohydrate.]

6.3 Vitamins and Minerals

6.3.1 Vitamin A

Minimum

The majority of eWG were supportive of establishing a higher minimum vitamin A requirement than that currently specified in the Infant Formula Standard (60 µg RE/100 kcal). This was based on the fact that since the time of the scientific review which informed the Infant Formula Standard, vitamin A requirements have been updated by WHO/FAO[14] and EFSA[13]. Intakes of formula containing 60 µg of vitamin A per 100 kcal would not meet the vitamin A requirements of infants (0-6 or 6-12 months) specified by WHO/FAO[14] (375-400 µg/day), IOM[15] (400 -500 µg/day), or EFSA[13] (350 µg/day).

Based on the WHO/FAO recommended intake of vitamin A in infancy[14], to ensure that requirements during the first half of infancy were met formula would need to contain at least 75 µg/100 kcal assuming consumption of an average quantity of 500 kcal per day.

Considering the critical importance of vitamin A in infancy, many eWG members supported retaining the current minimum of 75 µg/100 kcal or adopting the minimum recommended by EFSA[2] (70 µg/100 kcal). Taking into consideration the majority view of the eWG it is recommended that the vitamin A minimum should be retained at current levels based on more recent recommended intakes of vitamin A by recognised authoritative scientific bodies.

Electronic working group members were of the view that for vitamin A there was no need to establish different requirements for infant and follow-up formula. One eWG member noted there was a case for elevating the minimum requirement of both standards and proposed that the Committee consider a targeted review of the Infant Formula Standard.

Maximum

eWG members were supportive of establishing a maximum level, with some diverging views as to the specific level to be selected. The eWG was equally split between those that recommended retaining the current maximum of 225 µg RE/100 kcal on the basis of a history of apparent safe use and vitamin A's importance in the diet, versus those that recommended lowering the maximum. Those in favour of lowering the maximum recommended either reducing the level to that of the Infant Formula Standard (180 µg RE/100 kcal) or to the revised maximum in EU legislation (114 µg RE/100 kcal). It was generally considered unnecessary to provide extra vitamin A beyond requirements. Furthermore it was also noted that average consumption of formula at the maximum limit of 225 µg RE/100 kcal would provide vitamin A in excess of the tolerable upper level (UL) established by WHO/FAO[16] (600 µg retinol) and EFSA[17] (800 µg retinol).

The maximum established in the EU allows for vitamin A requirements to be met and allows for some contribution of vitamin A from the complementary diet without exceeding the UL at consumption levels of 500 kcal per day. The majority of eWG members preferred to establish a maximum limit aligned with the Standard for Infant Formula for consistency and noting that vitamin A is critically essential in some countries. Taking into account the majority view of the eWG it is recommended that a maximum level in alignment with the Standard for Infant Formula is established.

Footnote

All eWG members supported the inclusion of a footnote regarding retinol equivalents that was aligned with the Infant Formula Standard. It should be noted that the addition of vitamin A in the form of beta-carotene is

permitted to be added to both infant and follow-up formula but is not able to contribute to the calculation of vitamin A content of formulas (CAC/GL 10-1979).

Recommendation 8
That CCNFSDU agree to retain the current minimum vitamin A composition, and to revise the maximum level and footnote in accordance with the Infant Formula standard, as follows:

Vitamin A

Unit	Minimum	Maximum	GUL
µg RE [10)]/100 kcal	[75]	[180]	-
µg RE [10)]/100 kJ	[18]	[43]	-

[10)] expressed as retinol equivalents (RE)

1 µg RE = 3.33 IU Vitamin A = 1 µg trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

6.3.2 Vitamin D

The majority of the eWG were of the view that the vitamin D composition should be modified to that currently specified in the Standard for Infant Formula. Recommendations to deviate from the Infant Formula Standard were based on more recent evidence which has resulted in elevated vitamin D requirements, proposed by recognised authoritative scientific bodies[13,18], for infants when exposure to sunlight is limited.

There was no consensus with regards to the level at which the minimum or maximum vitamin D composition for follow-up formula for older infants should be set. Many members of the eWG highlighted the regional differences which exist in vitamin D requirements and prevalence of inadequate vitamin D status. Two approaches were recommended to address the variable prevalence of inadequate vitamin D status regionally, either to elevate the minimum or elevate the maximum vitamin D composition of follow-up formula for older infants. Some eWG members noted that different public health approaches were used to address vitamin D insufficiency, including the use of supplementation programmes in some countries.

Minimum

Although many eWG members preferred to elevate the minimum requirement for vitamin D to 2 µg/100 kcal in line with the recommendations of EFSA[2], there were many that raised concerns that not all countries required an elevated minimum level due to the regional variation in vitamin D requirements and status. As such alignment with the minimum requirements specified in the Infant Formula Standard with minor modifications is recommended. It is noted that there is an error in the rounding of the minimum level per 100 kJ, when using the ISU conversion factor[4]. The minimum level equates to 0.239 µg /100 kJ which should be rounded to 0.24 µg /100 kJ using conventional rounding methods.

Maximum

Members of the eWG were split between those that preferred to align with the Infant Formula Standard and establish a maximum of 2.5 µg /100 kcal and those that wished to elevate the maximum to 4.5 µg /100 kcal. Those that preferred to elevate the maximum based this on the evidence of sub-optimal vitamin D status in some regions, and the recommendation of an international expert group coordinated by ENA[3] (9 CM, 4 CO). The majority of eWG members were concerned with establishing a maximum level which would lead to excessive intakes through regular consumption of follow-up formula without taking into consideration intakes of complementary foods. Taking into account the eWG's view to enable a wider range of vitamin D concentrations to be added to follow-up formula to accommodate regional variation in vitamin D requirements, it is recommended that the maximum is retained at 3.0 µg /100 kcal. This level was considered suitable as it provides vitamin D intakes which meet the requirement level and does not lead to intakes which exceed the UL. In addition to this it is aligned with the Draft EC legislation. Using ISU conversion factors[4], 3.0 µg /100 kcal equates to 0.717 µg /100 kJ, which should be rounded to 0.72 µg /100 kJ.

Title

There is an inconsistency between the presentation of vitamin D in the Standard for Infant Formula and the permitted forms of nutrients listed in the Codex Advisory List of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children (CAC/GL 10-1979). Vitamin D is listed only as cholecalciferol (D3) however two forms of vitamin D are permitted to be added to infant and follow-up formula (ergocalciferol (D2) and cholecalciferol (D3). It is recommended that as two forms of vitamin D are permitted for the addition to follow-up formula that the compositional requirements are simply stated as "vitamin D" rather than "vitamin D_3".

Recommendation 9

That CCNFSDU agree to revise the minimum and maximum for vitamin D as follows:

Vitamin D

Unit	Minimum	Maximum	GUL
µg [11)]/100 kcal	[1.0]	[3.0]	-
µg [11)]/100 kJ	[0.24]	[0.72]	-

[11)] Calciferol. 1 µg calciferol = 40 IU vitamin D.

6.3.3 Vitamin B_6

The majority of eWG members recommended that the vitamin B_6 composition for follow-up formula for older infants be aligned with that specified in the Infant Formula Standard (16 CM, 7 CO). There was consensus, amongst those eWG members that provided feedback, that the GUL for vitamin B_6 should be that specified in the Infant Formula Standard (17 CM, 6 CO).

Currently the *Standard for Follow-up Formula* contains a footnote:

Formulas should contain a minimum of 15 µg Vitamin B6 per gramme of protein.

The Infant formula Standard does not contain an equivalent statement. Although it is recognised that the dietary requirement for vitamin B_6 varies in relation to the dietary consumption of protein[2,19], neither the IEG nor EFSA recommends that a footnote is necessary. No consensus was reached within the eWG regarding the need to include a footnote, with the eWG members equally divided as to whether the standard should contain a footnote. As there is no scientific reason to deviate from the Infant Formula Standard it is recommended that a footnote is not included.

Applying the ISU conversion factors[4] to the minimum and GUL vitamin B_6 level specified in the Infant Formula Standard would result in a minimum of 8.365 and GUL of 41.825 µg /100 kJ. Applying conventional rounding it is recommended that the vitamin B_6 minimum is rounded to 8.4 µg /100 kJ and GUL to 41.8 µg /100 kJ.

Recommendation 10

That CCNFSDU agree to revise the minimum and GUL for vitamin B_6 as follows:

Vitamin B_6

Unit	Minimum	Maximum	GUL
µg /100 kcal	[35]	-	[175]
µg /100 kJ	[8.4]	-	[41.8]

6.3.4 Folic acid

Currently the Standards for Infant and Follow-up Formula specify folate compositional requirements in the form of folic acid. The *Advisory List of Nutrient Compounds for use in Foods for Special Dietary Uses Intended for Infants and Young Children* (CAC/GL 10-1979) specifies that only folic acid in the form of N-Pteroyl-L-glutamic acid can be added to infant and follow-up formula (with the exception of infant formula for special medical purposes intended for infants). The naturally occurring folate present in formula is deemed negligible.

Some eWG members preferred stating folic acid requirements as folate, and providing dietary folate equivalents. If this approach was taken then it would be unnecessarily inconsistent with the Infant Formula Standard.

It is recommended that the revised Standard for Follow-up Formula is consistent with the Infant Formula Standard. If, and when, other forms of folate are permitted for addition to infant and follow-up formula, the standards should be updated accordingly.

Applying the ISU conversion factors[4] to the minimum and GUL folic acid level specified in the Infant Formula Standard would result in a minimum of 2.39 and GUL of 11.95 µg /100 kJ. Applying conventional rounding it is recommended that the folic acid minimum is rounded to 2.4 µg /100 kJ and GUL to 12 µg /100 kJ.

Recommendation 11

That CCNFSDU agree to revise the minimum and GUL for folic acid in accordance with the Infant Formula standard, as follows:

Folic acid

Unit	Minimum	Maximum	GUL
µg /100 kcal	[10]	-	[50]
µg /100 kJ	[2.4]	-	[12]

6.4 Minerals and Trace Elements

6.4.1 Iron

Full-term infants have iron stores sufficient to cover their needs during the first 4–6 months of life. Consequently, exclusive breast feeding during this period can meet infant iron requirements despite the low concentrations of iron in breast milk (0.3 mg/L). Between six and 24 months of age infants become dependent on additional dietary iron, due to exhaustion of endogenous body iron stores and rapid growth during this time lead to high iron requirements[2,3,19]. As such, iron rich complementary foods are recommended during this time.

Generally the eWG recommended that the minimum iron content of follow-up formula for older infants should be greater than that specified in the Infant Formula Standard. This approach is aligned with the recent EFSA recommendation, whereby iron is considered the only micronutrient for which it is considered that follow-up formula should provide higher amounts than that specified for infant formula[2].

The majority of eWG members preferred retaining the current minimum iron level for follow-up formula of 1 mg/100 kcal (11 CM, 1 CO), whereas others preferred adopting the minimum recommended by EFSA[2] of 0.6 mg/100 kcal (3 CM, 1 CMO).

