CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

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Agenda Item 5 **CX/NFSDU 16/38/6**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME
CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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Hamburg, Germany, 5 – 9 December 2016

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 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 30 October 2016.**

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.

INTRODUCTION

At the 37th Session of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU37) the Committee agreed to establish an electronic working group (eWG) chaired by New Zealand, co-chaired by Indonesia and France and working in English only with the following terms of reference:

Terms of Reference for the electronic working group:

- Finalise Section 3 on the Essential Composition of Follow-up Formula for older infants (6-12 months);
- Review the compositional requirements of Follow-up Formula for young children (12-36 months) based on the discussions at CCNFSDU37 and the approach outlined in CX/NFSDU 15/37/5;
- Refine Definition 2.1.1 based on the outcomes of the review of the compositional requirements for 6-36 months with a point of differentiation at 12 months;
- Explore issues for further consideration by CCNFSDU38 on Section 9 (Labelling) to inform the revision of the Sections of the Standard on Scope and Labelling.

Physical working group

CCNFSDU37 agreed that a physical working group (pWG) would meet immediately prior to the next CCNSFDU session (3rd December 2016). The pWG will be chaired by New Zealand, co-Chaired by France

[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).

and Indonesia and will work in English, French and Spanish. The pWG will consider the recommendations of the eWG with emphasis on the compositional requirements of the 12-36 months age group, and taking into account comments submitted at Step 3, and prepare further recommendations for consideration by CCNFSDU38.[2]

[2] See provisional agenda, CX/NFSDU 16/38/1, for details of the PWG.

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1 EXECUTIVE SUMMARY

The eWG has undertaken two rounds of consultation to help address its terms of reference (ToR) and believes that the Committee is now is a position to finalise the composition of follow-up formula for older infants and make informed decisions regarding the composition of follow-up formula for young children.

In relation to the compositional requirements for the 6 – 12 month age group, the Committee made significant progress at CCNFSDU37 with several requirements for the essential composition agreed to and progressed to Step 4. The focus of the 2016 eWG was to finalise the remaining essential compositional requirements. The essential compositional requirements for follow-up formula for older infants aged 6-12 month that are still to be finalised include: protein, vitamin K, vitamin C, zinc, docahexanoic acid (DHA) and L(+) lactic acid producing cultures.

As agreed to at CCNFSDU37, the requirements for the essential composition of follow-up formula for young children (12 – 36 months) are to be based on a narrow set of mandatory requirements, with the option that national authorities may require additional mandatory nutrients based on the nutritional needs of their population. This approach was based on the outcome of the 2015 eWG which stated that the Standard should be; flexible in the composition to address key nutrients of concern which may vary regionally; less prescriptive, as follow-up formula for young children does not need to contain the full range of nutrients that are mandated for addition to follow-up formula for older infants; consistent with compositional parameters for follow-up formula for older infants (where possible); contain the key nutrients of global concern in the diets of young children, as well as the key nutrients in cows' milk; and maintain nutritional integrity. The 2016 eWG has further elaborated on the proposed approach and developed three principles to help guide and justify nutrient addition, as well as identify those nutrients requiring specific compositional parameters for follow-up formula for young children. These are presented below.

Evidence to support:

1. contribution to the nutritional needs of young children where the consumption of the nutrient is inadequate on a global scale; and/or
2. contribution of adequate amounts of key nutrients from cows' milk, where such nutrients are key contributors to the diet of young children; and/or
3. the nutritional quality and integrity of product to ensure nutritional safety.

The 2016 eWG also explored issues for further consideration at CCNFSDU38 to inform the revision of the Scope (Section 1) and Labelling (Section 9) sections of the *Standard for Follow-up Formula*. Recognizing that the Scope and Labelling sections are interlinked, consideration will need to be given to the concepts which may be best managed or presented within the Scope or Labelling section. As part of this process, key WHA resolutions and documents have been considered.

Consideration of the name of the food for young children and definition 2.1.1 has up until now been deferred until sufficient clarity on the composition of product for young children is reached. It is clear from 2016 eWG feedback that the majority preference is for two very distinctly different product names to clearly distinguish follow-up formula for older infants from follow-up formula for young children, as the nutritional needs and role of product in the diet differs between older infant and young children. The eWG consider it appropriate for the Standard to consider the two age groups separately for both the essential composition and Scope and Labelling sections. A format similar to that of the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981) (hereafter referred to as the Infant Formula Standard) was supported by many eWG members, with a clear distinction in the naming of the two products, and a preamble which clarifies that the Standard is divided in to two parts.

Please note that for the purposes of this Agenda Paper, the Chairs have referred to product targeted to infants aged 6-12 months as follow-up formula for older infants, and products for young children aged 12-36 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 young children.

2 BACKGROUND

In 2013 the Commission approved new work to undertake a full review of the Standard for Follow-up Formula (CODEX STAN 156-1987) as proposed at CCNFSDU34 (REP13/NFSDU). An electronic working

group (eWG) was established in 2013. The initial focus of the review was the essential composition of follow-up formula.

The 2014 eWG generally agreed that there should be a recognised point of differentiation (in relation to essential compositional requirements) 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. The Committee at the 35th Session then tasked the eWG with reviewing nutritional requirements of the two age groups and comparing them with the existing infant formula and follow-up formula standards.

Discussions at CCNFSDU36 (2014) highlighted that there was consensus within the Committee that follow-up formula is not considered nutritionally necessary. There was, however, majority agreement that while not necessary, such products which are traded internationally, should be regulated to ensure their safety, quality and integrity. The Committee agreed to continue work on the revision of the Standard. In particular the eWG was tasked with reviewing Section 2 (Description) and Essential Composition (Section 3) for products designated for older infants (from age 6 months and not more than 12 months of age).

The Committee also noted that the Scope and Labelling would be considered at a later stage and this could include referencing the relevant WHA resolutions on optimal infant and young child feeding, and on the lack of the need of the products. The possibility of considering the name of these product categories would also be considered at that time.

At CCNFSDU37 (2015) it was agreed to:

a) Retain the definitions in section 2.1.2 and 2.2, and the agreed essential composition, and optional ingredients at Step 4 (Appendix III Part I, REP 16/NFSDU) until the revision of the other sections were agreed.

b) Return the definition in section 2.1.1 and remaining essential composition requirements (Appendix III, Part II, REP 16/NFSDU) to Step 2/3, for further consideration by the next Session of the Committee.

Conduct of the Electronic Working Group (eWG)

The 2016 eWG has considered two consultation papers circulated in March and June respectively. The focus of the first consultation paper was to progress the work on the essential composition of follow-up formula for young children (12-36 months) (Sections 4 & 5). Discussions centred on how the key themes which underpin the composition of follow-up formula for young children (12-36 months) identified in 2015 (REP16/NFSDU) can be used to establish compositional requirements.

In the first consultation paper, the Chairs of the eWG proposed delaying consideration of definition 2.1.1 until sufficient clarity on the composition of follow-up formula for young children is available. Such information would help determine whether the definition should separate out the older infants and young children, or combine them into a single broad definition.

The second consultation also requested the eWG provide information on issues and evidence to inform the revision of the Scope and Labelling sections of the Standard.

The Chairs of the eWG have used feedback from the March and June eWG consultations to prepare this Agenda Paper.

Please note the following abbreviations used throughout this paper:
CM: Codex Member
CMO: Codex Member Organisation
CO: Codex Observer

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

3.1 Overview

In 2015 the eWG was tasked with reviewing the compositional requirements of the Standard for Follow-up Formula with a point of differentiation at 12 months. Significant progress was made with several requirements for the essential composition agreed to by the Committee and progressed to Step 4 (as presented in REP16/NFSDU, Appendix III Part I) until the revision of the other sections of the Standard are

agreed. The focus of the 2016 eWG was to finalise the remaining essential composition requirements to be agreed to by the Committee as presented in REP16/NFSDU (Appendix III, Part II) and which remain at Step 2/3. The essential compositional requirements for follow-up formula for older infants aged 6-12 month that are still to be finalised include: protein, vitamin K, vitamin C, zinc, DHA and L(+) lactic acid producing cultures.

The guiding principle used for establishing the essential composition of follow-up formula for older infants is that it should be consistent with the requirements for infant formula unless differences are scientifically justified. 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.

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. The general principles used to establish the minimum and maximum levels specified in the Infant Formula Standard are outlined in Annex II of the Standard.

3.2 Protein

At CCNFSDU37 the Committee considered proposals to lower the minimum level to either 1.65 or 1.8 g/100 kcal. Noting that there was a connection between the minimum and the maximum levels, the maximum level proposals were also retained in square brackets for further consideration. The Committee has supported adoption of footnote 2, 3, 4 and 5 with some minor square brackets, and retained footnote 6 in square brackets.

In the eWG there was widespread support to revise the minimum protein level to 1.8 g/100 kcal during the eWG (13 CM; 1 CMO; 5 CO), although there still remain some who supported a lower protein minimum of 1.65 g/100 kcal (5 CM; 3 CO). Regarding the maximum protein content eWG members remained divided as to the appropriate maximum level with levels proposed at 2.5, 3.0 and 3.5 g/100 kcal. Justification for establishing minimum and maximum levels mainly related to information on protein requirements for this age group, protein intakes globally, and evidence from randomised controlled trials and systematic reviews, these topics are discussed in detail below.

Protein requirements

Since the development of the Follow-up formula standard lower estimates for protein requirements have been derived by several recognised authoritative scientific bodies, including the WHO/FAO/UNU[1], EFSA[2], IOM[3]. In 2014, the eWG reviewed the protein requirements developed by WHO/FAO/UNU[1] and EFSA[2]. Both RASBs calculated protein requirements using the same factorial method which take into consideration protein required for maintenance and growth (maintenance of requirements of 0.66 g/kg bodyweight per day and a protein efficiency utilisation of 58%)[1],[2] (CX/NFSDU 14/36/7). As reported in the 2014 eWG report the calculated individual nutrient requirements (INL_{98}) estimated to meet the protein requirements of 98 percent of older infants aged 6 to <12 months equates to 10.2 g per day; and 11.3 g per day for young children aged 12 to <36 months.

No upper limits for protein have been established by WHO/FAO/UNU or other recognised authoritative scientific bodies[1], [2]; [3]. The WHO/FAO/UNU report states that there is no risk to individuals with excessive intakes considerably above the safe intake levels and that the effects of a diet habitually high in protein intakes are unclear[1]. At the time of these reviews, available data on the effects of protein intakes in excess of requirements on body weight control, obesity risk and insulin sensitivity did not provide evidence that could be used to for deriving a UL[1],[2];. In the absence of deriving upper limits, the IOM have established an acceptable macronutrient distribution range (AMDR) of 5-20% of energy should come from protein for young children aged 1-3 years, no range was established for infants[3].

The Chairs note that both minimum protein levels that are being considered reflect the updated reductions in protein requirement levels which have been established by WHO/FAO/UNU, EFSA and the IOM[1], [2]; [3].

Although some eWG members referred to the recommendations of a 2013 international expert group on the protein composition of follow-up formula which was based on providing protein to meet these protein requirement levels[4] (3 CM, 2 CO). The IEG recommended protein levels of 1.65 g/100 kcal of formula,

based on the rationale that formula should not contain protein in excess of metabolic requirements and calculating this values using a daily energy intake of 80 kcal/kg bodyweight and applied to the population requirement of 1.31 – 1.14 g/kg bodyweight. One eWG member did not agree with an approach whereby protein requirements guided the calculation of protein formulation of follow-up formula citing the WHO/FAO/UNU[1]. In their report on protein recommendations it states that the protein composition of formula needs to exceed that of protein requirements due to differences in dietary protein digestibility, bioavailability and efficiency of utilization between human milk and infant formulas[1]

Protein intakes

Nationally and regionally representative surveys of dietary intakes of older infants and young children have generally demonstrated that population average protein intakes in this age group are adequate for the majority of infants and young children. Protein intakes are typically in the order of 10-20%, energy this was also found in the EFSA review of nutrient intakes of European infants and young children[5] (CXNFSDU 14/36/7).

Several eWG members highlighted that the standard needed to take into account the global diversity of protein intakes and quality in this age group. It was acknowledged that some sub-groups of the population will be at risk of protein deficiency in resource limited settings, and that the dietary surveys have generally only measured protein quantity and do not provide insight as to the quality of protein in the diets of older infants and young children (CX/NFSDU 14/36/7).

Randomised controlled trials comparing low and high protein formulas

More recently controlled trials have been conducted investigating the effect of lower protein formulas on growth during the first year of life and later impacts on body weight gain and obesity. Several eWG members cited clinical trials in support of either a minimum protein content of 1.65 g/100 kcal or 1.8 g/100 kcal. A brief summary of the systematic reviews and trials conducted to date are provided below.

In 2014, EFSA reviewed the evidence provided by these trials and concluded that the safety and suitability of formula containing 1.8-1.9 g/100 kcal had been demonstrated to promote normal growth when these formulae are fed ad libitum[6].

Since then a meta-analysis and systematic review has been conducted investigating the effects of infant and follow-on formulas with different protein concentrations on infants' and children's growth, body composition, and later risk of overweight and obesity[7,8]. The conclusions of these reviews was that current evidence is insufficient for assessing the effects of reducing the protein concentration in infant formulas on long-term outcomes[7,8]. Twelve randomised controlled trials (RCTs) were included in the meta-analysis but there was limited data available to assess all primary outcomes. Different formula protein concentrations did not affect linear growth other than a transient effect on mean length at 3 months observed in the meta-analysis of 4 studies (mean difference, – 0.27 cm; 95% CI: 20.52, 20.02). Lower mean weight and weight z scores obtained from the infants fed lower-protein formulas were observed only from 6 to 12 months of age. Of the trials included only one RCT, the Early Childhood Obesity Trial (ECOT), reported on the BMI at twelve months, those infants consuming formula containing lower protein levels had significantly lower BMIs (MD: -0.33 kg/m^2; 95% CI: -0.55, -0.11) (n=748) ; and the risk of obesity at six years (RR 0.44 95% CI: 0.21,0.91) (n=448)[8].

The ECOT is the largest and only multi-centre trial conducted to date and infants have been followed-up for eight years[9-11]. For the first year of life and followed up until 24 months of age, infants were randomised to receive either:

- low protein formula (infant formula 1.77 g protein per 100 kcal and subsequently follow-up formula 2.2 g protein per 100 kcal) (n=540); or
- high protein formula (infant formula 2.9 g protein per 100 kcal and subsequently follow-up formula 4.4g protein per 100 kcal) (n=540)

BMI was reported at four time points (i.e. 6, 12, 24 months and at 6 years) and was significantly lower in the lower protein group than the higher protein at all four time points[8]. At six years the risk of becoming obese was significantly lower in the lower protein group (RR 0.44; 95% CI 0.21, 0.91)[8]. It is noteworthy that of the formulas provided to the infants, all follow-up formulas used in the study contained more protein per

100 kcal than under consideration by the Committee (i.e. low protein FUF 2.2 g/100 kcal; high protein FUF 4.4 g/100 kcal). The proposed minimum and maximum levels would only accommodate low protein formulas used in the ECOT.

Since the publication of the ECOT, two new randomised controlled trials have been conducted investigating lower protein level[12], [13]. Inostroza and colleagues randomized infants (from age 3 months) of overweight mother either low protein formula containing 1.65 g/100 kcal; or a high protein containing 2.7 g/100 kcal[12] (n=305). Formulas were fed until twelve months of age, but the primary outcomes measured at six months[12]. At six months, those infants fed low protein formula gained significantly less weight than those consuming high protein formula (Mean difference -2.26 g/day; 95% CI -3.88, -0.64; P=0.006). At 24 months those infants fed low protein formula had a slower weight gain than those fed high protein formula (mean difference -0.86; 95% -1.64, -0.08, P=0.031); and no difference between growth rate in the breast fed control group (mean difference -0.11; 95% -0.93, 0.71, P=0.798).

Ziegler and colleagues conducted a randomised controlled trial in healthy infants[13]. At three months of age, formula fed infants were assigned to either low protein formula 1.61 g/100 kcal; or high protein formula 2.15 g/100 kcal until 12 months of age. Weight gain at six months was similar between the two groups (-0.84 g/day; 95% confidence interval -2.25 to 0.57). It was concluded by the authors that the low protein formula supported normal growth of infants[13].

Several eWG members did not consider there to be sufficient evidence to support lowering protein amount to 1.65 g/100 kcal based on the reviews by EFSA, Abrams and colleagues in 2015, and Patro-Golab and colleagues in 2016 investigating the early protein hypothesis and effect of reduced protein formulas in reducing the risk of obesity [2,5,7,8]. In addition to this it was noted that studies in this area vary by: study design, duration of the intervention, number of participants, inclusion of probiotics, different types of protein, or inclusion of other nutrients. Often other substances such as pre- and pro-biotics and ingredients such as milk fat globule membrane, alpha lactalbumin are not disclosed. Many of these substances have been associated in the scientific literature with protein utilization in infants and effect on growth. In addition a number of studies do not report the full composition of the trial formulas; subsequently the amounts and specific types of fats and carbohydrates, or the structure of the delivery within the formula are unknown.

3.2.1 Protein minimum

There was widespread support in the eWG for the establishing a minimum protein level of 1.8 g/100 kcal (13 CM; 1 CMO; 5 CO). This level is aligned with the Infant Formula Standard and the recently revised EU regulation and signifies a marked decrease in the protein content compared to current requirements for follow-up formula (minimum 3.0 g/100 kcal). The eWG considered in detail the results of recent systematic reviews and randomised controlled trials, and while it was acknowledged that there is developing evidence, the overall conclusion was that there is a paucity of strong scientific evidence, and no evaluation conducted by a recognised authoritative scientific body to support the safety and suitability of follow-up formula for older infants containing protein at levels below 1.8 g/100 kcal.

Some eWG members still preferred to reduce the minimum protein level to 1.65 g/100 kcal (5 CM; 3CO). This level is based on the recommendations of the international expert working group coordinated by the Early Nutrition Academy[4]. This was based on the protein requirements and the early protein hypothesis.

It was stated that the European Commission has received an application for the placing on the EU market a follow-up formula based on cow's milk intact protein with a protein content of at least 1.61 g/100 kcal. The European Food Safety Authority (EFSA) will be requested to advise on the safety and suitability of this formula and the EU expects to have EFSA's feedback by CCNFSDU38. The EU have stated that they will be able to provide further feedback on this matter at CCNFSDU38. While the Committee will need to take into account the result of the EFSA opinion, it was also highlighted by several eWG members that the Committee will need to consider how the opinion applies to a global context, particularly those countries where protein intakes are lower and/or of poorer quality.

3.2.2 Protein maximum

The working group could not come to agreement on a proposed maximum level and three options were considered:

- 2.5 g/100 kcal: align with EU legislation and in line with the EFSA scientific opinion and IEG (2 CM; 1 CMO; 6CO)
- 3.0 g/100 kcal: align with the Standard for Infant Formula (11 CM; 1 CO)
- 3.5 g/100 kcal: reduce the maximum level to 3.5 g/100 kcal (6 CM; 2CO).

As in the 2015 eWG, similar arguments were provided to justify the maximum level to be established by the Committee. Those who preferred to align with the requirements in the Standard for Infant Formula stated the importance of alignment, and concerns that as an international standard it should ensure adequate protein intake and protein quality for a range of populations, particularly of those in low income countries.

Of those wishing to lower protein maximum limits to 2.5 g/100 kcal, this was on the basis of the EFSA scientific opinion[5], IEG 2013[4] and the recently revised EU rules. It was stated that there is no evidence of a physiological need for protein intakes at amounts of 3.0 g/100 kcal in infancy, and protein intakes of infants are generally well above the requirements.

The rationale for lowering the protein maximum to 3.5 g/100 kcal were due to the long history of apparent safe use, that it was considered safe and suitable. Further to this it was considered that the Codex Standard should accommodate the diversity of protein intakes across the globe in establishing the maximum protein level, which should enable to both protein intake of older infants living in developed and developing countries. Concern was also expressed that reducing the protein level to a maximum of 3.0 g/100 kcal, or lower, would result in a mutually exclusive protein range between the current and the revised Codex Standard. A revised protein maximum that is mutually exclusive from existing Codex requirements was thought to generate significant risk of trade barriers and consumer trust in Codex standards.

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. All options represent a marked decrease from the current requirements for protein in follow-up formula (3.5-5.5 g/100 kcal). In addition to this the levels for consideration are all below the high protein follow-up formula levels evaluated by the ECOT (4.4 g/100 kcal)[9-11].

Due to the lack of strong scientific justification in establishing a maximum limit, it is recommended that a maximum level of 3.0 mg/100 kcal is established in alignment with the Codex Standard for Infant Formula.

3.2.3 Footnote 2

In footnote 2, the only remaining square brackets are around the nitrogen conversion factor for soy products. At CCNFSDU37 the Committee agreed to request the Codex Committee on Methods of Analysis and Sampling (CCMAS) to provide advice on the accuracy and appropriateness of 5.71 as the nitrogen conversion factor for soy protein isolates used in formula for infants and young children and to take into account the amino acid profile of the isolate.

> [2]For the purposes 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.