The EFSA recommendation is to establish a minimum iron composition of 0.60 mg/100 kcal for follow-up formula, and formula designed to be suitable for the whole first year of life[2]. This level was also supported by the American Academy of Pediatrics as the minimum level for infant formulas to maintain iron status of infants. The EFSA minimum is based on the assumption that other complementary foods can provide around 70% of an infant's daily iron requirements (requirement 8 mg/day). The EFSA recommendation to provide higher iron in formulas targeted to infants over six months is partly based on evidence of significantly lower iron status in infants fed low iron formula (0.35 mg/100 kcal) compared to higher iron fortified formula (1.95 mg/10 kcal)[20]. There is evidence that iron fortified formulas reduce the risk of low iron status, iron deficiency anaemia, particularly when compared to cows' milk [20-23]. Currently in Europe, follow-up formulas usually contain between 1.5 mg and 1.8 mg/100 kcal (10-12 mg/L) [24]. A recent review by the ESPGHAN Committee on Nutrition stated that while it is possible that iron fortification at lower concentrations may be safe and effective, further studies were warranted [24]. Based on available scientific evidence on the maintenance of iron stores and the views of the eWG it is recommended that a minimum of 1.0 mg/100 kcal is retained.

Maximum

The majority of eWG members stated it was important to establish a maximum iron level in follow-up formula (11 CM, 1 CMO, 1 CO). Some eWG member expressly supported the approach adopted in the Infant Formula Standard to leave the setting of maximum levels to National Authorities due to regional differences (5 CM, 2 CO).

It was considered important to establish a maximum limit by the majority of the eWG due to concerns of excessive iron intakes in iron replete individuals which have in some studies been associated with increased risk of infection, reduced growth[25], and the potential negative effective on neurodevelopment at 10 years[26]. Furthermore the setting of maximum amounts or GULs for all vitamins and minerals in this Codex Standard was considered important.

Several papers were cited, including a review of the health benefits and risk of iron supplementation in infancy and young childhood in developing countries[27]. The studies included provided iron doses of between 10 and 50 mg/day. It was reported that three out of 10 studies showed a lower weight gain in the iron-fortified groups, and four out of 16 studies showed an increased incidence of infections.

Another study on infants in Sweden and Honduras observed negative growth consequences associated with higher iron intakes (supplementation at 1 mg/kg body weight per day vs. no supplementation), although the effects were small, i.e. 0.2-0.6 cm difference in length gain in both Honduras and Sweden between the ages

of four and nine months and, in Swedish infants, there was a difference in weight gain of 100-200 g and in head circumference of 0.2-0.3 cm over the five-month period[25].

In a follow-up of the study by Walter and colleagues[20] at 10 years of age, scores on tests for spatial memory and visual motor integration, but not on tests for IQ, visual perception, motor coordination and arithmetic achievement, were statistically significantly lower in the group who had received high-iron formula (1.95 mg/100 kcal)[26]. Effects were generally small. Among a sub-group of children with the highest haemoglobin concentrations at six months of age, scores on all tests (i.e. IQ, spatial memory, visual motor integration, visual perception, motor coordination and arithmetic achievement) were statistically significantly lower in the children who had been fed the high-iron formula. The drop-out rate between infancy and the age of 10 years was over 40 %. Other studies which investigated follow-up formula with 2 mg/100 kcal (12-14 mg/L) did not find any adverse effects at the levels of iron intake provided by these formulae [21-23,28-30].

In the recent EFSA review of infant and follow-up formula composition, a review of the health effects of iron in formula was conducted. In conclusion, EFSA noted that even though some data suggest that iron supplementation in iron-replete infants may lead to impaired growth and development and an increased risk of infections, the evidence is limited and does not allow conclusions to be drawn for the establishment of maximum iron content in infant formula and follow-up formula[2].

The recent ESPGHAN Committee on Nutrition reviewed iron requirements of infants and toddlers and the evidence around iron levels in follow-up formula and concluded that iron fortification of follow-up formula was recommended based on intervention trials, experience of current practice, and theoretical iron requirements. It was noted that further studies were warranted to determine the optimal level of iron fortification, particularly regarding long term follow-up of cognitive development for which there was conflicting evidence[24].

Based on available scientific evidence and the views of the eWG it is recommended that a maximum of 2.0 mg/100 kcal is retained. Applying the ISU conversion factors[4] and rounding this would equate to 0.48 mg/100 kJ.

Soy Protein

Almost all eWG participants supported the establishment of separate minimum and maximum values for formulas based on soy-protein (14 CM, 1 CMO, 1 CO). The recent EFSA[2] and IEG[3] review of compositional requirements continue to recommend the establishment of separate compositional requirements for iron in formulas containing soy protein isolate, to take into account potentially lower absorption efficiency[2]. Soy protein isolates used in infant and follow-on formula contain phytic acid which is an inhibitor of iron and zinc absorption. In the EFSA review, recommendations for minimum iron content of formulas based on soy protein isolates are 1.5 times higher than in cow's milk protein based formula. This approach was recommended by one CM. Both the European Union draft legislation and IEG recommend a maximum iron content of 2.5 mg/100 kcal for follow-up formula for older infants based on soy protein isolates. Based on the collective views of the eWG it is recommended that a footnote specifying the minimum and maximum iron content for formulas based on soy protein isolates is included.

Recommendation 12

That CCNFSDU agree to revise the minimum and maximum for iron as follows:

Iron[17)]

Unit	**Minimum**	**Maximum**	**GUL**
mg /100 kcal	[1.0]	[2.0]	-
mg /100 kJ	[0.24]	[0.48]	-

[17)] For Follow-up formula based on soy protein isolate a minimum value of 1.5/100 kcal (0.36/100 kJ) and maximum of 2.5 mg/100 kcal (0.6/100 kJ) applies.]

6.4.2 Calcium & Phosphorous

The eWG were split between those that wished to align with the Infant Formula Standard and those that wished to retain the current provisions within the *Standard for Follow-up Formula*. In the original development of the *Standard for Follow-up Formula*, the Committee established higher minimum requirements for calcium and phosphorous than those established in the Infant Formula Standard as cows' milk was considered a major source of calcium and phosphorous in the diet and can be limited in the diets of this age group. In addition to this, the Committee had deemed that lowering the calcium and phosphorous

requirements to those presented in the Infant Formula Standard (calcium 50 mg/ 100 kcal; phosphorous 25 mg/100 kcal) was unacceptable (CX/FSDU 85/26, para 55-56). Several eWG members supported retaining a higher minimum level based on the increase in calcium requirements for this age group, reduced intakes of follow-up formula at this age, and noting that calcium intakes are often limited in the diets of this age group.

In the development of the Infant Formula Standard [1,19], and the recommendations of the EFSA opinion[2], minimum calcium and phosphorous requirements are based on their content in human milk, taking into account the lower absorption from formula and adjusted accordingly.

Guiding Upper Levels

Generally the eWG supported the establishment of GULs for both calcium and phosphorous. Regarding a GUL for calcium many eWG members supported establishing a higher GUL based on the recognition that older infants have achieved a greater degree of renal maturation at this age and that the UL for calcium is higher in the second half of the first year of life (1500 mg/day)[3]. Others preferred to align completely with the Infant Formula Standard.

Calcium to Phosphorous Ratio

Almost all eWG members supported the addition of a calcium-to-phosphorous ratio as specified in the Infant Formula Standard (18 CM, 1CMO, 5 CO).

The EFSA Scientific opinion provides the following review of the ratio[2]: "*The concept of maintaining a certain calcium-to-phosphorus ratio in the diet has little relevance in adults but may have some utility under conditions of rapid growth. An absorbed calcium-to-phosphorus molar ratio of around 1.3:1 is assumed to be sufficient to support the sum of bony and soft tissue growth in infants (IoM, 1997)*[31]*. In order to derive an intake ratio, this value has to be corrected for the fractional absorption of calcium and phosphorus. Assuming an absorption efficiency of 60 % for calcium and of 80 % for phosphorus, the US Institute of Medicine has suggested a calcium-to-phosphorus molar intake ratio of 2:1 for infants. However, fractional absorption may vary with age and type of formula consumed and the ratio by itself is of limited value if the consumption of absolute quantities of both nutrients is insufficient to support adequate growth (IoM, 1997)*[31]*. The currently permitted lower calcium-to-phosphorus ratio of 1:1 reflects the calcium-to-phosphorus molar ratio of cows' milk, which does not change if cows' milk is diluted for the manufacturing of formula. There are no reports which indicate that the currently permitted calcium-to-phosphorus ratio together with the current minimum content of calcium and phosphorus in infant formula and follow-on formula is insufficient to ensure adequate growth of infants."*

Taking into consideration the eWG's range of views regarding the calcium content of follow-up formula for older infants it is recommended that a more flexible range is provided to enable consistency but also allow for slightly higher levels of addition to reflect the increase in dietary calcium requirements for older infants.

It is recommended that the minimum composition of calcium and phosphorous and ratio specified in the Infant Formula Standard is adopted for follow-up formula for older infants. Regarding the GUL it is recommended that an elevated GUL of 180 mg/100 kcal for calcium is provided and that the GUL for phophorous specified in the Infant Formula Standard is adopted for follow-up formula for use in older infants.

Recommendation 13

That CCNFSDU agree to revise the minimum and GUL for calcium and phosphorous as follows:

Calcium

Unit	**Minimum**	**Maximum**	**GUL**
mg /100 kcal	[50]	-	[180]
mg /100 kJ	[12]	-	[43]

Phosphorous

Unit	**Minimum**	**Maximum**	**GUL**
mg /100 kcal	[25]	-	[100]
mg /100 kJ	[6]	-	[24]

Ratio calcium/ phosphorus

Min	**Max**
1:1	2:1

6.4.3 Manganese

The majority of eWG members were supportive of aligning the manganese requirements for follow-up formula for older infants with that specified in the Infant Formula Standard. This approach was consistent with that proposed by EFSA[2] which informed the draft European Commission Regulation on infant and follow-on formula. A minimum manganese content of 1 µg /100 kcal is based on the manganese content of human milk and adjusted for lower absorption from formula[1,2]. Some eWG members (7 CM, 1 CO) did not support establishing a minimum compositional requirement, and considered that the addition of manganese should be considered an optional addition. This was based on the view that the manganese levels established for infant formula are not based on firm evidence of quantitative requirements but on human milk concentrations[3].

As the basis for establishing nutrient requirements for infant and follow-up formula is generally based on the contribution of nutrients from human milk, and there is no new scientific evidence to deviate from the specifications in the Infant Formula Standard it is recommended that levels in follow-up formula for older infants are based on the Infant Formula Standard.

All eWG members supported establishing a GUL of 100 µg /100 kcal in alignment with the Infant Formula Standard (18 CM, 1 CMO, 3 CO). For consistency in application ISU conversion factor[4] the minimum level should be rounded to 0.24 µg /100 kJ.

Recommendation 14

That CCNFSDU agree to revise the minimum and GUL for manganese as follows:

Manganese

Unit	**Minimum**	**Maximum**	**GUL**
µg /100 kcal	[1]	-	[100]
µg /100 kJ	[0.24]	-	[24]

6.4.4 Iodine

The eWG had varying views as to the appropriate minimum and GUL for the iodine composition of follow-up formula for older infants. Electronic working group members were of the view that for iodine there was no need to establish different requirements for infant and follow-up formula. One eWG member noted there was a case for modifying both standards and proposed that the Committee consider a targeted review of the Infant Formula Standard to accommodate this approach.

Minimum

Of the 24 eWG members which provided an opinion on the iodine content of follow-up formula, all were supportive of increasing the minimum from the current level specified in the *Standard for Follow-up Formula* (5 µg/100 kcal). There were different views as to whether it should be increased to the level proposed in the Codex Standard for Infant Formula (10 µg/100 kcal) (15 CM, 5 CO), or to the level proposed by EFSA (15 µg/100 kcal)[2] (4 CM, 1 CO).

The Infant Formula Standard minimum requirements were based on meeting the nutrient requirements of infants estimated to be 50 µg/day and within the range of human milk[1]. Of those that supported elevating minimum requirement to 15 µg/100 kcal this was based on providing adequate quantities of iodine to meet nutrient requirements for infants. In 2014 the eWG reviewed the recommendations of several RASBs regarding iodine requirements for this age group. The 2014 eWG reported that the WHO/FAO adequate intake value for iodine (90 µg/day) was considered suitable[14]. The iodine content of human milk varies markedly according to maternal intakes and as such the WHO /UNICEF/ICCIDD do not recommend basing dietary requirements for iodine on breast milk concentrations but on achieving iodine balance[32]. This approach was also taken recently in the derivation of European dietary intake reference values for iodine, in which EFSA calculated that approximately 70 µg per day were adequate for the majority of infants to achieve a urinary iodine concentration of at least 100 µg/L[10].

Based on the majority views of the eWG it is recommended that the minimum iodine content of follow-up formula for older infants is elevated to 10 µg/100 kcal in alignment with the Codex Standard for Infant Formula. For consistency in application ISU conversion factor[4] the minimum level should be rounded to 2.4 µg /100 kJ.

Maximum

The majority of eWG members supported amending the GUL to 60 µg /100 kcal - aligning the GUL for iodine with that specified in the Infant Formula Standard (15 CM, 1 CO).

Seven eWG members raised concerns that setting the GUL at 60 µg /100 kcal would provide iodine at levels in excess of the UL established by the IOM[15] and recognised by the WHO/FAO[14] and EFSA[10] (3 CM, 1 CMO, 3 CO). The UL for young children (1-3 years) of 200 µg /day is based on biochemical changes in thyroid stimulating hormone levels[15]. Consumption of the average intake of formula (500 kcal/day) would lead to an intake of iodine of 300 µg/day.

The GUL established for the Infant Formula Standard was based on a history of apparent safe use, as it was reported that there were products on the market containing 75 µg/100 kcal – the upper limit in the US. It was also recognised that the iodine content of milk is not constant and depends on seasons, hygienic and agricultural practices which make setting a maximum limit challenging. The ESPGHAN IEG report had recommended a maximum of 50 µg/100kcal to be established[1].

Based on the previous discussions by the Committee in establishing a GUL for iodine, and the majority view of the eWG it is recommended that a GUL of 60 µg /100 kcal is established in alignment with the Infant Formula Standard.

Recommendation 15

That CCNFSDU agree to revise the minimum and GUL for iodine, as follows:

Iodine

Unit	**Minimum**	**Maximum**	**GUL**
µg /100 kcal	[10]	-	[60]
µg /100 kJ	[2.4]	-	[14.3]

6.4.5 Selenium

There was consensus amongst the eWG to establish compositional requirements for selenium, and to adopt the GUL specified in the Infant Formula Standard.

Minimum

Recently the US FDA and European Commission have proposed elevated the minimum selenium requirements for infant formula products. As such the eWG had mixed views as to the appropriateness of the current minimum selenium requirements within the Infant Formula Standard (1 µg /100 kcal). Two Codex Members recommended that the minimum was elevated to 2 µg /100 kcal on the basis of the US FDA ruling. This value is based on meeting the Institute of Medicine's AI level for selenium 15 µg/day from an intake of 500 kcal per day, and a recent randomised controlled trial which demonstrated the improvement in circulating biochemical indicators of selenium status in selenium supplemented with both 1.9 and 3.1 µg /100 kcal[33]. The infants consuming formulas containing at least 1.9 µg selenium/100 kcal received sufficient selenium to meet their nutritional needs, however those consuming formulas containing 3.1 µg /100 kcal excreted significantly more urinary selenium, suggesting that this level may be superfluous to requirements.

The recommendations of EFSA were based on selenium content of human milk from European mothers (2.5 µg/100 kcal) and rounded up to 3 µg/100 kcal[2]. This approach was supported by four Codex Member Countries and one Codex Observer. Based on the study of Daniels and colleagues it appears that formula containing 3 µg/100 kcal provides more selenium than required in some populations[33], it is therefore recommended that the minimum requirement is elevated to 2 µg /100 kcal.

Based on more recent evidence supporting the need to elevate the minimum requirement for selenium in formula products for infants, it is recommended that the Committee agree to establish a minimum selenium requirement of 2 µg /100 kcal.

Recommendation 16

That CCNFSDU agree to establish a minimum and GUL for selenium as follows:

Selenium

Unit	Minimum	Maximum	GUL
µg /100 kcal	[2]	-	[9]
µg /100 kJ	[0.48]	-	[2.2]

6.4.6 Copper

The majority of eWG members were supportive of aligning the copper requirements for follow-up formula for older infants with that specified in the Infant Formula Standard (15 CM, 3CO). However some eWG members preferred adopting the minimum requirement recommended by EFSA[2] which has informed the draft European Commission Regulation on infant and follow-on formula.

The minimum copper requirement in the Infant Formula Standard was based on a level similar to the copper content of human milk, noting that there is no major difference in bioavailability between human milk and formula[2]. The EFSA opinion based minimum requirements levels on the average copper content of human milk of European mothers (350 µg/L), and subsequently the copper requirements of infants in the first half of the first year of life (300 µg/day)[2]. The WHO/FAO have not established copper requirements[4], however the IOM have established an adequate intake (AI) value for copper based on copper content of human milk (250 µg/L) which equates to an AI of 200 µg/day for young infants aged 0-6 months[15]. Calculation of the copper requirements for young infants based on the IOM requirements and an intake of 500 kcal per day would result in a minimum of 40 µg/100 kcal.

In establishing an upper level in the development of the Infant Formula Standard, the ESPGHAN IEG initially recommended a maximum level of 80 µg /100 kcal which is about three times higher than in human milk[2]. The review of the copper content of formula products available at the time of the review found products containing 190 µg /100 kcal. Based on a history of apparent safe use the GUL was established at 120 µg /100 kcal. Some eWG members suggested raising the GUL on the basis that copper excess was rare, and that liver toxicity of higher copper intakes is particularly high during the first few weeks and month of life[3], whereas as the older infant ages, the liver appears to be far more resistant to the adverse effects of copper. However there were concerns expressed by other members of the eWG that this would lead to intakes in excess of the UL. Taking into account the eWG views adoption of the GUL specified in the Infant Formula Standard (120 mg/100 kcal) is recommended.

The majority of eWG members supported adopting the footnote which accompanies the essential composition copper requirements in the Infant Formula Standard.

Based on the views of the majority of the eWG it is recommended to align the essential composition requirements for copper in the Infant Formula Standard with that specified for follow-up formula for older infants.

Recommendation 17

That CCNFSDU agree to revise the minimum and GUL for copper as follows:

Copper[19)]

Unit	Minimum	Maximum	GUL
µg /100 kcal	[35]	-	[120]
µg /100 kJ	[8.4]	-	[29]

[19)] Adjustment may be needed in these levels for infant formula made in regions with a high content of copper in the water supply.]

6.4.7 Zinc

There was consensus within the eWG to retain a minimum requirement for zinc in follow-up formula for older infants at 0.5 mg/100 kcal. The minimum zinc composition of 0.5 mg per 100 kcal is consistent with the requirements of the Infant Formula Standard, and the recommendations of EFSA[1] and the IEG[3].

Maximum

There were diverging views on the level at which the GUL for zinc should be set. Many eWG members wished to adopt the GUL specified in the Infant Formula Standard (1.5 mg.100 kcal) (13 CM, 2 CO). However it was highlighted that consumption of 500 kcal per day containing 1.5 mg/100 kcal would lead to intakes exceeding the tolerable upper level established by EFSA[17] and the IOM[38] (3 CM, 1 CMO, 3 CO). To address this it was recommended by some eWG members to set a GUL of 1.0 mg/100 kcal in alignment with the recent Draft EU legislation on the essential composition of infant and follow-up formula. Based on the view of many in the eWG that the maximum should be lowered to prevent excessive intakes of zinc it is recommended that the maximum is lowered to 1 mg/100 kcal.

Soy Protein Isolate

The eWG were asked to consider if it was necessary to establish higher zinc minimum and GULs for formulas containing soy protein isolate, particularly if modified compositional requirements are established for iron for these formulas. This approach was recommended by EFSA in establishing minimum levels for zinc in formulas containing soy protein isolate at 0.75 mg/100 kcal[1]. The majority of the eWG supported the need to have separate zinc compositional requirements for formulas based on soy protein isolate (12 CM, 1 CMO, 5 CO). This was considered necessary to take into account the lower absorption efficiency due to the phytate content of soy based formula which inhibits the absorption of both iron and zinc. As such it is recommended that a footnote is established for separate zinc compositional requirements for formulas containing soy protein isolate.

Recommendation 18

That CCNFSDU agree to revise the minimum and GUL for zinc as follows:

Zinc[20)]

Unit	**Minimum**	**Maximum**	**GUL**
µg /100 kcal	[0.5]	-	[1.0]
µg /100 kJ	[0.12]	-	[0.24]

[20)] For Follow-up formula based on soy protein isolate a minimum value of 0.75 mg/100 kcal (0.18 mg/100 kJ) and maximum of 1.25 mg/100 kcal (0.3/100 kJ) applies.]

6.5 Other substances: choline, myo-inositol & L-carnitine

The addition of choline, myo-inositol and L-carnitine is not currently specified in the Follow-up Formula Standard, however their addition to infant formula is mandatory under the current Infant Formula Standard. For these *other substances* the recommendations of EFSA[2] and the IEG[3] regarding composition of follow-up formula for older infants have in some cases stated that these substances are not necessary. The rationale provided is that the addition of these *other substances* to follow-up formula was deemed unnecessary as they can be synthesised endogenously and provided for by other foods in the complementary diet.

The eWG were asked whether compositional parameters for choline, myo-inositol and L-carnitine should be established in the revised *Standard for Follow-up Formul*a. The eWG were presented with the below values for *other substances* as part of the second Consultation Paper for their consideration, comment and justification:

Choline

Unit	Minimum	Maximum	GUL
mg /100 kcal	[7] [-]	-	[50] [150]
mg /100 kJ	[1.7] [-]	-	[12] [36]

Myo-inositol

Unit	Minimum	Maximum	GUL
mg /100 kcal	[4] [-]	-	[40] [-]
mg /100 kJ	[1] [-]	-	[9.5] [-]

L-Carnitine

Unit	Minimum	Maximum	GUL
mg /100 kcal	[1.2] [-]	-	-
mg /100 kJ	[0.3] [-]	-	-

6.5.1 Choline

The eWG was divided in its view on whether choline should be an optional (11 eWG members) or mandatory (10 eWG members) addition to follow-up formula for older infants with slightly more respondents preferring optional addition or not including specifications (4 eWG members) in the Follow-up Formula Standard at all. This was based on the premise that choline is not necessary as it can be synthesised endogenously, therefore the diversified diet of older infants would provide this nutrient. Other eWG members were of the view that the diet may not provide adequate choline and therefore it should be a mandatory addition to follow-up formula for older infants. Comment was made that as part of the review of the Infant Formula Standard, rigorous scientific review of nutrient levels, including choline, was undertaken, and as such this should provide adequate justification for including a minimum level for choline in follow-up formula for the older infant age group. Several eWG members stated that although there is no rationale to add choline to follow-up formula for older infants, in order to retain consistency as much as possible between the Infant Formula and Follow-up Formula Standards, its addition should be mandatory.