At the CCMAS37 the Committee agreed that it was not in a position to reply this question as the determination of conversion factors was in the remit of CCNFSDU. The Committee agreed that conversion factors are scientifically based and that these factors should be harmonized between different Codex standards. The Committee noted that it might be timely for FAO and WHO to convene an expert panel to review available literature to assess the scientific basis for protein conversion factors and to possibly update the report of the joint FAO/WHO/UNU expert consultation, Protein and Amino Acid Requirements in Human Nutrition (2002)[1] (paras 12-13; REP16/MAS).

It is important for the Committee to consider the outcomes of the CCMAS report with regards to the conversion factor for soy protein which remains in square brackets and the potential for FAO and WHO to convene an expert panel to review available literature to assess the scientific basis for protein conversion

factors. Based on this response the Chairs propose that alignment with the Infant Formula Standard is sought and that the square brackets are removed. Amino acid requirements: footnote 3

At CCNFSDU37 the Committee agreed to include footnote 3 of the Infant Formula Standard with some amendments:

> [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 and the concentrations of methionine and cysteine may be added together.

At CCNFSDU37 it was agreed that the reference protein for follow-up formula should be the amino acid composition of breast milk as defined in Annex I of the Infant Formula Standard. This annex provides the requirements for individual essential and semi-essential amino acids and is based on the PDCAAS method. The current draft standard does not contain an Annex I and there is now widespread support within the eWG to include the Annex I of the Infant Formula Standard.

3.2.4 Requirements for clinical evaluation: footnote 6

The majority of eWG members supported alignment with the Infant Formula Standard where possible with regards to footnote 6. As such it is recommended that the footnote continues to include reference to hydrolysed protein, and to refer to non-hydrolysed protein rather than intact protein.

Although the need for hydrolysed protein was questioned by some eWG members, others stated that it is necessary to have formulas based on hydrolysed milk for this age group and that clinical evaluation was therefore necessary. The Chairs propose that the reference to hydrolysed protein is aligned with that provided in the Infant Formula Standard.

The need for clinical evaluation of intact, non-hydrolysed, protein is dependent on the outcome of the minimum value derived for formulas based on intact cows' milk protein. It was noted by several eWG members that there was no need for clinical evaluation of follow-up formula products containing between 1.8 and 2 g/100 kcal as these had been reviewed by EFSA in 2014[5]. EFSA concluded that the scientific data is sufficient to prove the safety and suitability of all formulae (infant and follow-on) manufactured from intact milk protein with a protein content higher than 1.8 g/100 kcal[5]. Dependent on the outcome of the minimum value, it is not recommended to include further requirement that follow-up formula containing 1.8-2.0 g/100 kcal requires clinical evaluation.

Several eWG members stated that if the eWG and Committee considered it appropriate to lower the minimum protein content to 1.65 g/100 kcal, then it would be appropriate to include a statement to the effect that any formula containing protein between 1.65 and 1.8 g/100kcal should be clinically evaluated. One Codex Member stated that if this option was adopted it should be clarified that an assessment by a competent national and/or regional authority is required. If this option is pursued, the following wording is proposed:

> Follow-up formula based on non-hydrolysed milk protein containing [1.65-1.8 g protein/100 kcal] should be clinically evaluated by a competent national and/or regional authority.

3.2.5 Conclusion

There was widespread support in the eWG to lower the protein content of follow-up formula for older infants to 1.8 g/100 kcal, based on the current evidence available to the eWG this approach has been evaluated to be safe and suitable for this age group. It is recommended that this level is adopted by the Committee. It is noted that EFSA will soon be releasing a scientific opinion on the safety and suitability of follow-up formula for older infants containing 1.61 g/100 kcal. The Committee will need to consider the results of this opinion in finalising a minimum protein requirement, and assess whether the opinion is globally relevant.

No consensus was reached on the establishment of a maximum limit by the eWG and similar justification was provided by the eWG as the 2015 consultation. It is proposed that the a maximum limit of 3.0 g/100 kcal is adopted by the Committee in alignment with the Codex Standard for Infant Formula acknowledging that there is limited evidence upon which to determine a maximum.

On the basis of the eWG support for alignment with the Codex Standard for Infant Formula it is proposed that the square brackets are removed in footnote 2; that clarification is provided on the source of Annex I in footnote 3; and that dependent on the minimum level established that footnotes 5 and 6 are adopted with the modifications highlighted below.

Recommendation 1:

That CCNFSDU agree to revise the protein requirements as follows:

Protein

Unit	Minimum	Maximum	GUL
g/100 kcal	[1.8]	[3.0]	-
g/100 kJ	[0.43]	[0.72]	-

[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* (CODEX STAN 72-1981)]**); nevertheless for calculation purposes the concentrations of tyrosine and phenylalanine may be added together and the concentrations of methionine and cysteine may be added together.

[4)] Isolated amino acids may be added to 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 follow-up formula based on non-cows' milk protein other minimum values may need to be applied. For follow-up formula based on soy protein isolate, a minimum value of [2.25 g/100 kcal (0.5 g/100 kJ)] applies.

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

3.3 Vitamin K: minimum requirements

At CCNFSDU37 it was agreed to continue discussions on the minimum vitamin K composition of follow-up formula for older infants. Two options were left in square brackets:

- to retain the current minimum vitamin K value of 4 µg/100 kcal, which is aligned with the Standard for Infant Formula; or
- to lower the minimum value to 1 µg/100 kcal as per the recommendation of EFSA.

At CCNFSDU37 some Committee members expressed concern with reducing the minimum level and noted that more recent evidence demonstrates that vitamin K requirements for infants were higher than originally thought for the prevention of vitamin K deficiency bleeding. Arguments to retain the higher level of 4 µg/100 kcal were based on the history of safe use, alignment with the Standard for Infant Formula, and the importance of vitamin K in overcoming haemorrhagic problems. Arguments to lower levels were based on meeting the vitamin K levels considered adequate for the majority of infants aged 0-6 months established by EFSA[5] and WHO/FAO[14] (REP16/NFSDU, para 57).

The majority of eWG members supported retaining the current minimum of 4 µg/100 kcal (1.0 µg/100kJ) (13 CM; 7 CO). However two Codex Members and one Codex Member Organisation continued to prefer lowering the minimum vitamin K requirements to 1.0 µg/100 kcal (0.24 µg/100kJ) to align with the recently revised EU legislation. The same rationale to support both minimum values were reiterated during the eWG

with some further discussions on the minimum values with regards to the prevention of vitamin K deficiency bleeding disorder.

Vitamin K is needed for synthesis of various proteins required for maintenance of normal coagulation. Vitamin K deficiency bleeding, although rare, represents a significant public health problem throughout the world due to the potentially life-threatening bleeding disorder[3]. Typically, the onset of vitamin K deficiency bleeding occurs in the first 1-12 weeks of life and up to six months of age[14,15].

Vitamin K deficiency bleeding occurs almost exclusively in breast fed infants. The contribution of vitamin K from current formulations of infant formula is sufficient to confer a protective effect, even for those infants most at risk of haemorrhagic problems (i.e. malabsorption of vitamin K). As bleeding can occur spontaneously it is recommended that countries implement vitamin K supplementation regimes either via intramuscular injection or oral supplements[14-16]. However, vitamin K prophylaxis has not been integrated into all national healthcare programmes globally[14,15]. It is important to note that even in those countries with national programmes, this does not always occur uniformly, and the programmes implemented are not always effective to confer protection to all infants particularly those with undiagnosed disorders which result in malabsorption of vitamin K.

It is evident that current formulations of infant formula provide sufficient vitamin K to confer a protective effect for the prevention of vitamin K deficiency bleeding, which is of particular relevance to young infants. There is limited evidence regarding the suitability of vitamin K levels for older infants.

Those in support of retaining current minimum vitamin K levels (4µg/100 kcal) based their decision on alignment with the Standard for Infant Formula, the history of safe use, lack of evidence demonstrating the efficacy of formulas with reduced vitamin K. Whereas those in favour of reducing vitamin K minimum requirements in follow-up formula to 1 µg/100 kcal stated that this level meets requirements established by several recognised authoritative scientific bodies (i.e. WHO/FAO, EFSA, IOM), that haemorrhagic problems associated with vitamin K only occur in young infants (aged less than six months) and are best managed through national supplementation programmes.

3.3.1 Conclusion

The majority of eWG members supported retaining the current minimum of 4 µg/100 kcal (1.0 µg/100kJ). However 2 Codex Members and One Codex Member Organisation continued to prefer lowering the minimum vitamin K requirements to 1.0 µg/100 kcal (0.24 µg/100kJ) to align with the recently revised EU legislation. As there is no further evidence that can be provided to support either approach, the Committee must consider whether a compromise can be sought on this issue.

Based on the discussions of the eWG it is recommended that the current minimum requirements are retained as there is insufficient evidence to deviate from the vitamin K requirements of the Standard for Infant Formula.

Recommendation 2:

That CCNFSDU agree to revise the minimum level for vitamin K as follows:

Vitamin K

Unit	Minimum	Maximum	GUL
µg/100 kcal	[4.0]	-	27
µg/100 kJ	[1.0]	-	6.5

3.4 Vitamin C: minimum requirements

At CCNFSDU37 the Committee agreed to establish a GUL of 70 mg/100 kcal (17 mg/100 kJ) for vitamin C and it was agreed to continue discussion on two minimum levels for the vitamin C composition of follow-up formula for older infants:

- to align with the Standard for Infant Formula minimum vitamin C value of 10 mg/100 kcal; or
- to lower the minimum value to 4 mg/100 kcal as per the recommendation of EFSA.

To further the discussions held at CCNFSDU37, the Chairs requested additional evidence on the outstanding issues: the suitability of lowering the minimum vitamin C content of follow-up formula for older infants; the impact of dietary intakes of vitamin C; iron absorption; and shelf life stability of vitamin C.

The eWG continue to have diverging views as to the minimum vitamin C composition for follow-up formula for older infants. The main point of contention is whether there is scientific justification for follow-up formula for older infants to differ from that of the Codex Infant Formula Standard, and whether the nutritional suitability as demonstrated by EFSA is applicable to all countries at a global level[5]. The research on vitamin C losses during a products shelf life indicate that the GUL of 70 mg/100 kcal is sufficient[17]. The issue of whether a reduced minimum vitamin C level would result in impaired iron absorption in follow-up formula was unable to be addressed.

Based on the summary of responses, the Chairs consider that the views in the eWG to derive a minimum vitamin C composition of follow-up formula for older infants can be divided by those who wish to:

1 take a precautionary approach and align with the Codex Standard for Infant formula; or

2 base vitamin C levels on the assessment of EFSA and taking into account that complementary foods are consumed from six months.

Of those eWG members that supported alignment with the Codex Standard for Infant Formula (12 CM; 6CO) there was a strong view that although the revised EU legislation to lower the vitamin C minimum to 4 mg/100 kcal was adequate in Europe, this was not necessarily adequate for a global standard. It was stated that lowering the minimum would not necessarily cover the needs of all populations and the source of vitamin C from other foods may not be available or adequate from the developing diversified diet and the limited dietary intake of the older infant. Furthermore, the importance of vitamin C in the absorption of iron was stressed, particularly for those countries where iron deficiency is a widespread public health issue. It was highlighted that the development of the international standard should cover the needs of all populations.

3.4.1 Conclusion

Taking the views of the eWG into account, the Chairs recommend that the Committee adopt a minimum vitamin C level of 10 mg/100 kcal to align with the Codex Infant Formula Standard as there is insufficient evidence to demonstrate the global nutritional suitability or need to decrease the minimum to 4 mg/100 kcal.

It is noted that this approach is not supported by all eWG members (2 CM, 1 CMO and 1 CO) who would prefer adoption of the EU minimum vitamin C level. As there is no further evidence that can be provided to support either approach, the Committee must consider whether a compromise can be sought on this issue in the development of a global standard which will enable vitamin C to be provided in adequate quantities to older infants regardless of the contribution from complementary diets.

Recommendation 3:

That CCNFSDU agree to revise the minimum level for vitamin C as follows:

Vitamin C

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.

3.5 Zinc: guiding upper level

At CCNFSDU37 the Committee agreed to establish a minimum zinc composition for follow-up formula for older infants of 0.5 mg/100 kcal and to include an elevated zinc minimum for formulas based on isolated

soy protein (REP15/NFSDU, Appendix III). It was agreed to continue discussions on establishing a GUL for zinc in follow-up formula for older infants.

As noted in the first consultation paper, two options are being considered by the eWG for the GUL for formula based on milk protein and hydrolysed protein:

- to align with the Codex Standard for Infant Formula zinc GUL value of 1.5 mg/100 kcal; or
- to lower the minimum value to 1 mg/100 kcal as per the revised EU legislation.

There is almost full support in the eWG to adopt a GUL of 1.5 mg/100 kcal for formulas based on milk protein and hydrolysed protein (13 CM; 5 CO). However it is important to note that one Codex Member Organisation still prefers adopting a GUL of 1 mg/100 kcal as supported by the recently revised EU legislation in order to avoid excessive intakes.

Arguments for aligning with the Codex Standard for Infant Formula include the demonstrated history of apparent safe use in infants and insufficient evidence to warrant establishing different compositional requirements for infant and follow-up formula. Several eWG members also stressed the importance of zinc in the diets of older infants globally as it remains a cause of morbidity in low income countries. The eWG acknowledged that although intakes could lead to exceeding the tolerable upper level established by some recognised authoritative scientific bodies that any risk associated with this was deemed negligible. The Committee has previously noted the uncertainty of the UL for zinc for this age group (CX/NFSDU 13/35/4). It was also noted that if the GUL was to be lowered, this would result in a narrow range for formulation which industry have acknowledged would be technologically difficult to accommodate.

3.5.1 Follow-up formula based on soy protein isolate

At CCNFSDU37 it was agreed to establish separate minimum zinc requirements for follow-up formula based on soy protein isolate (0.75 mg/100 kcal). 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. The minimum level for formula based on soy protein isolate is 1.5 times that of milk protein based formula.

It was noted by several eWG members that if the GUL for milk-based formulas was established at 1.5 mg/100 kcal this could accommodate formulas based on both milk and soy protein isolate.

3.5.2 Conclusion

The Chairs of the eWG recommend that a GUL of 1.5 mg/100 kcal is established in alignment with the Codex Standard for Infant Formula. This GUL is applicable to all types of follow-up formula for older infants, including those based on soy protein isolate.

This is on the basis of the evidence provided by eWG members suggesting that there is a low possibility that the zinc GUL specified in the Codex Infant Formula Standard would lead to any impairment in the nutrient absorption of iron or copper. In addition to this several eWG members noted that technological feasibility is not an issue for zinc within this range (0.5 - 1.5 mg/100 kcal). It is noted that some eWG members still prefer to establish a GUL of 1.0 mg/100 kcal (1CMO; 1CO).

Recommendation 4:

That CCNFSDU agree to revise the minimum, guiding upper level and associated footnote for zinc as follows:

Zinc

Unit	Minimum	Maximum	GUL
mg/100 kcal	0.5	-	[1.5]
mg/100 kJ	0.12	-	[0.36]

[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~~.]

3.6 Optional addition: DHA

At CCNFSDU37 the Committee agreed that the addition of docosahexanoic acid (DHA) should be **optional**, but the establishment of a minimum level to guide voluntary addition should be further discussed (REP16/NFSDU para 58(d)).

Further consideration of establishing a minimum level to guide voluntary addition would be for the purposes of ensuring that the product contains sufficient amounts to achieve the intended effect as per principle 3.3.2.2:

> *3.3.2.2 When any of these ingredients or substances is added the formula shall contain sufficient amounts to achieve the intended effect, taking into account levels in human milk.*

The Chairs note that minimum values for optional ingredients have not been established for any other optional ingredients listed in either the Codex Infant Formula Standard, or the proposed draft Standard for Follow-up Formula (REP16/NFSDU Appendix III).

The eWG had mixed views as to the appropriateness of establishing minimum requirements for the optional addition of DHA. Of those recommending establishing a minimum, the preference was to set this at 0.3% of total fatty acids.

Of those that did not recommend establishing a minimum value, the rationale provided was due to the highly variable nature of DHA content in human milk,[18, 19] and intakes from complementary foods globally, which has led to difficult in establishing in global recommendations. It was further noted by several eWG members that the conclusions of systematic reviews of DHA have not shown beneficial effects on neurodevelopmental outcomes, or visual acuity[20, 21, 22]. The conclusions of these systematic reviews was that at this time, routine supplementation could not be recommended[20, 21, 22]. It was suggested by some eWG members that due to this uncertainty, minimum levels could not be established and that the general provision contained within section 3.3.2.2 of the proposed draft revised standard for older infants ensures that the level of addition must be scientifically justified.

Arguments for the inclusion of a minimum limit stated that DHA is considered conditionally essential by both the FAO and EFSA and is an essential structural component of the nervous tissue and retina, as well as being important in normal structural brain and eye development[19, 45]. FAO has recommended adequate intakes of long chain polyunsaturated fats of between 0.2-0.36% of total fatty acids[19] , whereas EFSA has concluded that 100 mg of DHA per day is adequate for the majority of infants[45]. In addition to this, submitters commented that a minimum level should be based on the average concentrations in human milk, that intakes of DHA are low in many countries[23], and that conversion of alpha-linolenic acid to DHA in infants is limited[18, 5].

3.6.1 Conclusion

Due to the divergence in opinions, the Chairs proposed in the second consultation paper that the footnote would allow for national authorities to require minimum levels for the optional addition of DHA at their discretion. This approach was favoured by the majority of the eWG (8CM; 2 CO), with the clarification from

one Codex Member Organisation that should this be included it should also enable competent national authorities to mandate the addition of DHA. The Chairs note that the text drafted at CCNFSDU37 currently permits competent and/or regional authorities to deviate from the optional conditions, as appropriate for the nutritional needs.

Recommendation 5:

That CCNFSDU agree to the drafting of the optional addition of docosahexanoic acid as follows:

Docosahexanoic acid [20)]

Unit	Minimum	Maximum	GUL
% of fatty acids	-	-	0.5

[20)] If docosahexanoic acid (22:6n-3) is added to follow-up formula, arachidonic acid (20:4 n-6) contents should reach at least the same concentrations 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. Competent national and/or regional authorities may deviate from the above conditions**,** as appropriate for the nutritional needs.

3.7 Optional addition: L(+) lactic acid producing cultures

At CCNFSDU 37 the Committee noted that the inclusion of L+ lactic acid producing cultures should be further considered. Some within the Committee stated that the long term effects of these cultures were not yet fully scientifically demonstrated in this age group (REP16/NFSDU para 58 e). The majority of eWG members supported inclusion of provision 3.3.2.4 (14 CM, 1 CMO, 9 CO), although several supported some modification of the drafting to clarify the two purposes for the addition of L(+) lactic acid producing culture: the technological function and for a nutritive purpose.

Technological function

Several submitters highlighted that L(+) lactic acid producing cultures can be used for a technological purpose (the acidification of formula). The manufacture of acidified formula can be achieved either through the direct addition of lactic acid, or through the addition of L(+) lactic acid producing cultures. Those fermented with L(+) lactic acid-producing bacteria during the production process do not contain significant amounts of viable bacteria in the final product, and are widely available in many countries[24,25]. Fermented formula without live bacteria needs to be differentiated from infant formula supplemented with probiotics.

Nutritive Purpose

Probiotics are defined by the WHO/FAO as 'live microorganisms which when administered in adequate amounts confer a health benefit on the host'[26]. The eWG reviewed several recent systematic reviews with regards to the use of probiotics in formula used during infancy, a summary of which are provided below.

Mugambi and colleagues conducted a systematic review on the use of synbiotics, probiotics and prebiotics in infant formula for full term infants on growth and clinical outcomes[27]. Of the studies reviewed synbiotics failed to significantly increase growth in boys and girls, increased stool frequency, in addition to no impact on stool consistency or other outcomes evaluated (3 studies, N=475). The addition of probiotics also failed to have any significant effect on the outcomes measured (growth, stool frequency or consistency (10 studies, N=933). The authors concluded that there was insufficient evidence to state that supplementation resulted in improved outcomes in term infants and as such the authors stated that the review did not support the routine supplementation of formula with synbiotics, probiotics or prebiotics[27].

ESPGHAN published a systematic review on the safety and health benefits of supplementation of infant formula with probiotics[28]. On the basis of the review, the authors concluded that the addition of probiotics to healthy infants did not raise any safety concerns with regards to growth or other adverse effects[28]. It was also concluded that the addition of probiotics to infant or follow-up formulae may be associated with some clinical benefits, such as a reduction in the risk of nonspecific gastrointestinal infections, reduced risk of antibiotic use, and a lower frequency of colic and/or irritability. Despite these findings the overall conclusion of ESPGHAN was that there was insufficient evidence to support the routine use of formulas containing probiotics[28]. It was also noted that the safety and clinical effects of one probiotic microorganism should not

be extrapolated to others. One eWG member stated that this concept should be included in the revised statement regarding the optional addition of L(+) lactic acid producing cultures.

The EFSA Scientific Opinion on the essential composition of infant and follow-on formula reviewed the evidence related to the health benefits of products containing live bacteria, generally referred to as probiotics[5]. It was concluded that the safety of synbiotics and probiotics added to infant and follow-up formulae did not give rise to concerns with regard to growth or other adverse effects, although it was acknowledged that the evidence is limited[28]. EFSA concluded that taking into account the lack of convincing evidence for a benefit from the addition of the "probiotics" or the "synbiotics" evaluated in humans so far, the Panel considers that there is no necessity to add those "probiotics" and/or "synbiotics" to infant and follow-up formulae.

One eWG member referred to the report of Thomas and Greer in 2010, which stated that there had been some anecdotal reports of adverse effects from consumption of probiotics in seriously ill or immunocompromised children[29]. Another eWG member referred to a report of the Norwegian Scientific Committee for Food Safety which stated that early composition of the human gastro-intestinal tract microbiota can have long term functional effects[30]. This report did not consider there to be sufficient evidence on the long term suitability of infant formula supplemented with *Lactobacillus fermentum* CECT 5716. Other eWG members noted that although there are no recorded adverse events from the consumption of infant formula supplemented with probiotics, the long term effects were unclear and should be subject to further studies. As such, they recommended that a precautionary approach should be taken, and did not support the inclusion of the addition of L(+) lactic acid producing cultures as an optional ingredient in the standard.

To summarise, the reviews conducted to date have not given rise to any safety concerns with regards to growth, clinical outcomes or other adverse effect [5],[27], [28]. It is acknowledged that further evaluations of safety in long-term studies is warranted. It is also noted that the safety and health effects of one probiotic microorganism should not be extrapolated to others. Regarding health benefits, there is insufficient evidence to date to warrant the need to add probiotics to infant formula but it is noted that some strains have shown some positive effects.

Codex permissions for the acidification of formula

In the current Standard for Follow-up Formula L (+) lactic acid and L(+) lactic acid producing cultures are included as part of the Section on Food Additives and listed within the pH-adjusting agents (4.3.10 and 4.3.11, respectively). The Infant Formula Standard reference to L(+) lactic acid producing cultures is only contained within sub-section 3.3.2.4 Optional ingredients.

Under the *General Standard for Food Additives* (CODEX STAN 192-1995)(GSFA) lactic acid, L-, D- and DL- (INS 270) are permitted to be used in Infant Formulae, Follow-up Formulae and Formulae for Special medical Purposes for infants as an acidity regulator at GMP levels.

Lactic acid producing cultures are not included within the GSFA, as bacterial cultures are not considered to be food additives. A food additive is by definition a substance, and not a living organism. Additionally, bacterial cultures are not regulated internationally as food additives. Therefore the Chairs do not propose referring to CCFA for the consideration of the inclusion of L(+) lactic acid producing cultures in the GSFA or to retain the permission within the Food Additives section of the Codex Follow-up Formula standard as has been suggested by two eWG members.

It was noted that at the time the Codex Infant Formula Standard was revised the permission to add L(+) lactic acid producing cultures as a food additive was moved from the additive permissions to the optional ingredients section. The Chairs note that this is due to the fact that bacterial cultures are not considered food additives by Codex Alimentarius.

Proposed approach

Some eWG members presented suggestions for amended drafting of sub-Section 3.3.2.4, these included reference to:

- the purpose of addition (i.e. for the acidification of formula),
- specification of the strains with demonstrated safety and suitability,

- restating the principles for permitting optional ingredients for nutritional purposes
- ensuring stability in final product due to heat instability in addition to safe dilution temperature as recommended by FAO/WHO and the Code of Hygienic Practice
- non-pathogenic cultures may be used (including DL or D-lactic acid producing cultures)

The current draft principles for the addition of optional ingredients to follow-up formula for older infants are:

> *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 to follow-up formula for older infants where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.*
>
> *3.3.2.2 When any of these ingredients or substances is added the formula shall contain sufficient amounts to achieve the intended effect, taking into account levels in human milk.*

Of those the drafting amendments listed above, the majority of eWG members considered it important that the purpose of addition was clarified in this Standard to prevent the current ambiguity. In addition, many of the eWG members also highlighted the need to reiterate and modify some of the concepts including principles for the addition of optional ingredients (3.3.2.1 -3.2.2.2). This included specification that the specific strain of L(+) lactic acid producing cultures was proven to be safe and suitable using generally accepted scientific evidence at the level of use; and that when added for a nutritional purpose the final product contains sufficient amounts of viable bacteria to achieve the intended effect.

Conclusion

The majority of the eWG recommended including a statement that L(+) lactic acid producing cultures may be added to follow-up formula for older infants as an optional ingredient (sub-section 3.3.2.4). There were mixed views as to whether this was applicable to all forms of addition, or whether this should apply only to the addition of these cultures for the purpose of producing acidified formula as different eWG members interpreted the equivalent text in the Codex Infant Formula Standard differently.

The majority of the eWG considered it important to clarify the purpose for the addition of the L(+) lactic acid producing cultures. The Chairs recommend that the Committee modify 3.3.2.4 to highlight that the purpose of addition is to produce acidified follow-up formula for older infants. In addition to this the Chairs recommend an additional clause is included which refers to the specific criteria that would need to be achieved if these cultures are added for nutritional purposes.

Recommendation 6:

That CCNFSDU agree to the permission for the optional addition of L(+) lactic acid producing cultures as follows:

3.3.2.4 [Only L(+) lactic producing cultures may be used **for the purpose of producing acidified follow-up formula for older infants**.]

3.3.2.5 [**The safety and suitability of the addition of specific strains of L(+) lactic acid producing cultures for particularly nutritional purposes, at the level of use, shall be demonstrated by generally accepted scientific evidence. When added for this purpose, the final product ready for consumption shall contain sufficient amounts of viable bacteria to achieve the intended effect**.]

4 FRAMEWORK FOR THE ESSENTIAL COMPOSITION OF FOLLOW-UP FORMULA FOR YOUNG CHILDREN (12-36 MONTHS)

At CCNFSDU37, the Committee agreed to the proposed approach and key themes for the essential composition of follow-up formula for young children (12-36 months) as outlined in CX/NFSDU 15/37/5 (section 8). The outlined approach was for the requirements of the essential composition of follow-up formula for young children to be based on a narrow set of mandatory requirements, with the option that national authorities may require additional mandatory nutrients based on the nutritional needs of their population. This approach was based on the outcome of the 2015 eWG which stated that the Standard

should be; flexible in the composition to address key nutrients of concern which may vary regionally; less prescriptive as follow-up formula for young children does not need to contain the full range of nutrients that are mandated for addition to follow-up formula for older infants; consistent with compositional parameters for follow-up formula for older infants (where possible); contain the key nutrients of global concern in the diets of young children, as well as the key nutrients in cows' milk; and maintain nutritional integrity. The 2016 eWG has further elaborated on the proposed approach and developed three principles to help guide mandatory compositional requirements for follow-up formula for young children (see Section 4.2)

4.1 Role of product

In establishing the requirements for the essential composition of follow-up formula, it is considered important to define the role of product in the diets of young children. In previous eWG's this has been reviewed extensively. It is recognised that in general follow-up formula for young children is often used as a substitute, alternative or replacement for cows' milk, and could supplement the diet to provide those nutrients which are of key global concern for this age group.

This finding was recently reiterated by the European Commission report on milk based drinks and similar products intended for young children. Young child formulas were defined as those specifically processed or formulated and intended to satisfy the nutritional requirements of young children (aged 1 to 3 years), and will often replace cows' milk in whole or in part in the diet of young children[31]. It was reported that *'breastfeeding decreases significantly after the age of one year in the different Member States, both in terms of rates and intakes. Formula products are competing with cows' milk in the diet of young children, and differences in the preference exist depending on the Member State. However, it can generally be reported that consumption of young-child formula is at its highest in the age range 12-18 months.'*

As presented in the 2014 Agenda Paper CX/NFSDU 14/36/7, there is recognition that follow-up formula plays a distinctly different role in the diets of older infants in comparison to that of young children. The diversity of the diet of young children means that follow-up formula for this age group plays a different role particularly in relation to the variable contribution to a child's total daily nutrient intake. There is general agreement amongst the eWG that the composition of follow-up formula for young children does not need to contain the full range of nutrients that are mandated for addition to follow-up formula for older infants. The composition can therefore be less prescriptive due to the young child also obtaining essential nutrients from other foods in the complementary diet.

In some countries follow-up formula and specially formulated milk products for young children are considered an important source of nutrients in the diet, and in at least one instance has been recommended in national feeding guidelines. Based on the role of product the eWG considered it important that follow-up formula for young children provides those nutrients which are of key global concern for this age group.

In addition to this, many eWG members have previously commented that follow-up formula for young children is often used as a substitute for cows' milk, and as such it was important that the key nutrients from milk are provided. From one year of age many national feeding guidelines recommend the introduction of between one and two serves per day (300 to 500 mL) of cows' milk (2013 eWG). The introduction of cows' milk is also recommended by WHO in their 'Guiding principles for feeding non-breast fed children aged 6-24 months'[32]. The ability for these formula products to substitute cows' milk was considered particularly important in countries where availability of fluid milk was limited.

There was considerable comment that with the proposal for product for young children to contain a limited number of mandatory nutrients, compared to follow-up formula for older infants (which mandates 32 nutrients), the two products are distinctly different. It was considered important that product for young children needs to be easily distinguishable from product for older infants to avoid confusion about the suitability of individual products for different age groups. There was support to separate the standard into two separate parts to allow for different composition and labelling approaches to the two different product categories, and assist in being able to easily distinguish the different products and consequent roles in the diet. Subsequently the Chairs have proposed separation of the Standard into two parts, consistent with the approach taken in the infant formula standard (Appendix 5).

Recommendation 7:

That CCNFSDU agree to divide the Standard for Follow-up Formula in to two separate parts as presented in Appendix 5.

Section A will refer to the essential composition and labelling of follow-up formula for older infants, and Section B will deal with the essential composition and labelling of product for young children.

4.2 Principles for determining mandatory requirements

The eWG have developed three principles for the determination of the mandatory compositional requirements for follow-up formula for young children. These principles were developed to help guide and justify nutrient addition, as well as identify those nutrients requiring specific compositional parameters.

Principles for the mandatory (core) composition of product for young children

Evidence to support:

1. contribution to the nutritional needs of young children where the consumption of the nutrient is inadequate on a global scale; and/or
2. contribution of adequate amounts of key nutrients from cows' milk, where such nutrients are key contributors to the diet of young children; and/or
3. the nutritional quality and integrity of product to ensure nutritional safety.

Further considerations

The eWG also recommends that these principles, and the addition of any optional nutrients, ingredients or substances should be considered in the context of:

- the diversified complementary feeding diet;
- relevant national or regional, and global nutrition policies for young children (i.e. dietary guidelines, supplementation or fortification programmes); and
- formulating a product which is proven to be safe and suitable for the feeding of young children, and for which the nutritional safety and adequacy of such a product has been scientifically demonstrated to support growth and development of young children.

Further to this, when establishing the requirements for the essential composition, the following should also be taken into account:

- bioavailability, processing losses and shelf-life stability from the ingredients and product matrix;
- total levels of a nutrient in the final product, taking into account both naturally occurring nutrients in the ingredients and added nutrients;
- the inherent variability of nutrients in ingredients and in water that may be added to the product during manufacture; and
- contribution of nutrients from the remainder of the complementary feeding diet.

The Chairs note that some eWG members have requested the mandatory addition of nutrients which are sometimes limited in the diets of young children. The Committee will need to consider where intake and possible deficiency of these nutrients is a national or regional, rather than global issue. In some instances national fortification programmes are in place and therefore it may only be appropriate to mandate the addition of these nutrients if deemed necessary by individual national authorities.

It has seen suggested that a Standard that allows for too much flexibility in terms of composition could result in products that are so varied in composition that the consumer may be confused as to the appropriate use of the product. Such a flexible approach could render the standard 'meaningless' and could be viewed as problematic. Contrary to this, others have suggested that as young children have an increased consumption of other foods, follow-up formula for young children does not need to contain an extensive list of mandatory (core) nutrients. The eWG were reminded that 'less prescription' and 'flexibility' were common themes (with respect to composition) identified by the 2015 eWG.

When considering the compositional requirements of follow-up formula for young children, comment was made that the general requirement agreed to at CCNFSDU37 for follow-up formula for older infants under point 3.1.1 is also applicable to follow-up formula for young children. Point 3.1.1 states that; '***Follow-up formula*** *is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be safe and suitable for the feeding of older infants and young children.'*

4.3 Optional addition

In addition to the mandatory (core) composition, further essential nutrients may be added to follow-up formula for young children, either as a mandated addition to the (core) composition required by national authorities, or as an optional addition by manufacturers, provided such needs are substantiated by scientific evidence.

Whilst the majority of eWG members did not support adopting all the nutrient levels proposed for follow-up formula for older infants, for product for young children, there was widespread support for including some parameters for optional nutrient levels in follow-up formula for young children. Many suggested that the nutrient levels for follow-up formula for older infants could serve as the basis or starting point, with necessary adjustments where the nutritional needs of the local population and scientific justification warrants different levels for young children, compared to older infants.

The eWG considered a framework for the composition of follow-up formula for young children with three tiers; mandatory (core) composition, voluntary essential nutrient additions, and optional ingredients. Many thought this approach was confusing with the addition of the 'voluntary essential nutrient' category and favoured a two tiered framework; (1) mandatory (core) composition, and (2) optional additions.

For the optional addition of other ingredients and substances (separate to nutrients), the eWG considered a principles based approach (rather than a list), similar to the approach presented in 3.3.2.1 of REP 16/NFSDU Appendix III for older infants. This approach would require that the safety and suitability of the optional addition for particular nutritional purposes, at the level of use, must be evaluated and demonstrated by generally accepted scientific evidence. Further to this, when any of these ingredients or substances are added, the formula needs to contain sufficient amounts to achieve the intended effect. These principles for older infants could be amended, if required, to be applicable for young children.

It was the preference of the majority of the eWG to remove the requirement for follow-up formula for young children to take into account levels in human milk when ensuring that the product contains sufficient amounts (of the optional addition) to achieve the intended effect.

The eWG was divided in its views as to how the optional addition of other *nutrients* should be regulated for follow-up formula for young children, with two main approaches presented. Option 1 refers to using levels for essential nutrients in follow-up formula for older infants, whereas Option 2 is a principles based approach for the addition of other *nutrients* (similar to the approach for optional ingredients and substances).

Approximately two thirds of the eWG members who responded to questions relating to the approach were of the view that with respect to the optional addition by manufacturers of other *nutrients* to follow-up formula for young children, these *nutrients* should be chosen from the essential composition of follow-up formula for older infants (Option 1), and levels should be:

- as per the min, max, GULs stipulated for follow-up formula for older infants; or
- based on the min, max, GULs stipulated for follow-up formula for older infants, and amended if the nutritional needs of the local population and scientific justification warrants deviating from the level stipulated for older infants.

The remaining third of respondents favoured using a principle based approach (Option 2) for any optional addition to follow-up formula for young children, whether that be a nutrient, an ingredient or substance.

A low number of eWG members were of the view that optional additions should not be permitted.

Comment was also made that minimum levels may not be necessary for the optional nutrients (and substances and ingredients) as these are optional additions and not considered part of the "essential" composition.

Based on work and feedback from the 2016 eWG, the following modified framework is proposed for the composition of follow-up formula for young children.

Recommendation 8:

That CCNFSDU agree to the following revised framework for the essential composition of follow-up formula for young children and identify the preferred option for the optional addition of other nutrients:

Mandatory (core) composition

It is proposed that the mandatory (core) composition of follow-up formula for young children include a limited list of essential nutrients (specific recommendations are presented in Section 5).

For national authorities requiring the mandatory addition of other essential nutrients for their specific population, these nutrients should be chosen from the essential composition of follow-up formula for older infants. The nutrient levels must be:

- as per the min, max, GULs stipulated for follow-up formula for older infants; or
- amended if the nutritional needs of the local population and scientific justification warrants deviating from the level stipulated for older infants.

Note: all footnotes relevant to these listed essential nutrients for older infants, also apply when added to follow-up formula for young children.

Optional Additions

In addition to the mandatory (core) composition, other nutrients, ingredients or substances may be added to follow-up formula for young children. For the optional addition of other ingredients or substances, it is proposed that a principles based approach will continue.

With regards to the optional addition of other *nutrients*, two main options have been identified;

(1) optional nutrient additions are chosen from the essential composition of follow-up formula for older infants with corresponding levels as the starting point (Option 1); or

(2) optional addition of other nutrients are captured as part of the principles based approach as per the addition of other ingredients and substances (Option 2).

Draft text for the two different options and concepts are presented below. The proposed wording represents a starting point for discussion.

OPTION 1:

- In addition to the [essential] compositional requirements listed under [*insert appropriate subsection*] other ingredients or substances may be added to [name of product] for young children where the safety and suitability of the optional ingredient [or substance] for particular nutritional purposes, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.
- When any of these ingredients or substances is added, the [name of product for young children] shall contain sufficient amounts to achieve the intended effect, [~~taking into account levels in human milk~~].
- [~~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 competent national and/or regional authorities as to appropriate levels when these substances are added~~]. *It is proposed to delete the third bullet point in preference for a principles based approach rather than inclusion of any essential nutrients, ingredients or substances in a list.*
- [Additional nutrients may also be added to follow-up formula for young children provided these nutrients are chosen from the essential composition of follow-up formula for older infants and levels are:
  - as per the min, max, GULs stipulated for follow-up formula for older infants; or
  - amended if the nutritional needs of the local population and scientific justification warrants deviating from the level stipulated for older infants.

Note: all footnotes relevant to these listed essential nutrients for older infants, would also apply when added to [name of product] for young children]

OPTION 2:

- In addition to the [essential] compositional requirements listed under [insert appropriate subsection] other [nutrients,] ingredients or substances may be added to [name of product] for young children where the safety and suitability of the optional [nutrient,] ingredient [or substance] for particular nutritional purposes, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.
- When any of these [nutrients,] ingredients or substances is added, the [name of product for young children] shall contain sufficient amounts to achieve the intended effect, [~~taking into account levels in human milk~~].
- [~~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 competent national and/or regional authorities as to appropriate levels when these substances are added~~]. *It is proposed to delete the third bullet point in preference for a principles based approach rather than inclusion of any essential nutrients, ingredients or substances in a list.*

5 REQUIREMENTS FOR THE ESSENTIAL COMPOSITION OF FOLLOW-UP FORMULA FOR YOUNG CHILDREN (12-36 MONTHS)

5.1 Overview

It is proposed that the mandatory (core) composition of follow-up formula for young children include a limited list of essential nutrients. Based on comments from the eWG, there are two different approaches: a more extensive prescriptive list of mandatory (core) nutrients, and a simplified less prescriptive approach. In order to facilitate discussion at the pWG, the Chairs of the eWG have provided a third option and recommendations for the mandatory (core) composition of follow-up formula for young children. These recommendations are based on the principles outlined in Section 4 to ensure that product contributes to the nutritional needs of young children for those nutrients which are inadequate in the diet, as well as providing the key nutrients from cows' milk and ensuring the nutritional quality and integrity of product is maintained. The recommendations are also based on the principles of less prescription and ensuring flexibility. See below for further detail on these three options.

Extensive prescribed mandatory (core) composition	Simplified mandatory (core) composition	Chairs recommendation
Energy density	-	Energy density
Carbohydrate (total and associated footnotes)	Total sugars	Carbohydrate maximum Total sugars
Fat (total and associated footnotes)	Fat quality	Fat quality
Protein (total and associated footnotes)	-	Protein quality
Calcium	Calcium	Calcium
Vitamin B12	Vitamin B12	Vitamin B12
Riboflavin	Riboflavin	Riboflavin
Iron	Iron	Iron
Vitamin C	Vitamin C	Vitamin C
Vitamin D	-	-
Vitamin A	-	-
Zinc	-	-
Sodium	-	Sodium, maximum only

The Chairs have also summarised additional requirements which were supported by several members of the eWG for consideration by the pWG and Committee. The Committee will need to consider whether these requirements fulfil any of the necessary principles for the mandatory (core) composition of product for young children as well as balancing the need for a flexible standard which ensures adequate nutritional integrity of product.

The eWG highlighted the need for product composition to take into account nutrient levels in human milk and cows' milk, as both were considered important contributors of nutrients to the diet of young children. This view was supported by one Codex Member Organisation who recommended that the derivation of compositional parameters for follow-up formula for young children should be based on formulae consumed during the first year of life and cows' milk which is generally recommended for young children in national dietary guidelines. The Chairs note that the composition of follow-up formula for older infants, with the exception of iron, is based on the nutrient composition of human milk, and as such has been considered as the basis for determining requirements. The nutrient composition of cows' milk has been calculated by the Chairs in accordance with the approach used by the FAO in their report Milk and Dairy Products in Human Nutrition[33] (see Appendix 1).

A pragmatic approach which enables the nutrient composition of both follow-up formula for older infants and cows' milk has been sought to accommodate both. This approach was also suggested by one Codex Member Organisation. For those nutrients in the mandatory (core) composition that are not present or are present at very low levels in cows' milk (e.g. iron) the minimum and maximum/GUL levels of follow-up formula for older infants are recommended for follow-up formula for young children, and for those nutrients in the mandatory (core) composition that are naturally present in cows' milk (e.g. calcium) the minimum could be set at the minimum stipulated for follow-up formula for older infants, while the maximum/GUL could be set at the highest of two values: either the maximum/GUL permitted for follow-up formula for older infants, or the level in cows' milk (the highest value between full fat and low fat milk) to ensure flexibility.