Of those eWG members who supported the optional addition of choline to follow-up formula for older infants, no-one requested a minimum level be set if this substance is added. Five eWG members supported a GUL of 150 mg/100kcal, three favoured a GUL of 50 mg/100kcal, two suggested that a GUL did not need to be specified, and one member organisation suggested that further consideration should be given to whether a GUL should be set.

Of the 10 eWG members who supported the mandatory addition of choline, the majority supported adoption of the minimum and GUL levels stipulated in the Infant Formula Standard (min: 7 mg/100 kcal, max: 50 mg/100 kcal). Three eWG members favoured the higher GUL of 150 mg/100 kcal).

Recommendation 19

It is the recommendation of the Chairs that choline be included in the Optional Ingredients section of the *Standard for Follow-up Formula* for product for older infants with the following specifications:

Choline

Unit	Minimum	Maximum	GUL
mg /100 kcal	[-]	-	[150]
mg /100 kJ	[-]	-	[36]

6.5.2 Myo-inositol

Of those eWG members who provided comment on the addition of myo-inositol to follow-up formula for older infants, 13 supported optional addition, and five eWG members favoured mandatory. Three of the five eWG members supporting mandatory addition commented that there is no rationale for the addition of myo-inositol, however, to be as ‘consistent as possible for all breastmilk substitutes’ they supported mandatory addition. Five eWG members stated that there was no need to include specifications for the addition of myo-

inositol to follow-up formula for older infants as it can be synthesised endogenously and provided for by other foods in the complementary diet.

Of the 18 eWG members supporting including provisions for myo-inositol (either optional or mandatory) 16 supported aligning the GUL with the level stipulated in the Infant Formula Standard, that being 40 mg/100 kcal. One eWG member did not comment on a GUL level, and one member organisation suggested that further consideration be given to whether a GUL should be set.

All five eWG members supporting the mandatory addition of myo-inositol, recommended that the minimum level of 4.0 mg/100 kcal be adopted from the Infant Formula Standard. Those favouring optional addition favoured establishing a GUL only, with no requests for a minimum level of addition.

Recommendation 20

It is the recommendation of the Chairs that myo-inositol be included in the Optional Ingredients section of the *Standard for Follow-up Formula* (for product for older infants) with the following specifications:

Myo-inositol

Unit	Minimum	Maximum	GUL
mg/100 kcal	[-]	-	[40]
mg /100 kJ	[-]	-	[9.6]

6.5.3 L-carnitine

The Infant Formula Standard requires the mandatory addition of L-carnitine at a minimum amount of 1.2 mg/100 kcal. The Infant Formula Standard does not specify a maximum level or a GUL.

Of the 25 eWG members who provided comments on L-carnitine, 12 supported optional addition. Ten of these 12 eWG members did not request a minimum or GUL, one proposed a minimum level of 1.2 mg/100 kcal and a GUL of 2 mg/100 kcal if it is added, and one eWG member suggested that further consideration be given to whether a GUL for L-carnitine should be established.

Five eWG members were of the view that provisions for the addition of L-carnitine to follow-up formula for older infants do not need to be included in the Standard.

Eight eWG members supported the mandatory addition of L-carnitine to follow-up formula for older infants, with all supporting adoption of the minimum level of 1.2 mg/100 kcal stipulated in the Infant Formula Standard. Comment was made that not all complementary diets will provide sufficient levels of this nutrient to support adequate growth and development in older infants and therefore its addition should be mandatory. It was also commented by one eWG member that; as part of the review of the Infant Formula Standard, rigorous scientific review of nutrient levels, including L-carnitine was undertaken, and as such this should provide adequate justification for its mandatory addition with the same minimum level as established in the Infant Formula Standard.

One Codex Observer commented that follow-up formula formulated with soy, casein or casein hydrolysate contain little carnitine, and as such L-carnitine should be a mandatory addition.

Recommendation 21

It is the recommendation of the Chairs that L-carnitine be included in the Optional Ingredients section of the *Standard for Follow-up Formula* for product for older infants. As majority support is for not setting a minimum or GUL, the Chairs propose following a similar approach to that used for expressing the permission for the optional addition of total nucleotides. The proposed specification for consideration is presented below:

L-Carnitine

Levels may need to be determined by national authorities.

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

As part of the first Consultation Paper, the eWG was asked to consider the optional ingredient provisions under Section 3.3.2 of the *Standard for Follow-up Formula* and comment on whether (for older infants) these provision be retained, amended, or removed from the Standard.

Majority support was for retaining permissions for the addition of optional ingredients to follow-up formula for product for older infants. Most supported a principles based approach and alignment with equivalent provisions from the Infant Formula Standard but with several suggesting appropriate amendments to be made for the older infant target population consistent with the overall principles.

During the second round of Consultation, the eWG was asked if it supported incorporating the same list of permitted optional ingredients from the Infant Formula Standard (taurine, total nucleotides, DHA, and L(+) lactic acid producing cultures) into the Follow-up Formula Standard for product for older infants. If they supported this approach, they were asked to comment on whether the minimum, maximum, and GUL's should be aligned or reviewed for addition to follow-up formula for older infants.

There was widespread support for permitting optional ingredient additions where safety & suitability (at the level of use) for the particular intended benefit is evaluated & established by generally accepted scientific evidence (with some suggesting a systematic review be conducted).

Just over half of the eWG specifically supported incorporating provisions 3.2.3 & 3.2.4 of the Infant Formula Standard in to the Follow-up Formula Standard. Other eWG members expressed their concern that by including provisions 3.2.3 & 3.2.4, this may be viewed as an exhaustive, or 'positive list' of optional ingredients. One Codex Member suggested that it may be necessary to articulate (within the Follow-up Formula Standard) that any list of optional ingredients is not intended to be an exhaustive list, but provides a guide for national authorities as to appropriate levels when these substances are added.

Recommendation 22

As a result of the collective comments of the eWG, the Chairs propose the following amended drafting for consideration. As discussed in the previous section, the Chairs are also proposing that choline, myo-inositol, and L-carnitine be included as optional ingredients, they have therefore been added in the below section.

3.3.2 **Optional Ingredients**

3.3.2.1 *In addition to the compositional requirements listed under 3.2.4 to 3.2.6, other ingredients [**or substances**] may be added ~~when required~~ to ~~ensure that~~ the product [provided the product] is [**safe and**] suitable to form part of a [**progressively diversified diet**] OR [**the complementary diet**] intended for use [**from 6th months on**] OR [**from the age of 6 months/from 6 months of age**] OR [**by older infants**].*

OR *[In addition to the compositional requirements listed under 3.2.4 to 3.2.6, other ingredients or substances may be added to follow-up formula for older infants where the safety and suitability of the optional ingredient, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.]*

3.3.2.2 ~~The usefulness of these nutrients shall be scientifically shown.~~ *[The suitability for the particular nutritional uses [**in products for**] ~~of~~ [**older**] infants and the safety of these [**ingredients and**] substances shall be scientifically demonstrated. [**When any of these ingredients or substances is added**] ~~T~~ the formula shall contain sufficient amounts o~~f these substances~~ to achieve the intended effect~~, taking into account levels in human milk~~.]*

OR *[When any of these ingredients or substances is added the formula shall contain sufficient amounts to achieve the intended effect* OR *benefit, [taking into account levels in human milk].]*

3.3.2.3 ~~When any of these nutrients is added, the food shall contain significant amounts of these nutrients, based on the requirements of infants from the 6th month on and young children.~~ [*The following substances may be added in conformity with national legislation, in which case their content per 100 kcal (100kJ) in the Follow-up Formula ready for consumption shall not exceed the levels listed below. 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].*

Taurine

Unit	Minimum	Maximum	GUL
mg/100 kcal	-	12	-
mg/100 kJ	-	3	-

Total nucleotides

Levels may need to be determined by national authorities.

Docosahexaenoic Acid[20)]

Unit	Minimum	Maximum	GUL
% of fatty acids	-	-	0.5

[20)] If docosahexaenoic acid (22:6 n-3) is added to follow-up formula, arachidonic acid (20:4 n-6) contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. National authorities may deviate from the above conditions, as appropriate for the nutritional needs.

Choline

Unit	Minimum	Maximum	GUL
mg/100 kcal	-	-	150

Myo-inositol

Unit	Minimum	Maximum	GUL
mg/100 kcal	-	-	40

L-Carnitine

Levels may need to be determined by national authorities.

3.3.2.4 Only L(+) lactic producing cultures may be used.

NOTE: If the Committee considers that DHA should be a mandatory addition to follow-up formula (for older infants), then the provisions relating to DHA may need to be moved to point 3.2.2 – Fat, of the Essential Composition and Quality Factors section of the *Standard for Follow-up Formula* (Section 3). It was also suggested by several eWG members, that if DHA is considered a mandatory addition to follow-up formula (for older infants), then a minimum level should be set.

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

During 2015, the eWG has been working to identify an approach or process for determining the compositional requirements for the 12 to 36 month age group. When considering what this approach/process might be, the eWG reflected on the findings and common themes of previous eWG's. These are presented below:

- The essential composition of follow-up formula for young children should be based on scientific assessment of nutritional requirements and the nutritional status of the target population, in particular commonly reported nutrient deficiencies in young children.
- The findings from the 2014 eWG assessment of global dietary intake and nutritional status data highlighted several nutrients of global concern for which there is evidence to suggest young children (and older infants) may have difficulty in achieving adequate intakes. Globally, iron and the quality of dietary fat were consistently found to be inadequate in sub-groups of the population. Other nutrients which were most frequently found to be limited in the diets of older infants and young children included α-linolenic acid (ALA), docosahexanoic acid (DHA), vitamin A and D, calcium, zinc and iodine; however these differed regionally.
- Taking into consideration the role of product in the diet, it may not be considered necessary for follow-up formula to provide all essential nutrients for the 12-36 month age group i.e. the provisions for follow-up formula for young children may be less prescriptive (than follow-up formula for older infants) as there may not be a need for the full complement of nutrients that are in follow-up formula for older infants.

- Members of previous eWGs have suggested that flexibility in terms of compositional provisions (for follow-up formula for young children) will assist in accommodating the varying needs of different countries. This will allow for formulation of products for different markets depending on the nutritional status of the target population in that market.
- Follow-up formula is often used as a replacement for cows' milk. Nutritionally, cows' milk contributes to dietary requirements for calcium, riboflavin and vitamin B12.

In the first round of consultation, the eWG was presented with the following four options for determining the composition of follow-up formula for young children. Members were asked to consider each option and comment on their preferred approach.

1. Use the revised compositional requirements for follow-up formula for the 6 to 12 month age group as a basis for the review of compositional requirements for follow-up formula for young children. Supplement this with the findings of the 2014 eWG on the nutritional status of the target population, in particular commonly reported nutrient deficiencies and those nutrients for which there is evidence to suggest young children may have difficulty in achieving adequate intakes and therefore should be considered for mandatory addition to follow-up formula for young children.
    a. Identify compositional requirements for which minimum compositional requirements may differ for young children,
    b. Identify compositional requirements for which maximum or guiding upper levels may differ for young children,
    c. Identify compositional requirements which do not require minimum levels (i.e. optional addition) for young children.
2. As follow-up formula is often used as a replacement for cows' milk in young children, consider the nutritional composition of cows' milk and its contribution to dietary requirements. Use this information to guide the base composition of follow-up formula for young children. Also consider the 2014 eWG findings on the nutritional status of the target population, in particular commonly reported nutrient deficiencies and those nutrients for which there is evidence to suggest young children may have difficulty in achieving adequate intakes. Use this information to guide the mandatory addition of key nutrients.
3. Based on the assumption that follow-up formula for young children should provide approximately x% of a child's energy and nutrient intake, derive minimum values for micronutrients which are considered essential (or for which there is evidence to suggest young children may have difficulty in achieving adequate intakes). Note from the Chairs: the variation in amounts of follow-up formula consumed globally and the role that product plays in the diet make it difficult to determine what volume of follow-up formula should provide x%. Furthermore, a decision would need to be made as to what percentage of requirements should be met by products.
4. Any other suggested approach.

The second round of consultation asked a number of questions to further refine the findings from the first round of consultation. The following questions were asked as part of the second Consultation Paper:

1. Do you support an approach where not all nutrients or substances that have compositional requirements established for older infants are mandated for addition to follow-up formula for young children?
2. Do you support an approach whereby the compositional requirements established for older infants can be used as a basis for the composition of product for young children, in addition to ensuring that milk based drinks can be considered within the compositional requirements for this age group?
3. Are there other elements of flexibility that should be considered in the development of compositional requirements for follow-up formula for young children?
4. The findings of the 2014 eWG reported on key nutrients for which there is evidence of inadequate intakes/status in the target population. Globally, iron and the quality of dietary fat were consistently found to be inadequate in sub-groups of the target population. Do you consider that minimum compositional requirements for iron and fat quality will be required for product targeted to young children?
5. It has been recommended that nutritional requirements should be flexible enough to provide a source of the nutrients identified to be lacking in several countries internationally: α-linolenic acid (ALA), docosahexanoic acid (DHA), vitamin A and D, calcium, zinc and iodine. Do you consider that

minimum compositional requirements for these nutrients should be required to ensure the nutritional integrity of product targeted to young children? Do you consider that maximum compositional requirements for these nutrients should be required to ensure the nutritional integrity of product targeted to young children?

6. At a global level, what compositional parameters are considered important to mandate to ensure the nutritional integrity of product for the young child age group?
7. Do you consider that nutritional equivalence to products that follow-up formula may replace is required? What nutrients should be equivalent, and should they be mandatory or voluntary additions?
8. The eWG highlighted that consideration of the safety and suitability of nutrients and other substances, added to follow-up formula for young children is necessary and several proposed that the essential composition of follow-up formula for older infants should be used as a starting point. If a nutrient or other substance is added to follow-up formula (whether mandatory or voluntary), should the minimum and maximum levels of addition be consistent with the levels in follow-up formula for older infants?

8.1 Key Themes

There are a number of key themes that emerged from the eWG Consultation Papers. These will need to be considered in determining the composition of follow-up formula for young children.

8.1.1 Flexibility

There was majority support from the eWG for an approach which allows some degree of flexibility in the composition of products for young children to reflect the different role and purpose that such products play in the diets of this age group. It was considered that a Standard that provides flexibility in the composition of follow-up formula for young children was essential to address the differences in how these products are used in different countries. Many also commented that the need for specific nutrient additions, and the levels of these nutrients will vary from country to country, depending on what local supplementation programs and fortification practices exist, therefore compositional parameters for follow-up formula for young children needs to be flexible enough to accommodate this. Alternatively the standard could allow for national authorities to exert discretion as to the mandatory addition of certain nutrients based on the nutritional needs of the population, and consideration of national supplementation or fortification programs that exist locally.

Several eWG members emphasised that nutritional equivalence with cows' milk and ensuring milk-based drinks can be considered and accommodated within the compositional requirements for young children is important. As follow-up formula is often used as a replacement for cows' milk by young children, some eWG members were of the view that the composition of follow-up formula for young children may need adjustment where necessary to ensure that key nutrients from cows' milk are provided (calcium, vitamins B2 and B12). It is difficult to ascertain from the eWG comments, whether this approach is aligned (and would accommodate) the suggestion of some that the nutritional compositional requirements for follow-up formula for young children need to be flexible enough to accommodate both highly formulated formula products, as well as products that are based on cows' milk, or are milk based drinks, with the addition of key nutrients.

In summary, several considerations of flexibility emerged:

- Flexibility to address nutrients of concern, which vary regionally,
- Flexibility in the nutrients mandated in the composition of formula for young children,
- Flexibility to enable fortified milk drinks to be covered within the standard.

8.1.2 Less Prescription

A number of eWG members recommended a 'less prescriptive' approach to the composition of follow-up formula for young children with most eWG members who commented, agreeing that follow-up formula for young children does not need to contain the full range of nutrients that are mandated for addition to product for older infants. This is largely based on the increased consumption (and therefore nutrient contribution) of a more diversified range of other foods by young children, much more diversified than the diet of older infants.

Determination of which nutrients should be added on a mandatory basis was raised by eWG members, supporting a less prescriptive approach, and noting that it was not necessary for formula for young children to have the same level of requirements as follow-up formula for older infants.

8.1.3 Consistency (as much as possible) with follow-up formula for older infants
There was majority support for an approach which utilises the compositional requirements established for follow-up formula for older infants as the basis for the review of composition requirements for follow-up formula for young children.

8.1.4 Key nutrients

There was considerable support for the composition of follow-up formula for young children to address the nutrients identified in the 2014 eWG report for which young children may have difficulty in achieving adequate intakes. The 2014 eWG report concluded that globally, iron and the quality of dietary fat were consistently found to be inadequate in sub-groups of the population. Other nutrients which were most frequently found to be limited in the diets of older infants and young children included α-linolenic acid (ALA), docosahexanoic acid (DHA), vitamin A and D, calcium, zinc and iodine; however these differed regionally. In addition to this, possible excessive intakes of protein and sodium were reported in some countries.

With respect to iron and fat quality, there was majority support among eWG members for establishing minimum compositional requirements for product targeted to young children. Specific reference was made by several eWG members to ALA and DHA when discussing fat quality, with the suggestion that consideration be given to establishing minimum levels for these fatty acids.

Several eWG members specifically supported the inclusion of the above listed nutrients in the essential composition with the exception of DHA, with many suggesting it does not need to be a mandatory addition, nor does a minimum level need to be established.

One Member Country suggested that a consistent compositional profile for follow-up formula for young children should be developed in order to maintain a safe and nutritionally appropriate standard. Another eWG member suggested that CCNFSDU need to agree on what nutrients should be mandatory additions to follow-up formula for young children, and what flexibility should be left to the discretion of national authorities, depending on local conditions. It was proposed that higher importance should be given to those nutrients that are considered to be limited in the diets of older infants and young children globally.

Most eWG members considered that nutritional equivalence to cows' milk is important, and as such, the Standard should include adequate levels of those key nutrients present in cows' milk such as calcium, riboflavin, vitamins B12, A, D, and Zinc, for example.

Others were of the view that follow-up formula is a breast-milk substitute and therefore equivalence with the Infant Formula Standard would be important.

8.1.5 Nutritional integrity

A number of eWG members identified the importance of maintaining the integrity of the product. For example:

- Restrictions on the addition of sugars,
- Ensuring nutritional equivalence to products that follow-up formula for young children might be replacing,
- Establishing upper limits (max or GUL) to ensure safety.

It is difficult to ascertain from some of the eWG responses, whether those respondents supporting minimum levels be established, are also suggesting the nutrient addition should be mandatory, or, if they support minimum compositional requirements for nutrients (if added) as a means of maintaining product integrity.

Almost all eWG respondents' favoured scientifically supported maximum levels or a GUL.

The eWG was asked to comment on what compositional parameters are considered important to mandate to ensure the nutritional integrity of product for the young child age group. This question was not specifically answered by many eWG members. It was thought that nutritional composition and integrity should be linked to the purpose of the product. Some suggested that the balance of protein, fat and carbohydrate will need to be considered. Including restrictions on sugars was also supported by several members.

8.1.6 Other issues

There was a recognition by some eWG members that the consumption of either infant formula or follow-up formula for older infants would be considered an appropriate choice of product for consumption by young children. Conversely to this, follow-up formula for young children is viewed by some eWG members as a valuable option for delivering critical nutrients to young children in situations where they are unable to achieve adequate nutritional intakes from eating food.

Other issues raised by eWG members included: the necessity of product for this age group; and consideration of an alternative name for a milk based product to differentiate it from formula products if the approach outlined in option 2 was taken. It was also noted that the European Commission is currently working on a report analysing whether specific rules are necessary in the EU for milk-based drinks and similar products for young children.

There were specific comments made by a number of eWG members that did not support Option 3 from the first Consultation Paper of the 2015 eWG as it was not considered a viable option. The main concerns expressed about Option 3 were that it would be based on assumptions or theoretical considerations on a global basis of both the amount of product consumed and the contribution to daily energy intake that the product should make.

8.2 Option for consideration

It would be beneficial to work towards establishing a clear approach for establishing the nutrients that the Committee consider should be mandatory additions to follow-up formula for young children.

To do this, the Chairs recommend that the Committee take note of the key themes emerging from the eWG. The Chairs propose the following approach as a starting point for discussion and consideration by the Committee.

The composition of follow-up formula for young children (12-36 months) shall be presented as a narrow list of mandatory nutrients with the option of national authorities requiring additional mandatory nutrients based on the nutritional needs of their population.

Codex requirement - mandatory additions:

Core (mandatory) composition of follow-up formula for young children will include;

- Protein
- Fat – consider the fatty acid profile, including parameters for ALA and LA and maximum limits for trans fatty acids and saturated fatty acids
- Carbohydrate – based on residual energy after fat and protein contribution has been calculated. Consider including a limit for the addition of sugar.
- Iron
- Calcium
- Vitamin A

Codex requirement - voluntary additions:

In addition to those mandatory macronutrient and nutrient provisions list above, other vitamins and minerals listed for addition to follow-up formula for older infants, may be added to follow-up formula for young children on a voluntary basis. The level of addition for these vitamins and minerals shall meet the requirements stipulated for follow-up formula for older infants.

Codex requirement - Optional Ingredients:

Further to the mandatory and voluntary nutrient additions, other ingredients or substances may be added to follow-up formula for young children as per the optional ingredient principles established for follow-up formula for older infants.

National Authority discretion:

In addition to those provisions listed above, national authorities may require further nutrients be mandated for addition to follow-up formula for young children to meet the nutritional needs of their population. These nutrients can be chosen from the essential compositional requirements for follow-up formula for older infants, in which case the level of addition shall meet the requirements stipulated in that Standard.

9. NEXT STEPS

On the basis of the ToR for the eWG, the Chairs of the eWG believe that they have completed the required tasks and that the Committee is now in a position to move ahead with the review of the Standard on Follow-up Formula.

The Chairs of the eWG are of the view that the Committee has been provided with a significant amount of data to assist in their decisions on the essential composition of follow-up formula for older infants. There have also been two rounds of consultation on the approach to the essential composition of follow-up formula

for young children, and data provided on both the nutritional needs and status of the 12 – 36 month age group, as well as the role of product in the diet of young children. Significant discussion and progress have also been made on the definitions within the Description section.