Noting that follow-up formula for young children is part of the diversified complementary diet, the Chairs have calculated the average daily contribution from the recommended compositional requirements. Compositional parameters have been calculated from an average daily intake for young children and assuming a daily intake of 300 mL of formula per day. This value is based on the conclusions of the 2014 eWG which based this value on the WHO Guiding principles for feeding non-breastfed children 6-24 months of age.

5.2 Energy density

There was widespread support in the eWG for including parameters for energy density for follow-up formula for young children. It was highlighted that mandating the energy density of these products will enable a nutritionally appropriate contribution to the complementary diet, and ensure that the ranges specified for macronutrient and micronutrients in the Standard are within a nutritionally appropriate energy density range.

It was considered of particular importance to ensure that excessive energy is not provided through this product. Furthermore it was emphasised that the specification of energy density must be accompanied by appropriate limits on carbohydrates to ensure that the nutritional integrity of the product is retained with lower protein or fat formulations. Mandatory requirements for energy density were not supported by one Codex Member Organisation as it was considered that nutritional integrity could be maintained through regulation of sugar levels only, and that a less prescriptive standard should be sought.

Proposed requirements

As outlined above, the eWG considered the current energy requirements for follow-up formula for older infants and the energy density of cows' milk as the basis for determining requirements. The proposed Standard for follow-up formula for older infants specifies a minimum energy density of 60 kcal/100 mL (250 kJ/100 mL) and maximum of 70 kcal/100 mL (293 kJ/100 mL). This range is in line with the energy density of full fat cows' milk (60 kcal/100 mL); but not reduced fat cows' milk 46 kcal/100 mL (192 kJ/100 mL).

There were diverging views as to whether the Standard should accommodate the energy density of reduced fat cows' milk. Of those in support of establishing a minimum energy density of 45 kcal/100 mL (8 CM; 4 CO) it was noted that this would enable flexibility and take into account national dietary guidelines which allow for reduced fat cows' milk to be introduced to the diet of children aged over 24 months. This was considered of particular relevance in those countries where there was a significant risk of excessive weight gain and obesity in early childhood.

Those in favour of a minimum energy density of 60 kcal/100 mL (7 CM; 2 CO) highlighted that reduced fat cows' milk is not recommended for children aged 12-24 months in most national dietary guidelines as it could compromise intakes of energy and essential fatty acids necessary for growth and development[32,34]. The WHO/FAO also stress the adverse effects of low-fat diets on weight gain and growth in young children, and recommend the gradual reduction in the percentage energy contribution from fat from 40-60% of energy in the first six months of life to approximately 35% of energy between 6-24 months[19].

It was further noted that insufficient energy and dietary fat intakes have been reported in several low income countries. It was the view of several eWG members that the focus of the compositional requirements should be based on ensuring appropriate energy and nutrient contributions to the most vulnerable age group, those aged 12 to 24 months. The Chairs note that the rationale for a minimum energy density of 45 kcal/100 mL is limited to those children aged 24 to 36 months only.

Of those eWG members supporting the establishment of requirements for energy density, all supported establishing a maximum level of 70 kcal/100 mL. This ensures a maximum energy density which is no higher than that found in cows' milk, human milk, the Codex Infant Formula Standard, and the proposed Standard for follow-up formula for older infants.

Conclusion

On the basis of the comments received from the eWG, the Chairs propose that energy requirements are specified in order to ensure the appropriate energy density of products targeted to young children. The Chairs note that the rationale for a minimum energy density of 45 kcal/100 mL is limited to those children aged 24 to 36 months, and is relevant only to those countries where sub-groups of the population could be at risk of excessive energy intakes. Taking into account the requirements of the most vulnerable, the Chairs recommend that the mandatory energy requirement is focussed on alignment with full fat cows' milk and the requirements for formula for use in the first year of life which permit an energy density of 60 kcal to 70 kcal/100 mL.

If the Committee wishes to develop a broader range for energy density suitable for young children aged over 24 months, further wording could be added to the requirements specifying that a minimum of 45 kcal/100 mL is suitable for young children aged 24 to 36 months. This should be discussed by the

Committee as to whether this would enable sufficient nutritional integrity at a global level and enable flexibility within the Standard.

Recommendation 9:

That CCNFSDU agree to the following requirements for energy density:

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.

Additional option for further discussion:

[For products formulated for young children of more than 24 months of age, the product when prepared ready for consumption shall contain per 100 mL not less than 45 kcal (kJ)]

5.3 Energy contribution from macronutrients

Regarding specifications for percentage contributions from macronutrients, the eWG had mixed views as to the need to define minimum and maximum values for all macronutrients. Maximum limits on total carbohydrate and/or added sugar were most commonly cited requirements. However, some within the eWG requested that these levels were determined once protein and fat requirements were specified.

There was some support from the eWG to base the percentage energy contributions on the acceptable macronutrient distribution range (AMDR) established by the Institute of Medicine. This approach was taken by the international expert working group coordinated by the Early Nutrition Academy, where the following percentage contribution from macronutrients was proposed[35]:

6%E protein, 40%E fat, and 34%E carbohydrate (total 80%)

Others commented that it was not appropriate to base the product formulation on AMDRs as these are based on the daily intakes of macronutrients from a variety of foods. It was stated that it is appropriate for different foods to provide different proportions of macronutrients within the complementary feeding period and that it would be more appropriate to ensure that the contribution of macronutrients from cows' milk be used as a basis for setting requirements for composition. This would enable an appropriate substitute product to be formulated. Under this scenario the following percentage contribution from macronutrients was proposed:

12%E protein, 35%E fat, and 34%E carbohydrate (total 81%).

Based on these views, the Chairs have not proposed specific percentage energy contributions from macronutrients. A summary of the views of eWG members proposing specific requirements (minimum, maximum, or guiding upper levels) for individual macronutrients are described under the following sections.

5.3.1 Proposed requirements for minimum and maximum protein, total fat, and available carbohydrates

There were diverging opinions within the eWG as to the need for establishing minimum and maximum values for macronutrients. Those in favour of detailing requirements supported this approach to ensure that follow-up formula for young children contains a nutritionally appropriate, and balanced range of macronutrients. Of those opposing the need to establish requirements, it was highlighted that a flexible approach was sought by the Committee at CCNFSDU37 and that only those requirements which were of global significance should be specified. There was consensus within the eWG that requirements were necessary in order to limit the addition of free sugar to these products and ensure the nutritional integrity and suitability of product.

Protein

The eWG had mixed views on the need to specify minimum and maximum protein requirements for follow-up formula for young children. There was greater support for mandating a minimum requirement based on ensuring an appropriate macronutrient profile (12 CM; 6 CO), with limited numbers considering a maximum necessary (7 CM; 2 CO). It is noted that one Codex Member Organisation did not consider it necessary to

establish either a minimum or maximum protein content based on the outlined principles (Section 4.2) and that this could be left to national authorities.

Minimum protein levels

Of those supporting establishment of a minimum protein requirement, two options were proposed; provision of approximately 6% of the total energy of the product (1.5 g/100 kcal); or to provide approximately 12% of total energy of the product (3g/100 kcal). The rationale for a minimum protein level of 3 g/100 kcal was to ensure a nutritionally balanced macronutrient profile, particularly when a lower fat product was formulated. This level is approximately half the protein level of full fat cows' milk.

As there was no clear rationale provided by eWG members upon which to base minimum protein requirements, the Chairs do not recommend a minimum level is established at this time. The Chairs note that both cows' milk and formula for infants less than 12 months are recommended to be consumed by young children, both of which provide high quality protein at levels between 1.8 g and 5.5 g/100 kcal. Any minimum level should be allow for protein formulations at these levels.

Maximum protein levels

There was widespread support that if protein maximum levels were established, these must accommodate the protein levels found in full fat cows' milk, either listed as 22% of total energy or presented as 5.5 g/100 kcal. However, it is worth noting that the majority of the eWG did not consider it necessary to establish a maximum level. It was stated that WHO acknowledges the importance of cows' milk as a valuable source of protein in the diets of young children. It was further noted by one eWG member that evidence regarding a potential association between obesity and protein intakes for this age group was very limited and did not warrant restrictions on protein levels to those than cows' milk.

As there was no clear support for the establishment of a maximum protein level, the Charis do not recommend establishing a maximum level at this time. If the Committee wishes to further consider establishing minimum and maximum values for protein, these should be able to accommodate the composition of follow-up formula for older infants and cows' milk. It is noted that specifications for protein quality, as discussed in section 5.4, are an alternative approach to ensuring the nutritional integrity of product with regards to protein.

Total Fat

The eWG had similar views on the need to specify minimum and maximum fat requirements as with the need for protein requirements. The rationale to establish minimum and maximum fat requirements was based on ensuring an appropriate macronutrient profile (11 CM; 7 CO). However, one Codex Member Organisation considered it was not necessary to establish either a minimum or maximum fat content based on the principles outlined in Section 4.2.

Of those supporting a minimum level, three levels were proposed by more than one eWG member:

- 3.5 g/100 kcal to accommodate reduced fat cows' milk
- 4.4 g/100 kcal to align with follow-up formula requirements
- 4.0 g/100 kcal as reduced fat cows' milk is not recommended for children aged 12-24 months

As stated earlier, some eWG members noted that reduced fat cows' milk (3.5 g/100 kcal) is not suitable for young children aged 12-24 months as it could compromise intakes of dietary fat required for adequate growth and development.

There was no clear support for the establishment of minimum and maximum requirements for total fat levels, as such the Chairs do not recommend that these are established at this time. If the Committee wishes to further consider establishing minimum and maximum values these should be able to accommodate the composition of follow-up formula for older infants and cows' milk.

Available Carbohydrates

As stated above the eWG had mixed views on the establishment of minimum and maximum limits for total carbohydrates. Although all eWG members supported limiting the addition of excessive sugars to these products, the manner in which this is achieved differed.

As noted by one Codex Member Organisation, the need for carbohydrates in formulae for infants differs to that for product targeted to young children. Carbohydrates in formulae for infants are an important source of energy and need to be regulated to ensure a nutritionally appropriate contribution at an age when formula can act as the sole, or predominant source of nutrition. Energy needs and intakes of carbohydrates for young children are covered by a range of foods in the progressively diversified diet. As such, a minimum carbohydrate level does not need to be prescribed by the Standard.

The WHO guidelines recommend that intakes of free sugars are limited to less than 10% of total energy intake. Application of these requirements to the calculated energy requirements of young children (955 kcal/day (CX/NFSDU14/36/7)) equate to a maximum daily intake of approximately 24 g per day for young children aged 12-36 months. Consumption of 300 mL to 500 mL of follow-up formula for young children would provide 20-33% of energy requirements in the diet of young children. Products would need to contain less than 8 g of added sugars to provide appropriate levels of added sugar in proportion to the contribution of energy these products have to the diet.

Minimum total carbohydrate levels

There was very limited support from the eWG for establishing a minimum total carbohydrate level. Of those that did support establishing a minimum level (4 CM; 2 CO), the majority favoured a level of 7.5 g/100 kcal - the level of lactose found in cows' milk. At this level a predominantly cows' milk based product could be used as the basis without the need to add any sugar or other nutritionally available carbohydrate. Based on the views of the eWG and noting that the establishment of a minimum does not fulfil any of the required principles for mandatory requirements, a minimum total carbohydrate level has not been recommended. The Chairs recommend that if any minimum or maximum limits are proposed for protein or fat, that these levels should permit the inclusion of milk based products containing only lactose (i.e. no added sugars).

Maximum total carbohydrate levels

There was some support from the eWG for establishing a maximum level for total available carbohydrates (10 CM; 5 CO). Those in favour of doing so stated the importance of limiting the addition of all sources of carbohydrate to ensure nutritionally appropriate contributions of carbohydrate to the energy content of the product. It was also considered very important to ensure that product did not taste sweet as this could lead to children developing a preference for sweetened products in early childhood.

Several of the eWG members that supported establishing maximum limits considered that this should be based on residual energy once protein and fat requirements had been established. Others stated that 14 mg/100 kcal was too high, and that a level closer to that naturally present in cows' milk would be optimal (~7.5 g/100 kcal). One eWG member proposed a level closer to 9 g/100 kcal for products for young children.

5.3.2 Modelling macronutrient requirements

In order to highlight the nutritional appropriateness of macronutrient levels, one eWG suggested that modelling be conducted to evaluate the outcomes of varying minimum and maximum levels. The Chairs have conducted some modelling on the approaches outlined by the eWG which are presented in Appendix 2. The models are based on follow-up formula for young children containing 65 kcal per 100 mL (the mid-point of the recommended energy density in Section 5.2) with varying levels of fat, protein and carbohydrates. A total of 25 products variations were evaluated and results presented per 100 kcal, per daily serve of 300 mL, and as a percentage of total energy in the product.

As recommended by some within the eWG, the Chairs first evaluated the range of proposed fat and protein levels on the residual contribution that carbohydrates would need to meet for an energy density of 65 kcal/100 mL (Tables 1-3, Appendix 2). Product 1 represented a product containing a moderately high fat content which would be considered nutritionally equivalent to full fat cows' milk (5.5 g/100 kcal) and a low protein level (1.5 g/100 kcal). At these levels, 11.5 g/100 kcal would be provided by carbohydrates, and the percentage energy contribution from carbohydrates would equate to 46%E, providing approximately 22.5 g of nutritionally available carbohydrates per 300 mL. A product formulated at a moderately high fat (5.5 g/100 kcal) and high protein content (5.5 g/100 kcal) would be nutritionally equivalent to unmodified full fat cows' milk (7.5 g carbohydrate/100 kcal) (product 5).

Products formulated at lower levels of fat and protein will need to provide relatively higher contributions of carbohydrate (Tables 2-3, Appendix 2). For example, a low fat and protein product would consist of carbohydrates providing 64% of total energy, and 31 g per 300 mL (product 11). Under this scenario, even if specifying a minimum lactose content of 4.5 g/100 kcal, 72% of total carbohydrates would need to be provided by other nutritionally available sources of carbohydrates (22 g per 300 mL).

Based on the scenarios presented in Appendix 2, the Chairs note that if the Committee are mainly concerned with limiting excessive added sugars, an approach which firstly specifies appropriate maximum total carbohydrates can ensure this outcome is attained. An approach which establishes carbohydrate levels based on residual energy from protein and fat can lead to carbohydrate levels in excess of those recommended when low fat and protein formulations are selected.

As demonstrated in Table 4, specification of a maximum limit of 12g/100 kcal of carbohydrate can ensure that protein and fat levels are within the levels specified by the eWG (fat: 3.5-6 g/100 kcal; protein 1.5-5.5 g/100 kcal) whilst ensuring that excessive levels of carbohydrates are not provided. Under this scenario, products can only be either low fat or low protein, but not both. Specification of a maximum of 12g/100 kcal of carbohydrate will ensure that at either low fat or low protein levels; the residual energy from carbohydrates can be contributed to from lactose (at levels equivalent to cows' milk) and less than 8 g/serve of other nutritionally available carbohydrates. Further details on the specific limitations on sources of carbohydrates are presented in Section 5.6.

5.3.3 Conclusion

It is considered important to define some parameters for macronutrients for the purpose of maintaining nutritional integrity of product. Of the macronutrients, there was consensus within the eWG for an approach which would ensure that follow-up formula products for young children do not provide excessive amounts of added sugars.

Taking into account the upper limit of free sugars established by the WHO of 10% of total energy[36], and assuming that these products can contribute between 20-30% of energy requirements per day, the Chairs have calculated that intakes of product must contain less than 8 g per day of added sugars.

The Chairs recommend that a maximum total carbohydrate level is specified to ensure nutritionally appropriate contributions from follow-up formula for young children. Based on modelling of macronutrient contributions, the Chairs recommend a maximum level of 12 g/100 kcal be considered by the Committee. At this level, specification of a minimum lactose content of 4.5 g/100 kcal will ensure that other types of carbohydrates will not exceed 20% of total carbohydrates. Further discussion of specific parameters for types of carbohydrates are discussed in detail in Section 5.6.

In light of the principle to establish a more flexible standard, and based on the views of the eWG and principles outlined in Section 4.2, the Chairs recommend that of the macronutrients only a maximum available carbohydrate content is defined within the Standard. Other options, detailed in the following sections can ensure that product contains high quality protein and fat and appropriate limits on the types of carbohydrates which can be added.

If the Committee wishes to develop a more prescriptive standard which mandates the protein and fat content of product, it is recommended that consideration is given to establishing minimum levels. As explained above, any option should ensure that full fat cows' milk and follow-up formula for older infants can be accommodated. These levels generally align well with the modelling of macronutrients to ensure nutritional suitability and the views of the eWG, with the exception of total fat. To ensure appropriate contributions of total fat for the 12-24 month age group, some eWG members suggested that a minimum level of 4.0 g/100 kcal could enable a lower fat formulation than follow-up formula for older infants. As expressed in Section 5.2 many eWG members were concerned with providing insufficient levels of dietary fat to young children aged 12-24 months and did not support a reduction in total fat levels to the levels present in reduced fat cows' milk (3.5 g/100 kcal).

If the Committee wishes to develop a more prescriptive standard which mandates the protein and fat content of product, the Chairs suggest the following additional option for further discussion by the Committee. Consideration must be given to whether this would enable sufficient flexibility and nutritional integrity at a global level where protein and fat intakes can vary significantly.

Recommendation 10:

That CCNFSDU agree to include a maximum limit for total carbohydrates as follows:

[Available carbohydrates]

The level of available carbohydrates should not exceed [12 g per 100 kcal (2.9 mg per 100 kJ)]

Additional options for further discussion:

[The level of protein shall not be less than 1.8 g/100 kcal]

[The level of total fats shall not be less than 4.0 g/100 kcal]

5.4 Protein Quality

Protein utilisation is a measure of protein digestibility (the amount of protein consumed and made available after digestion and absorption) and how well the absorbed amino acid profile matches that of the protein requirements[1]. The WHO and/or FAO have coordinated two expert consultations in the past ten years, one on protein and amino acid requirements in human nutrition[1] and a second on dietary protein quality evaluation[37].

Of those that responded to questions on protein quality, there was almost full support to specify requirements for protein quality in follow-up formula for young children (12 CM; 7 CO). As noted by many eWG members, cows' milk is a source of high quality protein in the diets of young children, containing a highly digestible source of amino acids. The following section reviews the recommendations of the FAO expert consultations and proposed approaches recommended by eWG members.

Evaluation of protein quality

In 1989 the joint FAO/WHO expert consultation on protein quality evaluation recommended the use of the Protein Digestibility Corrected Amino Acid Score (PDCAAS) to determine protein quality[38]. In calculating the PDCAAS the limiting amino acid score is multiplied by protein digestibility with the intention of assessing how well dietary protein can match the requirements for amino acids.

Since its development, the PDCAAS method has been in use for over 20 years and the age-specific amino acid scores used to inform the Infant Formula Standard (Annex 1) [37]. In 2007, the FAO/WHO/UNU convened an expert working group to discuss protein and amino acid requirements in human nutrition. During this consultation issues with the PDCAAS method were highlighted[1]. However, the PDCAAS method continued to be endorsed[1].

In 2011, an FAO expert consultation group met with the objectives of reviewing the effectiveness and use of PDCAAS and to recommend protein quality assessment and applications[37]. As a consequence of the review the FAO have now recommended use of the Digestible Indispensable Amino Acid Score (DIAAS) method. Under both the PDCAAS and DIAAS methods, dietary amino acids are treated as individual nutrients with amino acid scoring patterns developed for specific age groups. The main differences between DIAAS and PDCAAS methods are that the PDCAAS method uses faecal estimates of protein digestibility and truncates its score at 1; whereas the DIAAS method utilises true ileal amino acid digestibility and does not truncate scores[37].

The recommendations of the 2011 FAO expert group were that FAO convene a working group, as a matter of urgency to agree upon experimental protocol which would enable data on the true ileal amino acid digestibility of human foods[37]. However, until such time as this is achieved it is recommended that the DIAAS method be used to assess protein quality using values for faecal crude protein digestibility and applied to dietary amino acid contents[37]. The eWG were not aware of any further work that had yet been completed in this area.

A review of regulatory approaches to protein quality in national and international standards highlights the variable approaches that are taken internationally and within Codex standards[39]. Protein quality measures range from amino acid profiles and digestibility corrected scores to utilisation of reference proteins. The selection of method depends to some extent on the product type. For formula products for use by infants (infant formula and follow-up formula for older infants) amino acid profiles based on the profile of breastmilk are used. For cereal based foods for infants and young children, casein has been used as the reference

protein in both the Standard for Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 074-1981) and EU directive. The following statement is used in both standards:

- The chemical index of the added protein shall be equal to at least 80% of that of the reference protein casein or the Protein Efficiency Ratio (PER) of the protein in the mixture shall be equal to at least 70% of than that of the reference protein casein. In all cases, the addition of amino acids is permitted solely for the purpose of improving the nutritional value of the protein mixture, and only in the proportions necessary for that purpose. Only natural forms of L-amino acids should be used (CODEX STAN 074-1981).

The current Codex Standard for Follow-up Formula states:

- The quality[1] of the protein shall not be less than 85% of that of casein.