It is proposed that the Committee:

- Agree to a revised Section 2 (Description)
- Agree to requirements for the essential composition of follow-up formula for older infants
- Agree to an approach for, and consider the details of, the essential composition for follow-up formula for young children
- Propose steps to address the scope and the labelling components of the revised Standard.

11. FUTURE WORK AND TIMELINE

Proposed revised timeline for completion of work. Note: this timeline is dependent on the outcomes of the pWG and the Committee and may need to be modified.

November 2015- November 2016	A Working group to refine the work on the compositional parameters of follow-up formula for older infants and progress the approach and compositional parameters for follow-up formula for young children. Refine definitions. Review the Scope and Labelling.
November 2016- November 2017	Working group to review the scope and labelling requirements of the standard and other areas of the standard which require updating
November 2017	Consideration of draft standard and advancement
July 2018	CAC adoption of draft standard

The progression of this work is likely to require ongoing electronic and physical working groups.

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APPENDIX 1: ESSENTIAL COMPOSITION

Summary of eWG Recommendations for the Essential Composition of Follow-Up Formula for Older Infants

The following table provides an overview of the compositional requirements in the current Follow-up Formula Standard (CODEX STAN 156-1987) in column 1, the requirements of the Infant Formula Standard (CODEX STAN 72-1981) in column 2, and the results of the 2015 eWG consultations (column 3). Where there was consensus in the eWG values are presented in bold, the remainder of the values presented in column 3 represent the majority view of the eWG. Alternative proposals which were supported by more than one eWG member are presented in column 4. Bracketed numbers under the alternative proposals refers to the number of supporters within the eWG.

Nutrient	FUF standard CODEX STAN 156-1987		IF standard CODEX STAN 72-1981			2015 eWG report recommendations			Alternative proposals*
	Min	Max	Min	Max	GUL	Min	Max	GUL	
Energy kcal/100 ml kJ/100 ml	60 250	85 355	60 250	70 295	-	**60** **250***	**70** **293***	-	-
Protein g/100 kcal g/100 kJ	3.0 0.7	5.5 1.3	1.8 0.45	3.0 0.7	-	1.8 0.43*	3.5 0.84*	-	Min: 1.65 (8) Max: 3.0 (9) 2.5 (6)
Total fat g/100 kcal g/100 kJ	3.0 0.7	6.0 1.4	4.4 1.05	6.0 1.4	-	**4.4** **1.1***	**6.0** **1.4**	-	-
LA mg/100 kcal mg/100 kJ	300 71.7	-	300 70	-	1400 330	300 72*	-	1400 335*	Min: 500 (6) Max: 1200 (6)
ALA mg/100 kcal mg/100 kJ	-	-	50 12	N.S.	-	**50** **12**	N.S.	-	-
Total CHO g/100 kcal g/100 kJ	-	-	9.0 2.2	14.0 3.3	-	**9.0** **2.2**	**14.0** **3.3**		-
Vitamins									
Vitamin A µg RE/100 kcal µg RE/100 kJ	75 18	225 54	60 14	180 43	-	75 18	180 43	-	Min: 60 (4) 70 (2) Max: 114 (4) 225 (9)
Vitamin D µg/100 kcal µg /100 kJ	1 0.25	3 0.75	1 0.25	2.5 0.6	-	1.0 0.24*	3.0 0.72*	-	Min: 2 (14) Max: 2.5 (6) 4.5 (14)
Vitamin E mg /100 kcal mg /100 kJ	0.7 IU 0.15IU	-	0.5 0.12	-	5 1.2	0.5 0.12	-	**5** **1.2**	Min: 0.6 (3)
Vitamin K µg/100 kcal µg /100 kJ	4 1	NS	4 1	-	27 6.5	4 1	-	**27** **6.5**	Min: 1 (3)
Thiamin µg/100 kcal µg /100 kJ	40 10	NS	60 14	-	300 72	60 14	-	**300** **72**	Min: 40 (2)
Riboflavin µg/100 kcal µg /100 kJ	60 14	NS	80 19	-	500 119	80 19	-	**500** **119**	Min: 60 (2)
Niacin µg/100 kcal µg /100 kJ	250 60	NS	300 70	-	1500 360	300 72	-	**1500** **360**	Min: 400 (4)
Vitamin B6 µg/100 kcal	45	NS	35	-	175	35	-	**175**	Min: 20 (2)

Nutrient	FUF standard CODEX STAN 156-1987		IF standard CODEX STAN 72-1981			2015 eWG report recommendations			Alternative proposals*
µg /100 kJ	11		8.5		45	8.4		**41.8**	
Vitamin B12 µg/100 kcal µg /100 kJ	0.15 0.04	NS	0.1 0.025	-	1.5 0.36	**0.1** **0.024**	-	**1.5** **0.36**	-
Pantothenic µg/100 kcal µg /100 kJ	300 70	NS	400 96	-	2000 478	**400** **96**	-	**2000** **478**	-
Folic acid µg/100 kcal µg /100 kJ	4 1	NS	10 2.5	-	50 12	10 2.4	-	50 12	Folate (13)
Vitamin C mg/100 kcal mg /100 kJ	8 1.9	NS	10 2.5	-	70 17	10 2.4	-	**70** **17**	Min: 4 (2)
Biotin µg/100 kcal µg /100 kJ	1.5 0.4	NS	1.5 0.4	-	10 2.4	1.5 0.4	-	**10** **2.4**	Min: 1 (2)
Minerals and Trace Elements									
Iron mg/100 kcal mg /100 kJ	1 0.25	2 0.5	0.45 0.1	-	-	1.0 0.24*	2.0 0.48*	-	Min: 0.45 (5) 0.6 (4) 1.1 (2) Max: 1.9 (3) NS (8)
Calcium mg/100 kcal mg /100 kJ	90 22	NS	50 12	-	140 35	50 12	-	180 43*	Min: 90 (11) GUL: 180 (11)
Phosphorous mg/100 kcal mg /100 kJ	60 14	NS	25 6	-	100 24	25 6	-	100 24	Min: 60 (12)
Ratio	-	-	1:1	2:1	-	1:1	2:1	-	
Magnesium mg/100 kcal mg /100 kJ	6 1.4	NS	5 1.2	-	15 3.6	**5** **1.2**	**-**	**15** **3.6**	-
Sodium mg/100 kcal mg /100 kJ	20 5	85 21	20 5	60 14	-	20 5	60 14	-	Min: 25 (3) Max: 85 (6)
Chloride mg/100 kcal mg /100 kJ	55 14	NS	50 12	160 38	-	50 12	**160** **38**	-	Min: 60 (3)
Potassium mg/100 kcal mg /100 kJ	80 20	NS	60 14	180 43	-	60 14	**180** **43**	-	Min: 80 (4)
Manganese µg/100 kcal µg /100 kJ	-	-	1 0.24	-	100 24	1 0.24*	-	100 24	Min: NS (8)
Iodine µg/100 kcal µg /100 kJ	5 1.2	NS	10 2.5	-	60 14	10 2.4*	-	60 14.3*	Min: 15 (5) GUL: 29 (6)
Selenium µg/100 kcal µg /100 kJ	-	-	1 0.24	-	9 2.2	2 0.48*		**9** **2.2**	Min: 1 (16) 3 (5)
Copper µg/100 kcal µg /100 kJ	-	-	35 8.5	-	120 29	35 8.4*	-	120 29	Min: 60 (6) GUL: 250 (6)
Zinc mg/100 kcal mg /100 kJ	0.5 0.12	NS	0.5 0.12	-	1.5 0.36	**0.5** **0.12**	-	1.0 0.24	GUL: 1.5 (15)

* Application of International Standard unit conversion factor and conventional rounding. The conversion factors for joules and calories are: 1 kJ = 0.239 kcal; and 1 kcal = 4.184 kJ[4].

1. Summary of eWG report on the essential composition of follow-up formula

(FOR INFORMATION)

1.1 Energy

All eWG members supported the alignment of the energy requirements to those established in the Codex Standard for Infant Formula. The scientific rationale provided in establishing the values in the Codex Standard for Infant Formula were that the average energy density of human milk is approximately 650 kcal/L, which was 5-10% less than previously assumed[1]. It was also noted in the review at the time that energy expenditure was lower than previously assumed, and an energy density of 60-70 kcal/100 mL was proposed to support physiological rates of weight gain in healthy infants[1].

EFSA recently reviewed the evidence and recommended that energy density of infant and follow-up formula should be based on the average energy density of human milk (650 kcal/L) and that there was no scientific rationale to establish separate compositional requirements for the two age groups. This should ensure the growth and development of infants fed infant formula are similar to those exclusively breast fed, and the growth and development of infants fed follow-up formula in association with appropriate complementary foods is similar those of infants who continue to be breast fed while complementary food is introduced to their diet.

2.1 Vitamins

2.1.1 Vitamin E

The majority of eWG members supported alignment with the Codex Standard for Infant Formula for the minimum, maximum compositional requirements and associated footnotes. Some eWG members preferred the minimum requirement level recommended by EFSA[2] however several members acknowledged that there is no scientific rationale for deviation between the infant and follow-up formula standards.

The GUL set for the Codex Infant Formula Standard was considered more than sufficient to protect the maximum contents of polyunsaturated fats in the order of 1.5 g/100 kcal[1]. No eWG member raised concerns with the GUL established for the Codex Infant Formula Standard.

Footnotes

The inclusion of the two footnotes specified in the Codex Standard for Infant Formula was recommended by the eWG. The inclusion of footnote 13 was considered important to provide clarity in the standard and of importance as vitamin E requirements are largely based on the prevention of oxidation of PUFAs. Vitamin E requirements have been reported to increase with the number of double bonds contained in the dietary fat supply. One eWG member suggested that footnote 12 should be amended to remove the reference to α-TE (alpha-tocopherol equivalents) as all vitamin compounds of vitamin E in the Codex advisory list are forms of d-α-tocopherol and hence the footnote is redundant.

[12] 1 mg α-TE (alpha-tocopherol equivalents) = 1 mg d-α-tocopherol

[13] Vitamin E shall be at least 0.5 mg α-TE per g PUFA, using the following factors of equivalence to adapt the minimal vitamin E content to the number of fatty acid double bonds in the formula: 0.5 mg α-TE /g linoleic acid (18:2 n-6); 0.75 α-TE/g α-linolenic acid (18:3 n-3); 1.0 mg α-TE/g arachidonic acid (20:4 n-6); 1.25 mg α-TE/g eicosapentanoic acid (20:5 n-3); 1.5 mg α-TE/g docosahexaenoic acid (22:6 n-3).

Taking into consideration the comments from the eWG it is recommended that the compositional specifications for vitamin E in follow-up formula for older infants are aligned with that defined in the Codex Standard for Infant Formula.

2.1.2 Vitamin K

The majority of eWG supported the alignment of the vitamin K composition of the Codex Infant and Follow-up Formula standards. However three eWG members preferred the EFSA recommended minimum vitamin K composition value of 1 µg/100 kcal.

The Chairs of the eWG have reviewed the report provided by the ESPGHAN IEG to inform the Codex Infant Formula Standard and note that the recommendation was to establish a minimum based on formulations of infant formula at the time[1]. The formulations were considered to provide effective protection against vitamin

K deficiency and the occurrence of bleeding. At the time the report was written it was noted that reference intakes were set at a variety of levels varying from 4 to 10 µg/day.

The EFSA recommendations are based on the vitamin K requirements of infants. EFSA concluded that 5 µg/day was adequate for the majority of infants in the first year of life based on the requirement of 1 µg/kg bodyweight per day[2]. This recommendation is aligned with the WHO/FAO recommended nutrient intake for infants that 1 µg/kg bodyweight is sufficient to maintain haemostatic function and prevent subclinical deficiency [14]. The 2014 eWG considered that the WHO/FAO requirements were adequate for the majority of infants, application of the 1 µg/kg body weight to the revised WHO Growth Standards[34] equates to a recommended intake of 5.0 and 8.5 µg for infants in the first and second half of the first year of life, respectively. Lowering the minimum requirement to 1 µg/100 kcal would still enable infants to meet the WHO/FAO requirements assuming average intake of 500 kcal of formula.

Taking into consideration the majority view of the eWG and preference to align the Codex Infant Formula Standard and compositional requirements for follow-up formula for older infants it is recommended that the compositional specifications for vitamin K in follow-up formula for older infants are aligned with that defined in the Codex Standard for Infant Formula.

2.1.3 Thiamin

The majority of eWG supported the alignment of the thiamin composition of the Codex infant and follow-up formula standards. However two eWG members recommended the EFSA minimum thiamin composition value of 40 µg/100 kcal. As there is no scientific justification for deviating between the standards for infant and follow-up formula, or new scientific data to amend either standard, it is recommended that the essential compositional requirements for thiamin in follow-up formula for older infants is aligned with that defined in the Codex Standard for Infant Formula.

2.1.4 Riboflavin

As with the eWG response to thiamin, the majority of eWG supported the adoption of the riboflavin requirements of the Codex standard for Infant Formula. However slight differences exist in the derivation of minimum values in the Codex Standard for Infant Formula, and those established by EFSA.

The Codex Standard for Infant Formula is based on an AI of 300-400 µg/day for infants, and that typically human milk contains between 60 to 90 µg/100 kcal[1]. Whereas the EFSA recommendations are based on a lower estimated AI for infants aged 0-6 months (300 µg/day), based on the lower range of riboflavin in human milk (450 µg/L, approximately 70 µg/100 kcal)[2]. Consumption of 500 kcal of formula per day at the minimum level specified in the Codex Infant Formula standard would provide 100% of requirements for the older infant (400 µg/day). The WHO/FAO also set an AI of 300 µg/day for infants aged 0-6 months[14].

As there is no scientific justification for deviating between the standards for infant and follow-up formula, or new scientific data to amend either standard, it is recommended that the essential compositional requirements for riboflavin in follow-up formula for older infants is aligned with that defined in the Codex Standard for Infant Formula.

2.1.5 Niacin

The majority of eWG members support adoption of the compositional requirements specified in the Codex Standard for Infant Formula, however three members preferred adoption of the EFSA recommendation. Once more, only slight differences exist in the assumptions made in the derivation of the two values based on the niacin content of human milk. In the EFSA opinion the upper end of the range of niacin in human milk was used to establish an adequate intake levels and consequently the minimum requirement[2], whereas a mid-point of the range was used to establish the minimum of the Codex Standard for Infant Formula Standard[1]. One eWG member noted that once the contribution of tryptophan from formula is taken into account the adequate intake for niacin equivalents is met.

The GUL set for the Codex Standard for Infant Formula was established based on history of apparently safe use. No eWG member raised concerns with the GUL established for the Codex Standard for Infant Formula Standard, as such the Chairs propose recommending the establishment of a GUL of 1500 µg/100 kcal.

Taking into consideration the views of the majority of the eWG the specifications of the Codex Standard for Infant Formula are recommended for the composition of niacin in follow-up formula for older infants.

2.1.6 Vitamin B12

Of those eWG members that provided feedback on the essential composition of follow-up formula (18 CM , 1CMO, 6 CO) almost all supported establishing a minimum of 0.1 µg/100 kcal in line with the Codex Standard for Infant Formula, and the recommendations of EFSA[2] and the IEG[3]. The AI established by the WHO/FAO for infants aged 0-6 months is 0.4 µg/day[14], thus an average intake of 500 kcal per day would enable the nutrient requirements of an infant to be adequately met by the provision of formula at the minimum concentration. As such it is recommended that a minimum specification of 0.1 µg/100 kcal is sufficient to meet the B12 requirements for infants in alignment with the Codex Standard for Infant Formula and a GUL of 1.5 µg/100 kcal is established.

2.1.7 Pantothenic acid

Of those eWG members that provided feedback on the pantothenic composition of follow-up formula all supported establishing a minimum of 400 µg /100 kcal and maximum of 2000 µg/100 kcal in line with the Codex Standard for Infant Formula, and the recommendations of EFSA and the IEG[2,3] (18 CM, 1 CMO, 6 CO).

2.1.8 Vitamin C

The majority of eWG members favoured the adoption of the vitamin C composition of the Codex Standard for Infant Formula. Although two Codex Member Countries preferred a lower minimum as recommended by EFSA for both infant and follow-up formula[2]. Many eWG members stated that there was no scientific justification for establishing a minimum vitamin C composition which differed for the two product categories.

Based on the views of the majority of the eWG it is recommended that a minimum specification of 10 mg/100 kcal and GUL of 70 mg/100 kcal is established for follow-up formula for older infants in alignment with the Codex Standard for Infant Formula.

Regarding the addition of footnotes to vitamin C compositional requirements the eWG had mixed views as to whether this should align with the footnotes contained within the Codex Standard for Infant Formula:

> **Vitamin C**[15]
>
> [15)]expressed as ascorbic acid
>
> [16)]This GUL has been set to account for possible high losses over shelf-life in liquid formulas; for powdered products lower upper levels should be aimed for.

All eWG members supported adoption of footnote 15. With regards to footnote 16: nine Codex Member Countries and three Codex Observers supported its inclusion; compared to five Codex Member Countries and four Codex Observers which did not. Those in favour of its inclusion stated: it was in accordance with industry practice and aligned with the Codex Standard for Infant Formula. Two Codex Member Countries supported a modified version of the footnote which referred to the GUL to account for possible high losses, however some noted that vitamin C losses were equally applicable to powdered and liquid products and should be amended accordingly.

Those who did not support the inclusion of footnote 16 did not consider it necessary to include as vitamin C losses also occur in powdered products due to their longer shelf life. Taking into consideration the eWG comments, and the strong support for alignment with the Codex Standard for Infant Formula it is recommended that Footnote 16 is included in the revised standard.

2.1.9 Biotin

The majority of eWG members favoured the adoption of the minimum biotin composition of the Codex Standard for Infant Formula (17 CM, 7 CO) with the exception of two Codex Member Countries which preferred the values recommended by EFSA[2]. In the 2014 eWG report to the Committee it was noted that there is limited data available on biotin intakes and health consequences to base nutrient requirement levels. Consequently all recognised authoritative bodies based nutrient requirements for infants on the contribution of biotin from consumption of human milk (5-6 µg/L) , and range from between 4 – 5 µg/day for infants in the first half year of life.

All eWG members supported adoption of the GUL for biotin composition specified in the Codex Standard for Infant Formula (19 CM, 7 CO).

Taking into consideration the views of the majority of the eWG, the specifications of the Codex Standard for Infant Formula are recommended for the composition of biotin in follow-up formula for older infants.

2.2 Minerals

2.2.1 Magnesium

All eWG members that provided feedback on the essential composition of follow-up formula (17 CM, 1 CMO, 5 CO) supported establishing a minimum of 5 mg/100 kcal and GUL of 15 mg/100 kcal in line with the Codex Standard for Infant Formula. It is recommended that the Committee support updating the magnesium compositional requirements for follow-up formula for older infants.

2.2.2 Sodium, chloride, potassium

The majority of eWG members supported the alignment of the sodium, chloride and potassium content of follow-up formula for older infants with the requirements outlined in the Codex Standard for Infant Formula.

No scientific justification was provided to support establishing different composition for infant or follow-up formula products. As such it is recommended that the Committee support alignment of the compositional requirements for sodium, chloride, and potassium with the Codex Standard for Infant Formula.

APPENDIX 2

PROPOSED DRAFT REVISION TO THE *STANDARD FOR FOLLOW-UP FORMULA*

(CODEX STAN 156-1987)

At Step 3

1. SCOPE

xxxxxx

2. DESCRIPTION

2.1 Product Definition

2.1.1 **Follow-up formula** means a food intended for use as ~~a liquid part of the weaning diet for the infant from the 6th month on and for young children.~~

[a) the liquid part of the diet for older infants when complementary feeding is introduced; and

b) a liquid part of the progressively diversified diet of young children.]

2.1.2 **[Follow-up formula** is so processed by physical means only and so packaged as to prevent spoilage and contamination under all normal conditions of handling, storage and distribution in the country where the product is sold].

OR

[Follow-up formula is so processed ~~by physical means only~~ and ~~so~~ packaged as to prevent spoilage and contamination under all normal conditions of handling, storage [,] ~~and~~ distribution [and sale] ~~in the country where the product is sold~~].

2.2 Other Definitions

2.2.1 The term **infant** means a person of not more than 12 months of age.

2.2.2 [**Older infants** means persons from the age of 6 months and not more than 12 months of age.]

2.2.3 The term **young child** means persons from the age of more than 12 months up to the age of three years (36 months).

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS (for older infants 6-12 months)

3.1 Essential composition

3.1.1 ***Follow-up formula*** *is a [food] OR [product]* ~~*prepared from the milk of cows or other animals and/or other constituents of animal and/or plant origin,*~~ *[based on] OR [consisting of] milk of cows or other animals or a mixture thereof [,] and/or other ingredients which have been [proved] OR [proven] to be [safe and] suitable [and nutritionally adequate] [to support growth and development] for [the intended age range] OR [older infants and young children].* ~~*infants from the 6th month on and for young children.*~~

[The nutritional safety and adequacy of follow-up formula shall be scientifically demonstrated to support growth and development of older infants and young children.]

OR

[Consumption of the formula should appropriately contribute to normal growth and development of the intended age range].

3.1.2 When prepared ready for consumption in accordance with the instructions of the manufacturer, the products shall contain per 100 ml not less than 60 kcal (250 kJ) and not more than 70 kcal ([293 kJ]) of energy

3.1.3 Follow-up Formula prepared ready for consumption shall contain per 100 kcal (100 kJ) the following nutrients with the following minimum and maximum or guidance upper levels (GUL), as appropriate.

a) Protein[2), 3), 4)]

Unit	Minimum	Maximum	GUL
g/100 kcal	[1.8]	[3.5]	-
g/100 kJ	[0.43]	[0.84]	-

2) For the purpose of this standard the calculation of the protein content of the final product ready for consumption should be based on N x 6.25, unless a scientific justification is provided for the use of a different conversion factor for a particular product**.** The protein levels set in this standard are based on a nitrogen conversion factor of 6.25. ****The value of 6.38 is generally established as a specific factor appropriate for conversion of nitrogen to protein in other milk products, and the value of 5.71 as a specific factor for conversion of nitrogen to protein in other soy products.

3) For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex I); nevertheless for calculation purposes, the concentrations of tyrosine and phenylalanine and the sum of methionine and cysteine may be used.