  [1]protein quality shall be determined provisionally using the PER method as laid down in the section dealing with methods of analysis

Proposed approaches

Although several eWG members highlighted the importance of specifying protein quality parameters, very few specified approaches that could be included in the standard for follow-up formula for young children. The following approaches were suggested:

- Four eWG members stated that cows' milk protein should be considered the relevant reference protein, with one stating that the current requirement in the Codex Follow-up Formula Standard is sufficient.
- Two eWG members supported alignment with the provisions proposed for follow-up formula for older infants.
- Two eWG members referred to inclusion of the PDCAAS method, and two eWG members supported the DIAAS method, however no further clarification was provided on how these methods should be applied to the standard.

Although several eWG members referred to the DIAAS method in their response, it was highlighted by two eWG members that there were issues in its use by regulators at this point in time due to the limitations outlined by the FAO expert group which prohibited its full use. These include the limited data on true ileal amino acid digestibility, lack of international harmonized methods, and limitations of the regression model. It was further stated that neither PDCAAS nor DIAAS should be used as the sole approach to evaluate quality.

As stated by several eWG members it was considered that cows' milk protein should be considered the relevant reference protein for follow-up formula products for young children. This approach aligns with one of the key principles for establishing mandatory requirements: to provide the key nutrients in cows' milk.

Conclusions

Although the majority of the eWG consider it critical to ensure that the protein quality of follow-up formula for young children is mandated, very few provided approaches on how this might be addressed. As follow-up formula for young children is part of an increasingly diversified diet it is not deemed necessary that all amino acids requirements are met by this formula. As such, it is not recommended that the amino acid requirements for young children outlined by FAO[37],[38] be specified.

In order to ensure that high quality protein that is nutritionally equivalent to cows' milk is provided from follow-up formula for young children, it is proposed that a minimum percentage of casein is included as provided in the current Codex Standard for Follow-up Formula. Due to the limitations outlined in the FAO report, and by the eWG it is not recommended that the current DIAAS method is specified as the appropriate method to measure protein quality.

Recommendation 11:

That CCNFSDU agree to include minimum protein quality requirements as follows:

[Protein]

[The quality of protein shall not be less than 85% of that of casein.]

5.5 Quality of dietary fat

The eWG were asked questions regarding specific requirements for essential fatty acids, lauric, myristic and erucic acid, phospholipids, and trans fat and the ability to use commercially hydrogenated oils. The Codex Infant Formula Standard and proposed standard for follow-up formula for older infants both contain specific requirements for these aspects of dietary fat.

5.5.1 Essential fatty acids

The eWG assessed the need for specific mandatory requirements for essential fatty acids against whether they were considered inadequate on a global scale. Views within the eWG differed as to whether intakes of linoleic and/or α-linolenic acid were considered globally inadequate and a necessary addition to follow-up formula for young children.

Assessment of dietary intakes of essential fatty acids

The WHO/FAO convened an expert working group in 2009 to review requirements for fat and fatty acids[19]. For the 12 to 24 month age group there were limited data to establish adequate intake levels and requirements established for the 6-12 month age group were applied. There is convincing evidence that the adequate intake level (AI) for the essential fatty acids for optimal growth and development of this 6-24 month group are 3–4.5% of energy for linoleic acid and 0.4-0.6 % of energy for α-linolenic acid[19]. This equates to a daily intake of 329 - 494 mg of linoleic and 44 - 66 mg of α-linolenic acid[19] based on the energy requirements of young children aged 12-36 months (CX/NFSDU 14/36/7).

There is probable evidence that the AI for DHA is 10-12 mg/kg for children aged 6-24 months. The expert working group concluded that based on the evidence there was no rationale for recommending a specific ratio between linoleic and α-linolenic acid, or between omega-3 and omega-6 polyunsaturated fatty acids[19].

Standard practice when assessing the adequacy of intakes is that when observed mean intakes are below AIs no conclusions can be drawn with respect to the risk of inadequacy without additional information on the nutrient status of the population, whereas groups with mean intakes at or above the AI can be assumed to have a low risk of inadequate intakes[40].

During the 2014 eWG it was noted that there was limited data available on the intakes of the essential fatty acids in young children and there is difficulty in the ability to quantify the risk of inadequate intakes in this age group. In Europe, EFSA concluded that dietary intakes of linoleic acid did not give rise to concern over the risk of inadequate intakes based on dietary intake and status data[16]. Whereas for the intake in Europe of omega-3 polyunsaturated fatty acids: α-linolenic acid and DHA, these were considered low and it was recommended that particular attention should be given to providing an appropriate supply of these essential fatty acids in the diets of young children. Mean dietary intakes of α-linolenic acid were below or at the AI of 0.5% of energy and ranged from 0.32-0.5% in the available studies. EFSA concluded that in the absence of a clear relationship between intakes or biomarkers of omega-3 status and clinical outcomes, the risk of inadequate intakes could not be quantified[16].

Dietary intake data from low income countries have indicated that mean intakes of α-linolenic acid and DHA were low, whereas three out of five countries with data available, showed that linoleic acid intakes were adequate (above the AI)[41]. Data from low income countries indicate that there is limited availability of omega-3 rich foods in the food supply[23]. Similar to the European data, it is not possible to quantify the risk of inadequate intakes of omega-3 fatty acids at a global level based on dietary intake and status data.

Almost all eWG members agreed that dietary intakes of α-linolenic acid were considered to be inadequate on a global scale (7CM; 1CMO; 3CO). Fewer eWG members considered linoleic acid to be limited in the diets of young children, with many citing the conclusions of EFSA that this was not considered to be a nutrient of concern in Europe[16].

Contribution of essential fatty acids from cows' milk

Cows' milk is not considered a good source of the fatty acids: linoleic, α-linolenic acid, or DHA. The average amount of linoleic and α-linolenic acid present in full fat cows' milk is between 51-106 mg/100 kcal and 16-26 mg/100 kcal, respectively (Appendix 1). Slightly lower average amounts have been reported to be present in reduced fat cows' milk. Two eWG members did not consider it necessary to mandate the contribution of either linoleic or α-linolenic acid in follow-up formula for young children as they considered that the levels naturally present in cows' milk were sufficient to contribute to the diversified complementary diet of young children.

Proposed approaches

The eWG considered several approaches to mandate the requirements for the essential fatty acids linoleic and α-linolenic acid:

- Establish minimum requirements for follow-up formula for young children for linoleic and α-linolenic acid;
- Apply minimum requirements for α-linolenic acid only due to limited evidence of global inadequacy of linoleic acid; or
- Apply no requirements for either fatty acid due to limited evidence of global inadequacy of either essential fatty acid.

In general, eWG members suggested setting minimum and maximum levels for the essential fatty acids in alignment with the proposed standard for follow-up formula standard for older infants. Some eWG members also proposed alignment with the *Guidelines on Formulated Complementary Foods for Older Infants and Young Children* (CAC/GL 8-1991) which recommends that a minimum content of linoleic acid of 333 mg/100 kcal or 1.6 g per 100 g of dry product. This compares to the minimum of 300 mg/100 kcal specified in the Codex Standard for Infant Formula and in the proposed standard for follow-up formula for older infants. As specified above, the AI for children aged 6-24 months is approximately 330 mg/day. Consumption of 100 mL of formula containing 30mg/100 kcal would almost fully meet the AI. Assuming an average daily intake of 300 mL of product, daily requirements of linoleic acid could be met with formula containing 183 mg/100 kcal (with an energy density of 60 kcal/100 mL).

The minimum levels of α-linolenic acid proposed by the eWG were either 50 mg/100 kcal to align with the requirements of Codex Standard for Infant Formula and proposed standard for follow-up formula for older infants; or based on 0.4% of the total energy of the product, 44 mg/100 kcal. The Chairs note that the WHO/FAO AI level is based on 0.4-0.6% of total energy intakes for young children aged 6-24 months, this equates to a daily intake of 44 mg per day[19], based on WHO estimates for energy intakes for young children 12-36 months (955 kcal/day; 4 MJ/day) (CX/NFSDU 14/36/7). Assuming an average daily intake of 300 mL of product, daily requirements of α-linolenic acid could be met with 24 mg/100 kcal (with an energy density of 60 kcal/100 mL).

No eWG members proposed establishing a maximum or GUL for α- linolenic acid.

Conclusions

Based on the views and the evidence provided by the eWG, in addition to consideration of the principle to mandate the requirements of those nutrients that are limited in the diets of young children globally, the Chairs recommend that only the establishment of a minimum level for α-linolenic acid is warranted for follow-up formula for young children. It is recommended that the level aligns with that proposed for follow-up formula for older infants, 50 mg per 100 kcal (12 mg/100 kJ). At this minimum level the adequate intake would be met at consumption of approximately 150 mL per day.

Regarding linoleic acid, the Chairs do not propose a mandatory requirement for linoleic acid. If there is strong support within the Committee to establish requirements for the addition of linoleic acid, the eWG preference was to align with the requirements for follow-up formula for older infants (minimum: 300 mg/100 kcal (72 mg/100 kJ); GUL 1400 mg/100 kcal (335 mg/100 kJ)).

Recommendation 12:

That CCNFSDU agree to include a mandatory requirement for the addition of α- linolenic acid as follows:

The level of α-linolenic acid (in the form of glycerides) should not be less than [50 mg per 100 kcal (12 mg per 100 kJ)]

5.5.2 Lauric, myristic and erucic acids

There was limited support in the eWG for the need to specify maximum percentages for lauric, myristic and erucic acid. Several eWG members stated that in the interests of a less prescriptive standard it was unnecessary to include these requirements. The young child's diet is more diversified than that of older infants, and the requirements specified in the Codex Standard for Infant Formula were based on the profile of breast milk. It was also found that application of the requirements in the Infant Formula Standard would unduly restrict the percentage of milk fat which could be used in these products. Only one Codex Member provided justification to require maximum limits based on the effects of these saturated fatty acids on serum cholesterol in adults.

Therefore, the Chairs do not recommend inclusion of any specific maximum limits for these fatty acids.

5.5.3 Phospholipids

There was limited support for the mandatory addition of phospholipids to follow-up formula for young children in the eWG. It was stated by some eWG members that phospholipids are naturally present in cows' milk and lecithin - ingredients typically used in these products. The mandatory requirements for phospholipids do not fulfil any of the identified criteria specified in Section 4.

Based on the views of the eWG, the Chairs do not recommend inclusion of any specific requirements for phospholipids.

5.5.4 Trans fats and commercially hydrogenated fats and oils

There was consensus within the eWG that follow-up formula products for young children should not contain industrially produced sources of trans fatty acids. Different approaches were suggested in efforts to manage levels of trans fatty acids, particularly for those naturally present in cows' milk.

Within the *Guideline on Nutrition Labelling* (CAC/GL 2-1985) trans fatty acids are defined as:

> ***Trans fatty acids***: for the purpose of the *Guidelines on Nutrition Labelling* and other related Codex Standards and Guidelines, trans fatty acids are defined as all the geometrical isomers of monounsaturated and polyunsaturated fatty acids having non-conjugated, interrupted by at least one methylene group, carbon-carbon double bonds in the trans configuration.

As per the 2009 WHO Scientific Update on trans fatty acids, it is recommended that industrially produced trans fatty acids should be virtually eliminated from the food supply. Trans fatty acids have been found to be associated with adverse effects on blood lipoprotein profiles and coronary heart disease, and have no known nutritional benefit[42].

The WHO Nutrition Guidance Expert Advisory Group are in the process of finalising the recommendations on saturated fatty acids and trans fatty acids. One systematic review on the topic of trans fatty acids is published and confirms previous WHO recommendations, that total trans fatty acid intakes are associated with all-cause mortality (RR 1.34; 95%CI: 1.16-1.556) and coronary heart disease mortality (RR 1.28; 95%CI: 1.09-1.50). In the systematic review it was also found that industrial, but not ruminant, trans fats were associated coronary heart disease mortality (RR 1.42 vs 0.93)[43]. A second systematic review has been conducted by the WHO Expert Advisory group which has found that replacement of trans fatty acid from any source with cis-polyunsaturated fatty acids consistently lowers total cholesterol[44].

Sources of trans fat in formula products

Sources of trans-fatty acids in follow-up formula for young children could either be from those naturally present in cows' milk or derived from the use of industrially produced hydrogenated oils. While there was complete support that commercially hydrogenated oils should not be used in these products, many eWG

members highlighted the need for the Standard to allow for the contribution of trans fat intrinsically found in cows' milk.

Levels of trans fatty acids in full fat and reduced cows' milk are variable. In Appendix 1 the trans fatty acids content of cows' milk from four food composition tables are presented. Average levels of trans fatty acids in full fat cows' milk and reduced fat cows' milk were 3.8% total fat (range 3.5-4.3%) and 2.2% (range 0.1-6.5%), respectively. More recent analysis of skimmed milk available for retail sale in the UK found total trans fat levels ranging from 3.8% to 5.5% of total fatty acids, with seasonal variation due to farming practices[45]. In Sweden, average trans fat levels in milk were 2.7% but ranged between 0.6 and 3.9% total fatty acids[46]. In a study of fatty acid levels in cows' milk from 14 European countries, it was found that the proportion of trans fatty acids ranged from 3.2 to 5.2% total fatty acids[47].

Proposed approaches

Some eWG members recommended the inclusion of a limit for trans fat of either 2% of total fatty acids based on the recommendations of an international expert group, or 3% as per the current permissions within the Codex Infant Formula Standard. The expert group recommended a limit for trans fatty acids only, but no equivalent statement to prohibit the use of commercially produced hydrogenated oils, and no explanation is given as to whether the 2% limit would permit the inclusion of trans fat from industrially produced hydrogenated oils[35].

The Infant Formula Standard states *"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 formula."*

Several members of the eWG noted that limits on trans fatty acids should be limited to industrial sources only and that any maximum level that was derived should enable cows' milk to be used as an ingredient. It was noted that if a maximum limit of 3% of trans fat was included in the Standard, this would restrict the percentage of milk fat that could be used in products for young children to less than 50% of the total fat content. It was noted that this would prohibit the use of products primarily based on cows' milk which could be considered out of step with dietary guidelines for this age group.

Conclusion

Based on the views of the eWG, it is recommended that the Standard contains a prohibition on the use of commercially hydrogenated oils. This approach will effectively eliminate sources of industrially produced trans fatty acids from these products.

Follow-up formula for young children is largely used as a substitute for cows' milk and the Standard is being developed with increased flexibility to enable products to be predominantly based on cows' milk. As such, the eWG strongly supported limits on trans fat which but would accommodate the trans fat intrinsically found in cows' milk. Due to the variation of trans fat levels in cows' milk which can vary by season and farm practice it is difficult to determine an absolute maximum for total trans fatty acids. Consequently no maximum limit has been recommended.

Recommendation 13:

That CCNFSDU agree to limit commercially hydrogenated fats and oils with the following statement:

[Commercially hydrogenated oils and fats shall not be used in [name of product] for young children].

5.6 Types of carbohydrates

The eWG strongly supported establishing requirements which limit the addition of sugars to follow-up formula for young children. These views were based on the evidence of currently formulated products containing sugars in amounts generally not recommended for young children[31], and the revised WHO Guidelines which recommend reductions in free sugar intakes[36].

Limits on total available carbohydrates are discussed in Section 5.3, with the accompanying recommendation that product does not contain more than 12 g/100 kcal of available carbohydrates.

Discussions on the specific requirements for types of carbohydrates to be permitted or limited in follow-up formula for young children are discussed below.

Codex requirements

The current Codex Standard for Follow-up Formula does not contain minimum, maximum or GUL values for total or any specific carbohydrates. The only requirement is that product shall contain nutritionally available carbohydrates suitable for feeding older infants and young children (CODEX STAN 156-1987).

The Standard for Infant Formula (CODEX STAN 72-1981) and revised requirements for follow-up formula for older infants, as agreed at CCNFSDU37, require that products contain 9-14 g/100 kcal available carbohydrate. These carbohydrate requirements are based on the residual energy in formula that contain the permitted minimum and maximum amounts of protein and fat. The Codex Standard for Infant Formula (CODEX STAN 72-1981) and revised requirements for follow-up formula for older infants, as agreed at CCNFSDU37, also specify the preferred types of carbohydrates that should be used in these products. In the proposed standard for follow-up formula for older infants the Committee agreed to the following requirements:

> *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. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source, and provided the sum of these does not exceed 20% of available carbohydrate.*

Within the *Guidelines on Nutrition Labelling* it is required that where nutrient declaration is applied, the available carbohydrates (i.e. dietary carbohydrate, excluding dietary fibre) and total sugars are declared (3.2.1.2; CAC/GL 2-1985). The following definitions are relevant to calculating the available carbohydrate content of food:

> 2.7 *Sugars* means all mono-saccharides and di-saccharides present in food.
>
> 2.8 *Dietary fibre* means carbohydrate polymers with ten or more monomeric units, which are not hydrolysed by the endogenous enzymes in the small intestine of humans and belong to the following categories:
>
> - edible carbohydrate polymers naturally occurring in the food as consumed,
> - carbohydrate polymers, which have been obtained from food raw material by physical, enzymatic or chemical means and which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities,
> - synthetic carbohydrate polymers which have been shown to have a physiological effect of benefit to health as demonstrated by generally accepted scientific evidence to competent authorities.

It was also highlighted that the Standard for Sugars (CODEX STAN 212-1999) refers to various ingredient forms for sugar, including lactose, fructose, dextrose, glucose syrups.

Dietary Guidelines

In 2015, WHO strongly recommended that both adults and children reduce the intake of free sugars to less than 10% of energy and conditionally recommended a further reduction to less than 5% of energy[36]. Free sugars are defined as including "monosaccharides and disaccharides added to foods and beverages by the manufacturer, cook or consumer, and sugars naturally present in honey, syrups, fruit juices and fruit juice concentrates". Free sugars do not include intrinsic sugars and sugars naturally present in milk such as lactose because no reported evidence of adverse effects has been found.

As reported by the WHO and EFSA, there is increasing concern that intake of added/free sugars, particularly in the form of sugar-sweetened beverages increase overall energy intake and may reduce the intake of foods containing more nutritionally adequate calories[36,48,48,48]. The WHO recommendations were based on the effect of a reduction in free sugars on body weight and dental caries in both adults and

children[36]. As noted in the report of the European Commission on young child formula, the role of sugars in obesity development and its impact on flavour development affecting taste preferences should be kept in mind[31].

Lactose

Lactose was considered the preferred type of carbohydrate for use in follow-up formula for young children by the eWG. As stated above, the proposed Codex Standard for follow-up formula for older infants states that lactose and glucose polymers should be the preferred type of carbohydrate used in cows' milk protein and hydrolysed protein.

The revised EU regulation for follow-up formula for older infants (known as follow-on formula in Europe) specifies a minimum level for lactose of 4.5 g/100 kcal. This requirement is not applicable to follow-up formula in which soy protein isolates represent more than 50% of total protein content or those formulas with a "lactose free" claim [49].

The international expert working group coordinated by the Early Nutrition Academy also specify that the main source of carbohydrates should be lactose. Further specification is provided which states that lactose should provide not less than 50% of total carbohydrates, equivalent to 4.5 g/100 kcal. It was further highlighted that for products based on milk proteins there is no need to add sugars other than lactose for nutritional reasons[35]. No recommendation is provided for suitable sources of carbohydrate for product based on protein from plant sources[35].

Cows' milk naturally contains lactose. As per the WHO Guidelines, lactose found intrinsically in milk has no reported adverse effects and no limits have been established. The carbohydrate and lactose content of full fat cows' milk is approximately 7.5 g/100 kcal (range: 7.3-7.8 g/100 kcal) and in reduced fat milk is approximately 10.1 g/100 kcal (range: 9.6-10.5) (Appendix 1).

Sugars other than lactose

The proposed Codex Standard for follow-up formula for older infants states that sucrose and/or fructose should not be added, unless needed as a carbohydrate source, and provided that the sum of these does not exceed 20% of available carbohydrates.

The revised EU regulation for follow-up formula for older infants contains specifications for the addition of sucrose, fructose and honey, glucose and glucose syrup. A maximum limit has been set for the addition of sucrose, fructose and honey of 20% of the total carbohydrate content, either separately or combined[49]. If honey is used it is a requirement that this shall be treated to destroy spores of *Clostridium botulinum*[49]*.* Regarding glucose addition, this can only be added to follow-up formula manufactured from protein hydrolysates, and if added cannot exceed 2 g/100 kcal. Glucose syrup is permitted to be added if its dextrose equivalents do not exceed 32, and the addition does not exceed 0.84 g/100 kcal[49].

The international expert working group coordinated by the Early Nutrition Academy recommended the following to guide addition of sugars other than lactose: *if sugar is deemed necessary to achieve palatability, the content of sugars other than lactose should not exceed 10% of total carbohydrates or approximately 5% of total energy content*[35]*.* This level was considered similar to the WHO guideline on added sugars intake for adults and children[36].

Other types of carbohydrates (non-sugars)

Regarding the addition of other types of carbohydrates the proposed standard for follow-up formula for older infants contains a non-exhaustive list of other types of carbohydrates which can be added, stating that: *only precooked and/or gelatinised starches gluten-free by nature may be added.*

The international expert working group coordinated by the Early Nutrition Academy stated that other carbohydrates may be added provided maximum total carbohydrates were not exceeded. It was stated that oligosaccharides, glucose polymers, maltodextrin, and pre-cooked or gelatinized starches could be added to provide energy. In addition to non-digestible carbohydrates and fibres that are proven to be safe and suitable for age[35].