4) Isolated amino acids may be added to ~~Infant F~~ follow-up **f**ormula only to improve its nutritional value for infants. Essential and semi-essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only L-forms of amino acids shall be used.

5) The minimum value applies to cows' [and goats'] milk protein. For ~~infant~~ follow-up formula based on non-cows' milk protein other minimum values may need to be applied. For ~~infant~~ follow-up formula based on soy protein isolate, a minimum value of **[**2.25 g/100 kcal (0.5 g/100 kJ)**]** applies.

6) ~~Infant **[**Follow-up formula based on non-hydrolysed milk protein containing less than **[**2 g protein/100 kcal**]** and**]** infant **[**formula based on hydrolysed protein containing less than **[**2.25 g protein/100 kcal**]** should be clinically evaluated**]**~~.

b) Lipids

Total Fat[7],8

Unit	Minimum	Maximum	GUL
g/100 kcal	4.4	6.0	-
g/100 kJ	1.1	1.4	-

7) Commercially hydrogenated oils and fats shall not be used in follow-up formula

8) Lauric acid and myristic acids are constituents of fats, but combined shall not exceed 20% of total fatty acids. The content of trans fatty acids shall not exceed 3% of total fatty acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to 3% of trans fatty acids is intended to allow for the use of milk fat in follow-up formulae. The erucic acid content shall not exceed 1% of total fatty acids. The total content of phospholipids should not exceed 300 mg/100 kcal (72 mg/100 kJ).

Linoleic acid

Unit	Minimum	Maximum	GUL
mg/100 kcal	[300]	-	[1400]
mg/100 kJ	[72]	-	[335]

α-Linolenic acid

Unit	Minimum	Maximum	GUL
mg/100 kcal	50	[N.S.*]	-
mg/100 kJ	12	[N.S.]	-

*N.S. = not specified

[Ratio linoleic acid]

Min	Max
5:1	15:1

c) Carbohydrates

Total cabohydrates[9]

Unit	Minimum	Maximum	GUL
g/100 kcal	9.0	14.0	-
g/100 kJ	2.2	3.3	-

[9)] Lactose and glucose polymers should be the preferred carbohydrates in formula based on cows' milk protein and hydrolysed protein. Only precooked and/or gelatinised starches gluten-free by nature may be added. [If needed, sucrose, fructose may be added provided the sum of these does not exceed ≤20% of total carbohydrate.]

d) Vitamins

Vitamin A

Unit	Minimum	Maximum	GUL
µg RE[10)]/100 kcal	[75]	[180]	-
µg RE[10)]/100 kJ	[18]	[43]	-

[10)] expressed as retinol equivalents (RE)

1 µg RE = 3.33 IU Vitamin A = 1 µg trans retinol. Retinol contents shall be provided by preformed retinol, while any contents of carotenoids should not be included in the calculation and declaration of vitamin A activity.

Vitamin D

Unit	Minimum	Maximum	GUL
µg[11)] /100 kcal	[1.0]	[3.0]	-
µg[11)] /100 kJ	[0.24]	[0.72]	-

[11)] Calciferol. 1 µg calciferol = 40 IU vitamin D.

Vitamin E

Unit	Minimum	Maximum	GUL
mg α-TE /100 kcal	0.5	-	5
mg α-TE /100 kJ	0.12	-	1.2

[12)] 1 mg α-TE (alpha-tocopherol equivalents) = 1 mg d-α-tocopherol

[13)] Vitamin E shall be at least 0.5 mg α-TE per g PUFA, using the following factors of equivalence to adapt the minimal vitamin E content to the number of fatty acid double bonds in the formula: 0.5 mg α-TE /g linoleic acid (18:2 n-6); 0.75 α-TE/g α-linolenic acid (18:3 n-3); 1.0 mg α-TE/g arachidonic acid (20:4 n-6); 1.25 mg α-TE/g eicosapentanoic acid (20:5 n-3); 1.5 mg α-TE/g docosahexaenoic acid (22:6 n-3).

Vitamin K

Unit	Minimum	Maximum	GUL
µg /100 kcal	4	-	27
µg /100 kJ	1	-	6.5

Thiamin

Unit	Minimum	Maximum	GUL
µg /100 kcal	60	-	300
µg /100 kJ	14	-	72

Riboflavin

Unit	Minimum	Maximum	GUL
µg /100 kcal	80	-	500
µg /100 kJ	19	-	119

Niacin[14)]

Unit	Minimum	Maximum	GUL
µg /100 kcal	300	-	1500
µg /100 kJ	72	-	360

[14)] Niacin refers to preformed niacin

Vitamin B_6

Unit	Minimum	Maximum	GUL
µg /100 kcal	[35]	-	175
µg /100 kJ	[8.4]	-	[41.8]

Vitamin B_{12}

Unit	Minimum	Maximum	GUL
µg /100 kcal	0.1	-	1.5
µg /100 kJ	0.024	-	0.36

Pantothenic acid

Unit	Minimum	Maximum	GUL
µg /100 kcal	400	-	2000
µg /100 kJ	96	-	478

Folic acid

Unit	Minimum	Maximum	GUL
µg /100 kcal	[10]	-	[50]
µg /100 kJ	[2.4]	-	[12]

Vitamin C[15)]

Unit	Minimum	Maximum	GUL
mg /100 kcal	10	-	70[16)]
mg /100 kJ	2.4	-	17[16)]

[15)] expressed as ascorbic acid

[[16)] This GUL has been set to account for possible high losses over shelf-life in liquid formulas; for powdered products lower upper levels should be aimed for]

Biotin

Unit	Minimum	Maximum	GUL
µg /100 kcal	[1.5]	-	10
µg /100 kJ	[0.4]	-	2.4

e) Minerals and Trace Elements

Iron[17]

Unit	Minimum	Maximum	GUL
mg /100 kcal	[1.0]	[2.0]	-
mg /100 kJ	[0.24]	[0.48]	-

Calcium

Unit	Minimum	Maximum	GUL
mg /100 kcal	[50]	-	[180]
mg /100 kJ	[12]	-	[43]

Phosphorous

Unit	Minimum	Maximum	GUL[18]
mg /100 kcal	[25]	-	[100]
mg /100 kJ	[6]	-	[24]

[18] This GUL should accommodate higher needs with soy formula]

Ratio calcium/phosphorous

Min	Max
1:1	2:1

Magnesium

Unit	Minimum	Maximum	GUL
mg /100 kcal	5	-	15
mg /100 kJ	1.2	-	3.6

Sodium

Unit	Minimum	Maximum	GUL
mg /100 kcal	[20]	[60]	-
mg /100 kJ	[5]	[14]	-

Chloride

Unit	Minimum	Maximum	GUL
mg /100 kcal	[50]	[160]	-
mg /100 kJ	[12]	[38]	-

Potassium

Unit	Minimum	Maximum	GUL
mg /100 kcal	[60]	[180]	-
mg /100 kJ	[14]	[43]	-

Manganese

Unit	Minimum	Maximum	GUL
µg /100 kcal	[1]	-	[100]
µg /100 kJ	[0.24]	-	[24]

Iodine

Unit	Minimum	Maximum	GUL
µg /100 kcal	[10]	-	[60]
µg /100 kJ	[2.4]	-	[14.3]

Selenium

Unit	Minimum	Maximum	GUL
µg /100 kcal	[2]	-	9
µg /100 kJ	[0.48]	-	2.2

Copper

Unit	Minimum	Maximum	GUL[19)]
µg /100 kcal	[35]	-	[120]
µg /100 kJ	[8.4]	-	[29]

[19)] Adjustment may be needed in these levels for ~~infant~~ **follow-up** formula made in regions with a high content of copper in the water supply

Zinc[20)]

Unit	Minimum	Maximum	GUL
mg /100 kcal	0.5	-	[1.0]
mg /100 kJ	0.12	-	[0.24]

[[20)] For Follow-up formula based on soy protein isolate a minimum value of 0.75 mg/100 kcal (0.18 mg/100 kJ) and maximum of 1.25 mg/100 kcal (0.3/100 kJ) applies]

3.3.2 **Optional Ingredients**

3.3.2.1 *In addition to the compositional requirements listed under 3.2.4 to 3.2.6, other ingredients [**or substances**] may be added ~~when required~~ to ~~ensure that~~ the product [provided the product] is [**safe and**] suitable to form part of a [**progressively diversified diet**] OR [**the complementary diet**] intended for use [**from 6th months on**] OR [**from the age of 6 months/from 6 months of age**] OR [**by older infants**].*

OR *[In addition to the compositional requirements listed under 3.2.4 to 3.2.6, other ingredients or substances may be added to follow-up formula for older infants where the safety and suitability of the optional ingredient, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.]*

3.3.2.2 ~~The usefulness of these nutrients shall be scientifically shown.~~ *[The suitability for the particular nutritional uses [**in products for**] ~~of~~ [**older**] infants and the safety of these [**ingredients and**] substances shall be scientifically demonstrated. [**When any of these ingredients or substances is added**] ~~T~~ the formula shall contain sufficient amounts o~~f these substances~~ to achieve the intended effect~~, taking into account levels in human milk~~.]*

OR *[When any of these ingredients or substances is added the formula shall contain sufficient amounts to achieve the intended effect* OR *benefit, [taking into account levels in human milk].]*

3.3.2.3 ~~When any of these nutrients is added, the food shall contain significant amounts of these nutrients, based on the requirements of infants from the 6th month on and young children.~~ [*The following substances may be added in conformity with national legislation, in which case their content per 100 kcal (100kJ) in the Follow-up Formula ready for consumption shall not exceed the levels listed below. 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].*

Taurine

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	12	-
mg /100 kJ	-	3	-

Total nucleotides

Levels may need to be determined by national authorities.

Docosahexaenoic acid[20)]

Unit	Minimum	Maximum	GUL
% of fatty acids	-	-	0.5

[20)] If docosahexaenoic acid (22:6 n-3) is added to follow-up formula, arachidonic acid (20:4 n-6) contents should reach at least the same concentration as DHA. The content of eicosapentaenoic acid (20:5 n-3), which can occur in sources of LC-PUFA, should not exceed the content of docosahexaenoic acid. National authorities may deviate from the above conditions, as appropriate for the nutritional needs.

Choline

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	-	[150]
mg /100 kJ	-	-	[36]

Myo-inositol

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	-	[40]
mg /100 kJ	-	-	[9.6]

L-Carnitine

Levels may need to be determined by national authorities.

3.3.2.4 Only L(+) lactic producing cultures may be used.

Annex

GENERAL GUIDANCE FOR THE PROVISION OF COMMENTS

In order to facilitate the compilation and prepare a more useful comments' document, Members and Observers, which are not yet doing so, are requested to provide their comments under the following headings:

(i) General Comments

(ii) Specific Comments

Specific comments should include a reference to the relevant section and/or paragraph of the document that the comments refer to.

When changes are proposed to specific paragraphs, Members and Observers are requested to provide their proposal for amendments accompanied by the related rationale. New texts should be presented in **underlined/bold font** and deletion in ~~strikethrough font~~.

In order to facilitate the work of the Secretariats to compile comments, Members and Observers are requested to refrain from using colour font/shading as documents are printed in black and white and from using track change mode, which might be lost when comments are copied / pasted into a consolidated document.

In order to reduce the translation work and save paper, Members and Observers are requested not to reproduce the complete document but only those parts of the texts for which any change and/or amendments is proposed.