As noted by some within the eWG, limits applied only to total sugars will not limit the addition of other glycaemic carbohydrates such as malto-oligosaccharides (i.e. maltodextrin), polysaccharides (e.g glucose polymers and starches). These carbohydrates are widely used in formulae and are not regarded as sugars within Codex or by some regulatory authorities, yet they can have similar sweetening effects and metabolic properties. Although many eWG members were concerned with the addition of excessive maltodextrins, it was also stated that these should continue to be permitted as a source of carbohydrate. Of those eWG members that opposed establishing limits for total carbohydrates, it was still considered important to limit the addition of non-sugar, nutritionally available carbohydrates. These views have informed the establishment of a maximum limit of total nutritionally available carbohydrates of 12 g/100 kcal.

It is noted that non-digestible carbohydrates and dietary fibre are not included in the definition of available carbohydrate, and that their addition should be captured under the Optional Ingredients section. This will also ensure that the principles related to safety and suitability apply.

Proposed approaches

There was widespread support to establish specific limits on the addition of added sugars within the eWG. In general the eWG favoured two approaches as the starting point for determining requirements:

- the proposed standard for follow-up formula for older infants; or
- the recommendations of the international expert working group

The eWG widely supported an approach whereby lactose is the preferred source of carbohydrate used in follow-up formula for young children. It is noted that this approach is appropriate only for those formulas which are based on milk protein, alternative sources of carbohydrate are required for products containing protein from plant-based sources.

With regards to the addition of sugars other than lactose, the eWG strongly supported limits on the addition of these, particularly regarding the addition of sucrose and fructose which are the sweeter sugars. Many eWG members proposed text which applied more restrictions to the proposed standard for follow-up formula for young infants based on the recommendations of the international expert working group. These proposals were generally requesting that sugars (or sucrose and fructose) should provide less than 10% of total carbohydrates.

In general it was not considered necessary to include a list of permitted types of carbohydrates within the standard as this was inconsistent with the principle of flexibility.

Conclusions

Taking into account the views of the eWG, it is proposed that lactose is recommended as the preferred type of carbohydrate used in follow-up formula for young children with further restrictions on the ability to add sugars.

No minimum level is recommended at this time in accordance with a less prescriptive approach. If the Committee considers it necessary to take a more prescriptive approach it is recommended that a minimum of either 4.5 g/100 kcal, or more than 50% of total carbohydrates for lactose is prescribed.

The majority of the eWG were either open to, or suggested a more prescriptive approach to limit the addition of sugars, other than lactose, to follow-up formula for young children. Based on the proposals of some eWG members, the Chairs recommend that it continues to be stated that sucrose and/or fructose should not be added unless needed, in addition to restricting the total amount of sugars other than lactose to less than 10% of total carbohydrates. This provides further clarity on the acceptable amount of added sugars to product, and also that the sweetest sugars (sucrose and fructose) should not be added.

The Chairs note that the addition of a maximum limit of 12 g/100 kcal of available carbohydrates as recommended in Section 5.3 will in effect limit the amount of other types of carbohydrates such as maltodextrins. If the Committee decides to take a more prescriptive approach which prescribes the minimum lactose content of milk based products, a 12g/100 kcal maximum will ensure that less than 20% of the remaining carbohydrates are provided from other sources. As such no further restrictions are considered necessary for non-sugar sources of carbohydrates.

Recommendation 14:

That CCNFSDU agree to the following text on types of carbohydrates suitable for [name of product] for young children:

[Lactose should be the preferred carbohydrates in [name of product] based on milk protein. Only precooked and/or gelatinised starches gluten-free by nature may be added. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source. Sugars, other than lactose, should not exceed 10% of available carbohydrate].

Additional options for further discussion:

Lactose should be the preferred carbohydrates in formula based on milk protein [and should provide not less than 50% of total carbohydrates].

5.7 Iron

There was consensus amongst the eWG that iron is considered a nutrient which is inadequate in the diets of young children globally, thus fulfilling one of the principles required to establish mandatory requirements.

Dietary iron requirements and intakes

Iron requirements are very high amongst young children due to rapid growth and the exhaustion of endogenous body iron stores from six to 24 months of age. In 2014, the eWG reviewed iron requirements for young children developed by several recognised authoritative scientific bodies (CX/NFSDU 14/36/7). The results of the review were that iron intakes of between 7-9 mg/day were adequate for the majority of young children aged 12-36 months assuming moderate levels of absorption. This level is aligned with the recently revised individual nutrient level (INL98) derived by EFSA of 7 mg/day. In Europe it was estimated that approximately 10% of iron is absorbed from the whole diet in iron-sufficient children.

In the 2014 review of dietary intakes and status, a common theme was that globally iron was consistently found to be inadequate in sub-groups of populations (CX/NFSDU 14/36/7). Globally the prevalence of iron deficiency anaemia (haemoglobin <100 g/L) is estimated to be 18.1% in children under five years, ranging from 12% in Europe to 20% in the African region[50]. WHO has highlighted the need to improve iron intake in young children and iron rich complementary foods are recommended[51]. These findings are consistent with the findings of the EFSA review of dietary intakes in Europe[16], and review of global intakes by the international expert working group coordinated by ENA[35].

Iron fortified formula and cows' milk

Cows' milk does not contain appreciable amounts of iron and it is widely recognised that high consumption of cows' milk is a risk factor for iron deficiency anaemia[52]. During 2015, the eWG determined there is evidence that iron fortified formulas in older infancy reduce the risk of low iron status and iron deficiency anaemia, particularly when compared to cows' milk[53,54,55,56]. Consequently, higher levels of iron were agreed to by the Committee for follow-up formula for older infants as compared with infant formula.

Further to this, several studies have been conducted on the use of fortified milks and follow-up formula compared to whole cows' milk in the diets of young children. Milk and milk based formulas fortified with iron have been associated with higher body iron stores in children globally[55-61], and reducing the risk of iron deficiency anaemia in those children at higher risk of iron deficiency[56,57,59,60]. Of these studies, formula and milk were fortified with iron at levels ranging from 1-3.6 mg/100 kcal[55-61]. In addition to iron, all products used in these interventions were fortified with vitamin C at levels ranging from 6.6 - 30 mg/100 kcal[55-61].

Proposed approaches

The eWG explored the necessary requirements for the mandatory addition of iron to follow-up formula for young children. There was widespread support for ensuring that factors influencing the absorption of iron are also taken into account, with the majority of the eWG recommending higher requirements for products based on soy protein isolate, and ensuring that vitamin C is added to all products.

Minimum

All eWG member supported the adoption of the minimum requirement level specified in the proposed Standard for follow-up formula for older infants (1 mg/100 kcal; 0.25 mg/100 kJ). As indicated above, fortification at this level has been proven to improve the iron status of young children globally. As such, it is recommended that the Committee adopt this minimum mandatory requirement.

Maximum/Guiding Upper Level

There were diverging views as to whether to align with the proposed Standard for follow-up formula for older infants (maximum of 2 mg/100 kcal) or to establish a GUL of 3 mg/100 kcal in line with expert recommendations[35]. However, of those that responded, the majority favoured an approach which allowed for a wider range of iron fortification (3 mg/100 kcal) to allow for slightly higher levels of fortification in those settings where low iron stores are more prevalent.

Of those in favour of establishing a maximum level, concern was expressed over the potential that excessive iron intakes on the absorption of zinc and copper. It was deemed that there was sufficient evidence and need to establish a maximum value base on the risk of exposure to excessive iron intakes. A range of iron fortified complementary foods and public health programs exist in countries, which many stated was further rationale to identify a safe and suitable maximum level.

In the randomised interventions and effectiveness trials of iron fortified formulae and milk, the majority of studies provided young children with product containing 1.8-2.3 mg of iron per 100 kcal[55-59,61]. These trials all demonstrated increased body iron stores and serum ferritin levels and were conducted in a variety of countries, including India[57], Mexico[59], New Zealand[61] and the United Kingdom[55,56].

At intakes of 300 mL per day, formula containing 2 or 3 mg/100 kcal would provide 3.9 and 5.85 g/100 kcal, respectively. Assuming moderate absorption of iron, intakes at these levels would provide just over half of the INL_{98} at 2 mg/100 kcal; and approximately 80% at 3 mg/100 kcal. At intakes of 500 mL per day, 6.5 and 9.75 mg/100 kcal would provide sufficient iron to meet the requirements of almost all young children. All maximum levels ensure that intakes are substantially below the upper tolerable level of intake established by the Institute of Medicine (40 mg/day for children aged 1-3 years)[62].

Soy Protein Isolate

Of those eWG members that responded, the majority considered it necessary that product based on soy protein isolate require higher levels of iron to accommodate the lower absorption of iron in these products. A minimum of 1.5 mg/100 kcal, in alignment with the proposed standard for follow-up formula for older infants was recommended by all eWG members.

For follow-up formula for older infants, a range of 1.5-2.5 mg/100 kcal is recommended for product based on soy protein isolate. It is assumed that an extra 0.5 mg/100 kcal is sufficient to compensate for lower levels of absorption. Some eWG members supported applying the same process of adding an extra 0.5 mg/100 kcal to the maximum level, whereas others preferred to align fully with the proposed standard for follow-up formula for older infants. One eWG member suggested that if a maximum of 3 mg/100 kcal is adopted by the Committee for milk based formula then this would be sufficient to cover all types of formula products. This approach has also been recommended in establishing a GUL for zinc for follow-up formula for older infants.

Vitamin C

There was widespread support in the eWG to establish minimum vitamin C levels for follow-up formula for older infants based on its role in enhancing the absorption of iron. Of those that did not support the mandatory addition of vitamin C to product reasons included the lack of evidence that this was a nutrient of global concern.

Three levels were proposed by the eWG for consideration: alignment with the standard for follow-up formula for older infants (4 or 10 mg/100 kcal, yet to be finalised); 4.5 mg/100 kcal (international expert group[35]); or to retain the current requirement of 8 mg/100 kcal. There is limited evidence to support the selection of any of the values, as all would be able to accommodate the level of vitamin C used in the fortified milk trials. As suggested by one Codex Member Organisation, it is proposed that a pragmatic solution is sought and that the minimum and GUL for vitamin C be aligned with the proposed standard for follow-up formula for older

infants. As detailed in Section 3.4, the minimum value is yet to be agreed to by the Committee, but a minimum of 10 mg/100 kcal is recommended in this paper.

Conclusion

The mandatory addition of iron was supported by all eWG members due to evidence of inadequate intakes of iron in young children globally. Based on the views of the eWG it is strongly recommended that the Committee adopt a mandatory minimum iron requirement of 1 mg/100 kcal.

It is further recommended that a maximum limit of 3 mg/100 kcal is established to ensure slightly wider fortification permissions for this age group, particularly in settings were iron needs are greater. Establishing a maximum limit is recommended over the use of a GUL to ensure that excessive iron is not provided due to the potential adverse effects of high iron intakes on the absorption of other essential nutrients.

It was considered equally important to take into account factors which influence the absorption of iron when mandating its addition. As such the majority of eWG members supported establishing a higher minimum requirement for product based on soy protein isolate of 1.5 mg/100 kcal. Provided the maximum limit of 3.0 mg/100 kcal is agreed to by the Committee, this should be sufficient to accommodate all types of product formulated within the standard.

The mandatory addition of vitamin C was also considered important to aid absorption of iron. The Chairs propose that the levels agreed to by the Committee for follow-up formula for older infants are adopted for follow-up formula for young children.

Recommendation 15:

That CCNFSDU agree to the following recommendation on iron and vitamin C levels in [name of product] for young children:

Iron

Unit	Minimum	Maximum	GUL
mg/100 kcal	[1.0]	[3.0]	-
mg/100 kJ	[0.25]	[0.7]	-

[For [name of product] based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36 mg/100 kJ) applies.]

Vitamin C

Unit	Minimum	Maximum	GUL
mg/100 kcal	[10]	-	[70]
mg/100 kJ	[1.0]	-	[17]

5.8 Key nutrients in cows' milk: calcium, riboflavin and vitamin B12

One of the key principles to determine the nutrients which should be mandated in the standard for follow-up formula for young children, is that cows' milk provides a significant contribution to the dietary requirements of young children. As identified in the 2014 eWG, cows' milk is a major contributor to calcium, riboflavin, and vitamin B12 requirements of young children – providing over 70% of a young children's requirement in a 300 mL serve. It is considered important that products which may substitute cows' milk in the diets of young children provide sufficient quantities of these key nutrients. Consequently there was widespread support from the eWG to mandate minimum requirements for calcium, riboflavin, and vitamin B12.

There was concern within the eWG that follow-up formula for young children should provide equivalent levels of the key nutrients in cows' milk to ensure that they are not an inferior product. Others in the eWG recommended an approach which ensures that sufficient quantities of these nutrients are provided per serve and a range which accommodates the micronutrient level found in cows' milk. One Codex Member Organisation recommended that the minimum level should align with the permissions in the proposed standard for follow-up formula for older infants and maximum or GUL level set at the level found in cows' milk.

5.8.1 Calcium

The eWG were almost fully supportive that calcium should be a mandatory requirement for follow-up formula for young children (14 CO; 1 CMO; 9CO). The importance of calcium in bone development, limited intakes within the diet, and use as a substitute for cows' milk, which is a major source of calcium were cited as rationale to mandate its addition. When setting requirements, several members stressed the need to consider nutritional requirements and technological issues, particularly relating to the interaction between protein and calcium.

In 2014, after review of the scientific justification for daily intake reference values from a variety of recognised authoritative scientific bodies, the eWG considered that the WHO/FAO INL_{98} of 500 mg/day was considered adequate for the majority of young children[14].

Full fat cows' milk contributes 190 mg calcium/100 kcal (range 184 - 201 mg/100 kcal). The average amount of calcium in reduced fat cows' milk is 259 mg/100 kcal (range 240 – 280 mg/100 kcal) (Appendix 1). Assuming an average daily intake of 300 mL, cows' milk provides approximately 370 mg day, 74% of the INL_{98}. In those consuming higher intakes of cows' milk, 500 mL would provide approximately 615 mg and exceed the calcium requirements of the majority of young children.

Proposed requirements

Three approaches were proposed for the minimum requirements for calcium in follow-up formula for young children:

- 90 mg/100 kcal, retain the current minimum in the Standard for Follow-up Formula,
- 200 mg/100 kcal, in accordance with the recommendation of the international expert group,
- >90 and <200 mg/100 kcal, balancing technical feasibility and nutritional equivalence with cows' milk.

The majority of eWG members supported establishing a minimum value of 90 mg/100 kcal or more (10 CM; 4CO). It was considered important that follow-up formula for young children provide significant contributions of calcium to the diets of young children due to its role as a substitute for cows' milk and its important role in bone mineralisation. The current Standard requires a minimum of 90 mg/100 kcal. At this level of fortification, intakes of 300 mL per day would provide 35% of requirements, and 500 mL per day almost 60% of requirements (INL_{98} 500 mg/day). Many in the eWG considered this to be an adequate contribution of calcium from one food product in the complementary diet of young children.

The 2015 expert group coordinated by the Early Nutrition Academy proposed a minimum level of 200 mg/100 kcal for follow-up formula for young children, based on an average consumption of 300 ml/day and the energy density of whole cows' milk. Although the expert group stated that this would be equivalent to about 40% of the recommended intake established by the WHO/FAO (INL_{98}: 500 mg/day)[35], the Chairs clarify that this is 40% of the INL_{98} per 100 kcal. Fortification of 200 mg/100 kcal would provide approximately 78% of the INL_{98} per daily intake of 300 mL of follow-up formula for young children (390 mg/day).

Several eWG members stated that fortification at 200 mg/100 kcal exceeded the amount contained within cows' milk, and would encounter technical difficulties for products containing lower protein levels than that found in cows' milk. Two eWG members noted that a level that was less than 200 mg/100 kcal but greater than 90 mg/100 kcal should be sought to balance the technical difficulties associated with fortification at high calcium levels in low protein formulas, with the need for nutritional equivalence. One suggested that a level of 180 mg/100 kcal could achieve this balance but may need review once the protein requirements are agreed to.

Guiding Upper Level

The current Standard for Follow-up Formula does not specify a maximum or GUL. The proposed Standard for follow-up formula for older infants specifies a guiding upper level of 180mg/100 kcal. Electronic working group members either favoured an approach whereby no maximum or GUL was specified as per the current standard, or to ensure that the calcium content of cows' milk could be accommodated. The Chairs

recommend that a GUL of 280 mg/100 kcal is adopted by the Committee. This level represents the upper range of calcium in reduced fat cows' milk.

Calcium: phosphorous ratio

Some members of the eWG supported the establishment of a calcium to phosphorous ratio to ensure adequate mineral balance and to better support bone mineralisation. The WHO/FAO have not yet established a dietary intake reference value for phosphorous and as such no recommendations were made in the 2014 or 2015 eWG's on the necessity to require this mineral in follow-up formula for young children. Of those that supported its requirement, it was deemed adequate to align with the requirements for follow-up formula for older infants and specify a minimum ratio of 1:1 and maximum of 2:1.

The majority of eWG members did not recommend establishment of either minimum requirements or a calcium to phosphorous ratio in follow-up formula for young children. Many stated that this was not necessary as part of a mixed diet, or did not consider phosphorous a key nutrient in cows' milk which required its mandatory addition. It was also stated that no evidence has been provided on phosphorus being inadequate in the diets of young children. Whereas others stated that they would like to first determine the requirements for calcium prior to determining the need for the addition of phosphorous.

Conclusion

The eWG strongly supported the establishment of minimum requirements for calcium at a level either equivalent to or higher than the current permissions within the Codex Standard for Follow-up Formula (90mg/100 kcal). Taking into account the issues with technological feasibility with low protein formulas and the principle of flexibility within the Standard, the Chairs propose the minimum of 90 mg/100 kcal is retained. At this level, daily intakes of 300 mL can provide 35% of calcium requirements for the majority of young children.

In line with the principle of flexibility a GUL of 280 mg/100 kcal should be established to enable those products based predominantly on cows' milk to be accommodated.

In line with the principle of flexibility and limited evidence on the need for phosphorous to be added to follow-up formula for young children, the Chairs do not recommend that a calcium to phosphorous ratio is established. If the Committee considers that a calcium/phosphorous ratio is required for the purposes of providing the key nutrients in cows' milk, it is suggested that the proposed follow-up formula standard for older infants is used as a starting point.

Additional option for consideration

[Ratio calcium/phosphorous]

Min	Max
[1:1]	[2:1]

5.8.2 Riboflavin

There was widespread support within the eWG to establish mandatory minimum requirements for vitamin B12 in follow-up formula for young children (12 CM; 1 CMO; 6 CO). The purpose of which is to ensure that the key nutrients present in cows' milk are provided in this product.

Several eWG members highlighted that milk is an important contributor to riboflavin in the diets of young children, and can be found in relatively few foods, and as such were supportive of its mandatory addition to follow-up formula for young children. Full fat cows' milk contains, on average, between 273-456 µg/100 kcal, whereas reduced fat cows' milk contains between 366-546 µg/100 kcal (Appendix 1).

Proposed requirements

The eWG considered several options for the establishment of a minimum requirement level for riboflavin, either on the basis of providing: equivalent levels to that found in cows' milk; a proportion of dietary requirements; or in alignment with the proposed standard for follow-up formula for older infants. Electronic

working group members supported the establishment of either a GUL in alignment with the proposed standard for follow-up formula for older infants, or not specifying a level.

Those proposing nutritional equivalence recommended a minimum level of 342 µg/100 kcal, the average riboflavin content of full fat cows' milk. Intakes of 300 mL per day at this minimum level would provide approximately 650 per day, meeting the requirements of the majority of young children (INL_{98} 500 µg/day[14]).

Many eWG members proposed minimum levels ranging from 60-80 µg/100 kcal on the basis that this would provide a proportion of the INL_{98} level derived by WHO/FAO[14] per 100 kcal. The current Codex Standard for Follow-up Formula specifies a minimum level of 60 µg/100 kcal; in comparison to the proposed minimum level for follow-up formula for older infants which specifies a level of 80 µg/100 kcal.

Taking into account the views of the eWG, the Chairs recommend that the minimum and GUL specified in the proposed follow-up formula for older infants is applicable for follow-up formula for young children. With a minimum and GUL ranging between 80-500 µg/100 kcal products based on cows' milk can be accommodated as well as ensuring a sufficient proportion of the INL_{98} is provided to young children per serve.

5.8.3 Vitamin B12

There was widespread support within the eWG to establish mandatory minimum requirements for vitamin B12 in follow-up formula for young children (12 CM; 1 CMO; 7 CO). The purpose of which is to ensure that the key nutrients present in cows' milk are provided in this product.

Cows' milk contains slightly different levels of vitamin B12 dependent on its fat content. In full fat cows' milk vitamin B12 levels vary between 0.5-1.4 µg/100 kcal; in comparison to 0.7-2.0 µg/100 kcal in reduced fat cows' milk (Appendix 1). It was highlighted that the addition of vitamin B12 would be particularly important for those products based on plant based protein sources.

Proposed requirements

Three levels were proposed for the minimum requirements for vitamin B12 in follow-up formula

- 0.1 µg/100 kcal, alignment with the proposed standard for follow-up formula for older infants,
- 0.15 µg/100 kcal, in accordance with eh recommendation of the international expert group,
- 0.8 µg/100 kcal, for nutritional equivalence with cows' milk.

The international expert working group[35] per 100 kcal recommendation is based on 15% of the INL_{98} value of 0.9 µg/day for young children established by the WHO/FAO[14]. The GUL of 0.75 µg/100 kcal established by the group is based on 3-5 times the minimum level[35].

Although many eWG members recommended that a GUL of 0.75 µg/100 kcal should be established, this level would not be able to accommodate the level of vitamin B12 in cows' milk – the key principle for the addition of this nutrient. It was also highlighted that vitamin B12 content of product could be highly variable, dependent on levels within cows' milk, analytical methods used, and the need for overages to accommodate shelf life losses of up to 55%[17]. Many within the eWG highlighted the need for a GUL to be able to accommodate the variable levels of vitamin B12 in cows' milk and potential for shelf life losses. It was also noted that no tolerable upper level has been established for vitamin B12.

Taking into account the pragmatic approach suggested by one Codex Member Organisation, it is proposed that the requirements for vitamin B12 in follow-up formula for young children are able to accommodate the compositional requirements of follow-up formula for older infants and vitamin B12 content of cows' milk. In order to do so, a minimum of 1.0 µg/100 kcal should be established and GUL of 2.0 µg/100 kcal. The minimum requirement is aligned with the proposed standard for follow-up formula for older infants, and the GUL represents the upper bound of the range of vitamin B12 contained in reduced fat cows' milk.

Recommendation 16:

That CCNFSDU agree to the following recommendation for calcium, riboflavin and vitamin B12 levels in [name of product] for young children:

Calcium

Unit	Minimum	Maximum	GUL
mg/100 kcal	[90]	-	[280]
mg/100 kJ	[22]	-	[67]

Riboflavin

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

Vitamin B12

Unit	Minimum	Maximum	GUL
µg/100 kcal	[0.1]	-	[2.0]
µg/100 kJ	[0.024]	-	[0.48]

Additional Option for further consideration:

[Ratio calcium/phosphorous]

Min	Max
[1:1]	[2:1]

5.9 Zinc

Zinc deficiency has been cited by many eWG members as justification for the mandatory addition of zinc to follow-up formula for young children. Zinc deficiency is an important cause of morbidity in developing countries and is reported to account for 1.7% of deaths in children less than five years of age[50]. It has also been highlighted that, as vitamin A is being considered for mandatory addition, and zinc deficiency can negatively affect vitamin A status, the Committee should also give consideration to zinc as a mandatory (core) nutrient in follow-up formula for young children.

As reported by the 2014 eWG data on zinc intakes and zinc deficiency are limited and sometimes inconsistent (CX/NFSDU 14/36/7). Despite zinc intakes appearing to be adequate in many countries, the prevalence of zinc deficiency is often greater than 20% for this age group, even in high income countries (CX/NFSDU 14/36/7). This is observed in the recent EFSA report on dietary intakes and status of older infants and young children where dietary intake surveys report less than 5% of children with inadequate intakes, yet almost all national surveys measuring status have observed that between 21 and 56% of older infants and young children were zinc deficient[16]. Low and middle income countries have higher rates of stunting than high income countries (28% and 7.2%, respectively) [50].

Although one Codex Member Organisation does not consider the mandatory addition of zinc to follow-up formula for young children necessary, the majority of the rest of the eWG support the inclusion of zinc as a mandatory (core) nutrient.

Proposed approaches

Of those that supported establishing a minimum level, the majority supported a minimum level for zinc which was equivalent to that found in full fat cows' milk which (average 0.66 mg/100kcal range: 0.56 – 0.79 mg/100kcal) (Appendix 1). This level is aligned with the recommendation of the international expert group (0.6 mg/100kcal)[35]. The Chairs note that this level is higher than the level agreed to by the Committee at CCNFSDU37 for a minimum zinc composition for follow-up formula for older infants of 0.5 mg/100 kcal, and not aligned with the approach for other mandatory nutrients which accommodate both the follow-up formula for older infants and levels found within cows' milk. As recommended by one Codex Member Organisation, if it is deemed important to mandate zinc, a pragmatic approach would be to align with the levels specified

in the proposed standard for follow-up formula for older infants which can accommodate the levels found in cows' milk.

Maximum/Guiding Upper Level

Of those eWG members supporting the mandatory addition of zinc to follow-up formula for young children, the majority considered a GUL of 1.8 mg/100 kcal as recommended by an international expert group coordinated by the Early Nutrition Academy[35] to be acceptable. Modelling on an intake range of 300 – 500ml/day, and assuming an energy density of 65 kcal/100 ml (mid-point of the recommended range for energy density), this would equate to a daily zinc intake of 3.51 – 5.85 mg from the formula.

A GUL of 1.5 mg/100 kcal was presented as an alternative option by a small number of eWG members to ensure the risk of exceeding the UL was minimised. At this GUL, the daily zinc intake at 300ml and 500ml would be 2.93mg and 4.88 mg, respectively, at an energy density of 65 kcal/100ml.

The IOM provides a UL of 7mg/day of zinc for children aged 1- 3 years old. In 2004, the International Zinc Nutrition Consultative Group (IZiNCG) reviewed the dietary intake reference values for zinc and suggested that the NOAEL for young children should be increased to 8 mg/day[63]. It was noted that there was insufficient data to establish a UL with confidence for this age group. The review stated that the UL proposed by the IOM for older infants and young children may be *inappropriately low* and result in problems for interventions targeted to improving zinc intakes due to the narrow margin between the amount of zinc required (AI or individual nutrient level (INL_{98})) and the UL[63]. In the US there is evidence that a significant proportion of older infants and young children (68% and 47%, respectively) have usual zinc intakes greater than the UL[64]. Evidence used to inform the increased NOAEL included the results of a supplementation trial in Indonesia where children aged six months of age received 10 mg of zinc per day for six months which had no significant effect on plasma copper concentrations[65].

Conclusion

It is the proposal of the Chairs' that zinc is not included as this point in time as a mandatory (core) nutrient for addition to follow-up formula for young children. Data on zinc intakes and zinc deficiency are limited and sometimes inconsistent. Further consideration of whether the evidence supports the addition of zinc based on its 'contribution to the nutritional needs of young children where the consumption of the nutrient is inadequate on a global scale' (Principle 1) is required.

Due to diverging views, the Chairs acknowledge this proposed approach will need to be discussed further at the pWG and plenary session by the Committee. The Committee will need to decide if the addition of zinc is in line with any of the Principles presented in Section 4.2.

If the Committee is in agreement that zinc should be a mandatory nutrient added to follow-up formula for young children it is recommended that the minimum level proposed for follow-up formula for older infants is adopted. Regarding the increase in dietary requirements for zinc and higher NOAEL, it is proposed that a GUL of 1.8 mg/100 kcal is specified.

Recommendation 16:

That CCNFDSU agree that zinc should not be included as a mandatory (core) nutrient for addition to [name of product] for young children.

Alternative Option for consideration:

If the Committee consider there is sufficient evidence to require the mandatory addition of zinc to follow-up formula for young children, that CCNFSDU agree to the mandatory addition of zinc to [name of product] for young children with the following levels:

Zinc

Unit	Minimum	Maximum	GUL
mg /100 kcal	[0.5]	-	[1.8]
mg /100 kJ	[0.12]	-	[0.43]

5.10 Vitamin A

While many eWG members supported the mandatory addition of vitamin A, one Codex Member Organisation did not. It was the view of this member that in agreement with the principle of 'flexibility', it would be more appropriate for individual national authorities to require the mandatory addition of vitamin A at the national level if required to meet the specific nutritional needs of the local population. Vitamin A deficiency is a major nutritional problem for 12-36 month old young children in developing countries, particularly the Philippines, Mexico and Brazil and some subgroups of the population in Indonesia[35]. In contrast, vitamin A deficiency is relatively rare in European countries[16], the USA and Canada[35].

Proposed approaches

The eWG considered several options for the establishment of a minimum requirement level for vitamin A: a proportion of dietary requirements; in alignment with the proposed follow-up formula for older infants; or as per the Codex Infant Formula Standard.

Of those eWG members who supported the mandatory addition of vitamin A to follow-up formula for young children, the majority, favoured establishing a vitamin A requirement lower than the proposed minimum level for older infants (75 µg RE /100 kcal). The preference was for a minimum level of 60 µg RE /100 kcal (as per the Codex Infant Formula Standard and the international expert group coordinated[35]). It was reported by several eWG members that 60 µg RE /100 kcal is comparable with the average vitamin A level in whole cows' milk (Appendix 1).

Of those eWG members who supported the mandatory addition of vitamin A, half supported the establishment of a maximum level with the other half favouring a GUL. Of those eWG members who specified a maximum, the majority preference was for a level of 225 µg RE/100 kcal as per the current Follow-up Formula Standard. A maximum level was supported due to the potential toxicity of vitamin A. The IOM UL for vitamin A for young children 1 – 3 years of age has been set at 600 µg/day. Using a daily intake range of 300 – 500 ml of follow-up formula for young children, and an energy density of 65 kcal/100 mL, this would provide 438 – 731 µg of vitamin A (modelling on the maximum level of 225 µg RE/100 kcal). It is possible that at this level, and assuming a high intake of 500ml of product per day, the IOM UL for vitamin A could be exceeded.

Of those preferring a GUL, majority preference was for a GUL of 180 µg RE/100 kcal as per the proposed standard for follow-up formula for older infants and aligned with the 2015 IEG[35]. A small number of eWG members also favoured a vitamin A level of 180 µg RE/100 kcal, but set as a maximum, and not a GUL. Using a daily intake range of 300 – 500 ml of follow-up formula for young children, and an energy density of 65 kcal/100 mL (mid-point of the proposed energy density range), this would provide 350 - 585 µg of vitamin A (modelling 180 RE µg/100 kcal).

The EFSA review provided the following text regarding the health consequences of excessive vitamin A intakes: *Children are particularly sensitive to excessive vitamin A intakes with daily intakes of about 450 µg RE per kg bodyweight per day leading to toxicity*[66-69]*. Signs of chronic hypervitaminosis A in infants are reported as a loss of appetite, dermal dryness, loss of hair, fissuring of the corners of the mouth, bone pain, hepatomegaly, increased intracranial pressure, and failure to thrive*[70].

Footnote

At CCNFSDU37, the Committee agreed to a footnote for vitamin A for follow-up formula for older infants (6-12 months), based on the uncertainties around bioequivalence of β-carotene and retinol in infants. The footnote, which aligns with the Codex Standard for Infant Formula states:

> [10)] expressed as retinol equivalents (RE)
>
> 1 µg RE = 3.33 IU Vitamin A = 1 µg all-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. (REP16/NFSDU Appendix III).

Electronic working group members were asked if they supported the adoption of the above footnote for follow-up formula for young children. Of those eWG members who answered this question, all supported the footnote.

Conclusion

Taking in to account the views of the eWG, and noting that vitamin A deficiency is relatively rare in European countries, the USA and Canada, the Chairs are of the view that the evidence does not support

Principle 1, that the consumption of vitamin A is inadequate on a global scale. Furthermore, vitamin A would not be considered a key nutrient found in cows' milk (Principle 2). As presented CX/NFSDU 14/36/7, a 300mL serving of cows' milk only provides 30% of the DIRV (400 µg RE) for young children for vitamin A. With regards to Principle 3, the addition of vitamin A to follow-up formula for young children would not be required for the purposes of ensuring the nutritional quality and integrity of product to ensure nutritional safety. Section 4.2 requires that each nutrient for mandatory addition meets either Principle 1, 2 or 3.

If the Committee decide that the mandatory addition of vitamin A to follow-up formula for young children is required, based on the views of the eWG, a minimum level of 60 µg RE /100 kcal is proposed to accommodate the vitamin A levels in cows' milk. It is also proposed that a maximum level is established due to concerns with excessive vitamin A intakes. Based on eWG views, a GUL of 180 µg RE/100 kcal would be appropriate to ensure that excessive intakes are not reached and to align with the proposed standard for follow-up formula for older infants.

Recommendation 17:

That CCNFDSU agree that vitamin A should not be included as a mandatory (core) nutrient for addition to [name of product] for young children.

Alternative Option:

If the Committee consider there is sufficient evidence to require the mandatory addition of vitamin A to follow-up formula for young children, that CCNFSDU agree to the mandatory addition of vitamin A to [name of product] for young children with the following levels and associated footnote:

Vitamin A

Unit	Minimum	Maximum	GUL
µg RE[10)] /100 kcal	[60]	[180]	-
µg RE[10)] /100 kJ	[14]	[43]	-

[10)] expressed as retinol equivalents (RE)

1 µg RE = 3.33 IU Vitamin A = 1 µg all-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.

5.11 Vitamin D

The 2014 eWG noted that vitamin D can be synthesised endogenously through the exposure of skin to sunlight, as such vitamin D insufficiency is generally limited to populations or sub-groups of the population with limited sunlight exposure; and where no public health interventions (i.e. fortification and supplementation) have been implemented. Of the countries which have conducted nationally representative surveys, almost all reported significant levels of vitamin D insufficiency in older infants and young children (<50 nmol/L). Paradoxically, vitamin D insufficiency has also been observed in some lower latitude countries. In South-east Asia vitamin D insufficiency was observed in approximately a third of children in India[71], Malaysia [72], and Thailand[73]. In other regions; over a quarter of children in Mexico [74], 33% of children aged 15-23 months in Iran[75], and 28% of young children in Jordan[76] were reported to be vitamin D insufficient (<50 nmol/L) (see CX/NFSDU 14/36/7 for further details on vitamin D status globally).

Of those 2016 eWG members who requested additional nutrients be added to the mandatory (core) composition of follow-up formula for young children, most common was support for the addition of vitamin D due to reported deficiency in this age group, even in some lower latitude countries. Those that favoured the mandatory addition of vitamin D to follow-up formula for young children based this on the evidence of sub-optimal vitamin D status in some regions, and the recommendation of an international expert group coordinated by the Early Nutrition Academy[35]. It is worth noting that the eWG has previously highlighted that regional differences exist in vitamin D requirements and prevalence of inadequate vitamin D status,

the eWG also noted that different public health approaches are used to address vitamin D insufficiency, including the use of supplementation programmes in some countries.

One Codex Member Organisation didn't actively support mandatory vitamin D addition, unless it was confirmed to be a critical nutrient globally for this age group. Whilst a small number of other eWG members did not actively support mandatory addition, they did state they were not opposed to the inclusion of vitamin D in the mandatory (core) composition. Consideration will need to be given to the impact of any national fortification programmes and the risk of toxicity should follow-up formula for young children require the mandatory addition of vitamin D.

Most eWG members supporting mandatory addition were of the view a maximum level (not a GUL) should be set due to the potential toxicity of vitamin D and the risk of adverse effects with intakes exceeding the UL.

Proposed approaches

Minimum

The majority of the eWG supporting mandatory addition of vitamin D to follow-up formula for young children supported a minimum level of 1.5 µg/100 kcal as recommended by the international expert working group coordinated by the Early Nutrition Academy[35]. This value, per 100 kcal recommendation is based on the expert working group's consideration that 10 µg/day is adequate for the majority of young children and that 15% of this value should be provided per 100 kcal.

The proposed minimum vitamin D content of follow-up formula for older infants is 1.0 µg/100 kcal.

A small number of eWG members preferred to set the minimum requirement for vitamin D at 2 µg/100 kcal in line with the recommendations of EFSA for the essential composition of follow-up formula for older infants[5].

Maximum/Guiding Upper Level

The majority of the eWG supporting mandatory addition of vitamin D to follow-up formula for young children, support the level of 4.5 µg/100 kcal established by the international expert working group coordinated by the Early Nutrition Academy[35]. This is based on 3-5 times the minimum level[35]. It is worth noting that the international expert working group proposed this level as a GUL, whereas the eWG consider it should be set as a maximum level.

Conclusion

Whilst there is considerable support from the eWG for the mandatory addition of vitamin D to follow-up formula for young children, the Committee will need to consider if its addition meets the principles set out in section 4.2 for determination of the mandatory compositional requirements. Most important will be the need for evidence that the consumption of vitamin D is inadequate on a global scale (Principle 1), as vitamin D would not be considered a key nutrient found in cows' milk (Principle 2), nor would its addition be required to ensure the nutritional quality and integrity of product to ensure nutritional safety (Principle 3). Section 4.2 requires that each nutrient for mandatory addition or requiring specific compositional parameters meets either Principle 1 and/or Principle 2 and/or Principle 3.

It is the proposal of the Chairs' that vitamin D is not included as this point in time as a mandatory (core) nutrient for addition to follow-up formula for young children. Further consideration of whether the evidence supports the addition of vitamin D based on the 'contribution to the nutritional needs of young children where the consumption of the nutrient is inadequate on a global scale' (Principle 1) is required.

As different national public health approaches are used to address vitamin D insufficiency, including the use of supplementation programmes in some countries, the Committee will also need to consider if the mandatory addition of vitamin D to follow-up formula for young children should be left to the discretion of national authorities if deemed necessary for their local population.

Based on the collective comments from the eWG and support for adoption of the levels recommended by an international expert group coordinated by the Early Nutrition Academy[35], should CCNFSDU agree to the mandatory addition of vitamin D to follow-up formula for young children, the Chairs propose the below levels, noting that the eWG support a maximum, not a GUL as proposed by the international expert group.

Recommendation 18:

That CCNFDSU agree that vitamin D should not be included as a mandatory (core) nutrient for addition to [name of product] for young children.

Alternative Option:

If the Committee consider there is sufficient evidence to require the mandatory addition of vitamin D to follow-up formula for young children, that CCNFSDU agree to the mandatory addition of vitamin D to [name of product] for young children with the following levels:

Vitamin D

Unit	Minimum	Maximum	GUL
µg /100 kcal	[1.5]	[4.5]	-
µg /100 kJ	[0.36]	[1.08]	-

5.12 Sodium

The majority of 2016 eWG members requested that parameters for sodium be set for follow-up formula for young children. This request is in most part related to ensuring that a maximum level for sodium rather than for reasons of nutritional need.

The average level of sodium intrinsically present in full fat (64 – 72 mg/100 kcal) and reduced fat (85 - 94 mg/100 kcal) cows' milk would exceed the maximum level proposed for follow-up formula for older infants (60 mg/100 kcal). Further to this, the average level of sodium intrinsically present in reduced fat cows' milk would exceed the GUL for sodium proposed by the 2015 IEG (75 mg/100 kcal).

There was majority support from the eWG for a maximum level (not GUL) for sodium. A small number of members also requested a minimum level be set and this ranged from 20 – 25 mg/100 kcal. It was the view of some that a maximum level for sodium would ensure acceptable limits, whilst taking in to account the intake of sodium from other complementary foods, and the 2005 Institute of Medicine (IOM) UL of 1500mg sodium/day for young children.

Proposed approaches

Minimum

Based on the collective comments of the eWG, there was not strong support for the establishment of a minimum level for sodium.

Maximum/Guiding Upper Level

Based on the collective comments of the eWG, it is recommended that a maximum level, not a GUL, for sodium be set for the purposes of nutritional integrity. The eWG was divided in its preference for a maximum level, split between 85 mg/100 kcal as per the current Codex Follow-up Formula Standard, and 75 mg/100 kcal as recommended by an international expert group coordinated by the Early Nutrition Academy[35]. As mentioned above, a maximum level of 75 mg/100 kcal is lower than the average amount of sodium intrinsically present in reduced fat cows' milk.

Conclusion

The Chairs recommend that parameters for sodium, namely a maximum level is included for follow-up formula for young children. Whilst including parameters for sodium does not meet Principles 1 and 2, it does meet Principle 3, in that a maximum level will assist in ensuring nutritional integrity of product. The principles set out in section 4.2 have been developed to help guide and justify nutrient addition, as well as identify those nutrients requiring specific compositional parameters. Principle 3 requires that evidence is provided to support the nutritional quality and integrity of product to ensure nutritional safety) apply to each nutrient.

Based on the collective comments from the eWG and need to accommodate cows' milk, the Chairs recommend establishing a maximum level of 85 mg/ 100kcal.

Recommendation 19:

That CCNFDSU agree to the following recommendation for sodium levels in [name of product] for young children:

Sodium

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	[85]	-
mg /100 kJ	-	[20]	-

6 SCOPE & LABELLING

6.1 Overview

The 2016 eWG were tasked with exploring issues for further consideration at CCNFSDU38 to inform the revision of the Scope (Section 1) and Labelling (Section 9) sections of the Codex Standard for Follow-up Formula. Recognizing that the Scope and Labelling sections are interlinked, consideration will need to be given to which concepts may be best managed or presented within the Scope, and which within the Labelling section. The eWG has not undertaken any significant analysis of these sections.

As already mentioned, for the purposes of this Agenda Paper, the Chairs have referred to product targeted to infants aged 6-12 months as follow-up formula for older infants, and products for young children aged 12-36 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.

To assist the Committee with the next stages of consideration of the scope and labelling, the Chairs of the eWG have provided a summary of the Scope and Labelling requirements within current relevant Codex Standards and Guidelines, as well as summarized the eWG views and comments on the Scope and Labelling requirements within the current Standard for Follow-up Formula. A summary of key WHA resolutions and documents is also presented for information.

6.2 Current provisions

6.2.1 Scope

The Scope (Section 1) of the current *Standard for Follow-up Formula* (CODEX STAN 156-1987) simply states that the standard *'applies to the composition and labelling of follow-up formula' and 'does not apply to foods covered by the Codex Standard for Infant Formula (CODEX STAN 72-1981)'*.

Unlike other Codex Standards and Guidelines, the Scope of the current Codex Standard for Follow-up Formula does not describe the role or intended use of the product. Nor does it reference other policies to be taken in to account, such as the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding, or relevant WHA resolutions.

As a brief comparison, the Scope of the Codex Standard for Infant Formula states the form and intended use of the product; a reference to the inclusion of compositional, quality and safety requirements within the standard; a disclaimer for the marketing of infant formula; and how the application of the standard should take in to account the recommendations within specific WHO and WHA documents.

Table 1 presents the approach and content of the Scope section of more recently reviewed, and relevant Codex Standards and Guidelines:

STANDARD/GUIDELINE	SCOPE
Standard for Follow-up Formula (CODEX STAN 156-1987)	**1. SCOPE** This standard applies to the composition and labelling of follow-up formula.

	It does not apply to foods covered by the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981).
Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981)	**SECTION A** **1. SCOPE** **1.1** This section of the Standard [Section A] applies to infant formula in liquid or powdered form intended for use, where necessary, as a substitute for human milk in meeting the normal nutritional requirements of infants. **1.2** This section of the Standard contains compositional, quality and safety requirements for Infant Formula. **1.3** Only products that comply with the criteria laid down in the provisions of this section of this Standard would be accepted for marketing as infant formula. No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life. **1.4** The application of this section of the Standard should take into account the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA54.2 (2001). **SECTION B** **1. SCOPE** **1.1** This section of the Standard [Section B] applies to Formula for Special Medical Purposes Intended for Infants in liquid or powdered form intended for use, where necessary, as a substitute for human milk or infant formula in meeting the special nutritional requirements arising from the disorder, disease or medical condition for whose dietary management the product has been formulated. **1.2** This section of the Standard contains compositional, quality, labelling and safety requirements for Formula for Special Medical Purposes Intended for Infants. **1.3** Only products that comply with the criteria laid down in the provisions of this section of this Standard would be accepted for marketing as formula for special medical purposes intended for infants. 1.4 The application of this section of the Standard should take into account, as appropriate for the products to which the section applies and the special needs of the infants for whom they are intended, the recommendations made in the International Code of Marketing of Breast-milk Substitutes (1981), the Global Strategy for Infant and Young Child Feeding and World Health Assembly resolution WHA54.2 (2001).
Standard for Processed Cereal-Based Foods for Infants and Young Children (CODEX STAN 74-1981)	**1. SCOPE** This standard covers processed cereal-based foods intended for feeding infants as a complementary food generally from the age of 6 months onwards, taking into account infants' individual nutritional requirements, and for feeding young children as part of a progressively diversified diet, in accordance with the Global Strategy for Infant and

	Young Child Feeding and World Health Assembly Resolution WHA54.2 (2001).
Guidelines on Formulated Complementary Foods for Older Infants and Young Children (CAC/GL 8-1991)	**2. SCOPE** The provisions of these Guidelines apply to Formulated Complementary Foods for Older Infants and Young Children as defined in Section 3.1 below and include but are not limited to porridges containing cereals, ready to-use products and food-based home fortificants. Micronutrient supplements, processed cereal based foods, and canned baby foods2 are not covered by these Guidelines**.** These Guidelines should be used in accordance with the Global Strategy for Infants and Young Child Feeding and World Health Assembly Resolution WHA54.2 (2001).

6.2.2 Labelling

The Labelling section (Section 9) of the current Codex Standard for Follow-up Formula sets out labelling requirements for follow-up formula products. In the introduction to Section 9 both the Codex Infant Formula and Follow-up Formula Standards refer to other general Codex labelling standards and guidelines which are applicable to these respective products.

Both the Codex Infant and Follow-up Formula Standards specifically state that the requirements of the *General Standard for the Labelling of Pre-packaged Foods* (CODEX STAN 1-1985) apply. The Codex Standard for Infant Formula also specifies that the requirements of the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985) and the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997) apply to infant formula and formula for special medical purposes for infants. The Codex Guidelines for Use of Nutrition and Health Claims do not permit nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation (CAC/GL 23-1997).

Consideration may also need to be given to the *Code of Hygienic Practice for Powdered Formulae for Infants and Young Children* (CAC/RCP 66-2008), and its possible application to the preparation and use of follow-up formula, including the provision of information for reconstitution to safeguard against *Cronobacter sakazakii*.

Electronic working group members were asked whether any of the current labelling provisions for follow-up formula can be adopted as is, and if so, which provisions. Several eWG members suggested that as the Follow-up Formula Standard is outdated, it would be more appropriate to use the more recently revised Infant Formula Standard as the starting point for review, aligning where possible and appropriate.

Section 9 of both the Codex Infant Formula and Follow-up Formula Standards have product specific provisions under the following sub-headings:

9.1 The name of the ~~food~~ [product]

9.2 List of ingredients

9.3 Declaration of nutritive value

9.4 Date marking and storage instructions

9.5 Information for ~~utilization~~ [use]

9.6 Additional [labelling] requirements

6.3 Relevant WHA resolutions and WHO documents

At CCNFSDU36 it was discussed that the review of the Scope and Labelling sections could include referencing the relevant WHA resolutions on optimal infant and young child nutrition, and on the lack of the need of the products (REP16/NFSDU, para 54 b). The Representative of the WHO requested the

Committee include regulatory measures to avoid inappropriate marketing of follow-up formula, not only through necessary labelling requirements, but in line with marketing restrictions contained within the International Code (REP15/NFSDU para 98).

Further to this, members of previous eWGs have raised various issues which could inform the Scope and Labelling of follow-up formula products. This includes the view of the non-necessity of these products, how these products are considered in the context of the International Code of Breast-milk Substitutes, and relevant WHA resolutions and WHO documents. A brief summary of relevant WHA resolutions and WHO documents are provided below.

6.3.1 International Code of Marketing of Breast-milk Substitutes (the Code)

The Code was developed by WHO in 1981[77]. It defines breast-milk substitutes as *any food being marketed or otherwise presented as a partial or total replacement for breast-milk, whether or not suitable for that purpose.*

The Code *applies to the marketing, and practices related thereto, of the following products: breast-milk substitutes, including infant formula; other milk products, foods and beverages, including bottle-fed complementary foods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast-milk; feeding bottles and teats. It also applies to their quality and availability, and to information concerning their use.*

6.3.2 2013 WHO Clarification

In 2013 the WHO clarified the use and marketing of follow-up formula in the context of the Code[51].

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. 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.

6.3.3 WHA 39.28

WHA resolution 39.28 relates to the implementation of the International Code of Marketing of Breast-milk Substitutes. It requests the Director-General of WHO to specifically direct the attention of Member states and other interested parties to "*the practice being introduced in some countries of providing infants with specially formulated milks (so called "follow-up milks") is not necessary*" (WHA 1986[78]).

Consideration of WHA resolution 39.28 was important in the development of the Codex Standard for Follow-up Formula. These discussions are captured in the Report of the Fifteenth Session of the Codex Committee on Foods for Special Dietary Uses – January 1987 (ALINORM 87/26, para 59-63), as well as in the Codex Alimentarius Commission Report of the Seventeenth Session 1987 (ALINORM 87/39; para 436-439).

6.3.4 WHA 54.2

WHA resolution 54.2 urges member states to *strengthen national mechanisms to ensure global compliance with the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions, with regard to labelling as well as all forms of advertising, and commercial promotion in all types of media, to encourage the Codex Alimentarius Commission to take the International Code and relevant subsequent Health Assembly resolutions into consideration in developing its standards and guidelines; and to inform the general public on progress in implementing the Code and subsequent relevant Health Assembly resolutions*[79].

6.3.5 WHA 63.23 and WHA 69.9

At the 63rd World Health Assembly the resolution on infant and young child nutrition stated that '*the promotion of breast-milk substitutes and some commercial foods for infants and young children undermines progress in optimal infant and young child feeding*' (WHA 63.23[80]).

WHA 63.32 urged Member States to:

- *'Develop and/or strengthen legislative, regulatory and/or other effective measures to control the marketing of breast-milk substitutes in order to give effect to the International Code of Marketing of Breast-milk Substitutes and relevant resolutions adopted by the World Health Assembly;*
- *end inappropriate promotion of food for infants and young children, and to ensure that nutrition and health claims shall not be permitted for foods for infants and young children, except where specifically provided for in relevant Codex Alimentarius standards or national legislation*'.

Additionally, WHA 63.23 requested the Director-General of WHO to '*support Member states, on request, in their efforts to develop and/or strengthen legislative, regulatory or other effective measures to control marketing of breast-milk substitutes*'.

Guidance on ending inappropriate promotion of foods for infants and young children

The 65th World Health Assembly continued discussions on the inappropriate promotion of foods for infants, and the subsequent resolution requested the Director-General 'to provide clarification and guidance on the inappropriate promotion of foods for infants and young children cited in WHA63.23 taking into consideration the ongoing work of the Codex Alimentarius Commission'[81].

In response to this the WHO convened a Scientific and Technical Advisory Group to define what constitutes inappropriate promotion of foods for infants and young children and to develop a discussion paper on the clarification and guidance on inappropriate promotion of foods for infants and young children [82,83]. The draft paper as prepared by the Scientific and Technical Advisory Group[82] was consulted on in August 2015, and provided the following definitions of 'marketing' and 'promotion' and 'inappropriate promotion':

> *Marketing means product promotion, distribution, selling, advertising, product public relations and information services.*
>
> *Promotion broadly interpreted to include the communication of messages that are designed to persuade or encourage the purchase or consumption of a product or raise awareness of a brand. Promotional messages may be communicated through traditional mass communication channels, the Internet and other marketing media using a variety of promotional Methods. In addition to promotional techniques aimed directly at consumers, measures to promote products to health workers or to consumers through other intermediaries are included. There does not have to be a reference to a brand name of a product for the activity to be considered as advertising or promotion.'*
>
> *Promotion is inappropriate if:*
>
> *a) it undermines recommended breastfeeding practices;*
>
> *b) it contributes to childhood obesity and non-communicable diseases;*
>
> *c) the product does not make an appropriate contribution to infant and young child nutrition in the country;*
>
> *d) it undermines the use of suitable home-prepared and/or local foods;*
>
> *e) it is misleading, confusing, or could lead to inappropriate use.*

The World Health Organisation presented to their Executive Board in January 2016, draft 'Guidance on Ending the Inappropriate Promotion of Foods for Infants and Young Children' for further discussion and adoption at the WHA in May 2016. A summary of the scientific evidence used to inform the WHO Technical Guidance Document on Ending the Inappropriate Promotion of Foods for Infants and Young Children can be viewed at Appendix 3. At WHA69, the Resolution (WHA69.9) for 'Ending inappropriate promotion of foods for infants and young children' was agreed and subsequently adopted. The Resolution 'welcomes with appreciation the technical guidance'. The Resolution also recognizes the role of the Codex Alimentarius Commission and requests that *'reviews of Codex Standards and Guidelines should give full consideration to WHO guidelines and recommendations, including the International Code of Marketing of Breast-milk Substitutes and relevant WHA resolutions'*.

It is important that the Guidance recommendations and its Resolution are read together, as the Resolution also contains important information, and clarification that will help guide discussions about the Scope and

Labelling sections of the Codex Standard for Follow-up Formula. The resolution and accompanying technical guidance are provided in Appendix 4.

6.4 eWG views

A number of eWG members suggested that as the nutritional needs of the older infant differ to those of young children, it would be appropriate for the Standard to modify the Scope and Labelling sections to appropriately address these differences. Comment was also made by a limited number of eWG members that until the role and purpose of follow-up formula for young children is agreed upon, it is difficult to provide specific comment on the Scope and Labelling. It was suggested that starting with a preamble statement to set the scene for the entire document may add clarity. As a starting point for discussion, a format similar to that of the Infant Formula Standard could be followed, with a clear distinction in the naming of the two products, and a preamble which clarifies that the Standard is divided into two parts. The Scope and Labelling sections can then be tailored as appropriate for the two categories of product. The presentation of two separate parts within the Standard for the two different product categories was supported by several eWG members.

CODEX STANDARD FOR FOLLOW-UP FORMULA FOR OLDER INFANTS AND (NAME OF PRODUCT) FOR YOUNG CHILDREN

CODEX STAN 156-1987

PREAMBLE

This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants (6 to 12 months of age), and Section B deals with (Name of Product) for Young Children (12 to 36 months of age).

1. SCOPE

1.1 Section A of this Standard applies to the compositional, safety and labelling requirements of follow-up formula for older infants.

1.2 Section B of this Standard applies to the compositional, safety and labelling of (name of product) for young children.

Further items in the scope section can now be tailored as appropriate for the two categories of product.

Comments were made as to relevance of including and referencing WHA resolutions within the Standard, specifically those referring to marketing practices rather than labelling which was considered a separate entity by some. The Chairs have sought advice from the Secretariat, and it is worth noting that the Terms of Reference for the Codex Committee on Food Labelling are:

(a) to draft provisions on labelling applicable to all foods;

(b) to consider, amend if necessary, and endorse draft specific provisions on labelling prepared by the Codex Committees drafting standards, codes of practice and guidelines;

(c) to study specific labelling problems assigned to it by the Commission; and

(d) to study problems associated with the advertisement of food with particular reference to claims and misleading descriptions.

As such, it would appear that CCNFSDU must decide in the first place, if and how, the Standard could take into account any WHA resolutions and WHO policies on the marketing of follow-up formula, and whether the International Code or certain WHA resolutions apply to one or both types of follow-up formula. The Committee could refer issues related to advertising to the CCFL for consideration and endorsement if deemed necessary.

Further to this, comment was made that the recommendations contained within the WHO Guidance on ending the inappropriate promotion of foods for infants and young children have a broader scope than just

follow-up formula. Recommendation 2 of the Guidance is directly relevant to follow-up formula as it states that:

> *Products that function as breast-milk substitutes should not be promoted. A breast-milk substitute should be understood to include any milks (or products that could be used to*
>
> *replace milk, such as fortified soy milk), in either liquid or powdered form, that are specifically marketed for feeding infants and young children up to the age of 3 years (including follow-up formula and growing-up milks). It should be clear that the implementation of the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions covers all these products.*

Recommendation 2 is a change in WHO's assessment of follow-up formula. In WHO's 2013 information note concerning the use and marketing of follow-up formula, WHO considered that the International Code applies to follow-up formula only under certain conditions. It was suggested that the Committee needs to understand this change, and discuss and agree on how Recommendation 2 might impact on the review of the Standard, for one or both product categories.

Only two eWG members were of the view that the Scope as currently written in the Follow-up Formula Standard is adequate. Others supported consideration of aligning with elements contained within the Infant Formula Standard, such as including statements relating to the application of the standard, the intended role of product, exclusions, the form of food and whether the standard should take in to account other policies (such as WHO documents and WHA resolutions). Comment was made that the Scope should be simple and avoid duplication with product definitions. The Committee and future eWGs will need to consider if the role and form of the product is best captured in the Scope or as part of the product definitions. It has been suggested by a number of eWG members that the role of product for young children is not as a substitute for breast milk, but at a substitute for cows' milk, and is to be used as a supplement to the diet to support adequacy of intakes of nutrients of key global concern for this age group, or as the liquid fraction of the diversified complementary diet when energy and nutrient intakes may not be adequate to meet the nutritional requirements of young children.

Comments from the eWG relating to the name of product have been captured below under Labelling (see 6.5.2). Comments are also applicable to consideration of the Scope of the Standard, as the Scope would need to reference the two product categories and their respective names.

Electronic working group members were asked to comment on whether it was necessary for the Follow-up Formula Standard to make specific reference to WHA resolutions, and if so, how and where these should be captured. There was a diverse range of views with some expressing the opinion that reference to WHA resolutions within the Standard was not necessary as they do not refer to matters that are 'specifically relevant to the Standard', or they relate to marketing practices rather than labelling which some considered a 'separate entity'. The comment was also made that 'it is not appropriate that [Codex] product standards deviate in their scope into areas of public health policy or statements on nutritional policy. Policy statements relating to health are beyond the scope of the Codex Alimentarius' and the 'legitimate basis to include those statements based on the Codex Rules of Procedure' was queried.

With regards to those who supported referencing WHA resolutions, most suggested this be as part of the Scope. There were however differences in opinion as to what should be referenced. One view suggested an approach similar to that taken in 1.4 of the Infant Formula Standard. It was suggested that this reference could be generic in nature and refer to 'relevant' (rather than listing specific) 'resolutions'. Others suggested that in addition to WHA 54.2 (2001), that WHA 69.9 (2016) should also be listed, with two eWG members suggesting that in addition, WHA resolutions 32.22, 39.28, 47.5, 49.15, 55.25, 58.32, 61.20, and 63.23 be referenced in the Scope

Alternatively, it was suggested that if the Infant Formula Standard references WHA 54.2 within the Scope, this approach could be considered for follow-up formula for older infants if the Committee agreed that this product is a breastmilk substitute. However, for follow-up formula for young children, the eWG member was of the view that product for the 12 to 36 month age group is not a breastmilk substitute, and as such it was not appropriate to include WHA 54.2 in the Scope for this product category.

As mentioned above (see 6.3.5), WHA 69.9 relates to 'Ending the inappropriate promotion of foods for infants and young children'. The Resolution *'welcomes with appreciation the technical guidance'*. The Resolution also recognizes the role of the Codex Alimentarius Commission and requests that *'reviews of Codex Standards and Guidelines should give full consideration to WHO guidelines and recommendations, including the International Code of Marketing of Breast-milk Substitutes and relevant WHA resolutions'*. Electronic working group members were asked how CCNFSDU should give full consideration to this resolution. It was noted that giving *full consideration* is a process and not an outcome, and by presenting the information under section 6.3 (and associated appendices) of this Agenda Paper, the Chairs are allowing the Committee to have the same opportunity as the eWG with respect to considering the content of these documents, and its applicability, if any to the Scope and Labelling sections of the Follow-up Formula Standard. Whilst some eWG members suggested the Standard specifically reference WHA 69.9 in the Scope, others preferred that the Committee give consideration to the Resolution and associated Technical Guidance document by incorporating certain recommendations in the Labelling section of the Standard. See below for further comment.

6.4.1 Comments relating to Labelling

Electronic working group members were asked whether any of the current labelling provisions for follow-up formula can be adopted as is, and if so, which provisions. There was majority support for retaining the structure of the Labelling section. Several eWG members suggested that as the Follow-up Formula Standard is outdated, it would be more appropriate to use the more recent Infant Formula Standard as the starting point for review, aligning where possible and appropriate. Comments were also made as to the different role in the diet of follow-up formula for older infants compared to that of young children, and as such it was suggested that different labelling provisions for these two product categories are likely to be appropriate, and that for young children the labelling requirements could possibly be less prescriptive than for follow-up formula for older infants.

Many eWG members reiterated the decision made by the Committee as CCNFSDU37 to refer to 'product' rather than 'food' as part of definition 2.1.1, and to make consequential changes throughout the text as necessary, including Section 9 - Labelling. Overall, there was widespread support for retaining the current structure of the Labelling section within the Follow-up Formula Standard which aligns with the Infant Formula Standard, with some minor modifications to the titles.

There was widespread support for the name of product for young children to be distinctively different from follow-up formula for older infants and for it not to include 'formula' as part of the name.

The composition of the now proposed two follow-up formula products are distinctly different from one another, with the proposal for follow-up formula for young children to contain a limited number of mandatory nutrients, compared to follow-up formula for older infants which mandates the addition of 32 nutrients. It was considered therefore that follow-up formula for young children needs to be easily distinguishable from follow-up formula for older infants so as to avoid consumer confusion about the suitability of individual products for different age groups, and this could be achieved by using distinctly different names for the different product categories. As a starting point for discussion, 'fortified milk for young children', and 'processed milk for young children' were both suggested alternative names to follow-up formula for young children.

The eWG was asked to consider if the statement under section 9.6; that *'Products covered by this standard are not breast-milk substitutes and shall not be presented as such'* requires modification. Of those eWG members who responded to this question, the majority were of the view that follow-up formula for older infants should be classified as a breast-milk substitute. Only one eWG member commented that the statement under 9.6 remains and is applicable to both product categories, resulting in neither product category being considered a breast-milk substitute. Two thirds of respondents were of the view that follow-up formula for young children is not a breast-milk substitute, but rather a substitute for or alternative to cows' milk. The Committee therefore must consider if the Standard needs to state whether the products covered are breast-milk substitutes or not, or whether the Standard could instead refer to the presentation of product and require that products shall not be presented as a breast-milk substitute, or presented in a way that may cause confusion and have a negative impact on breastfeeding.

The below table presents the current labelling requirements of the Follow-up Formula Standard and the Infant Formula Standard. The text in the green boxes is a summary of eWG issues and comments for further consideration by the Committee.

Table 2: Summary of eWG issues and comments for further consideration:

STANDARD FOR FOLLOW-UP FORMULA (CODEX STAN 156-1987) **(FUF Standard)**	**STANDARD FOR INFANT FORMULA AND FORMULAS FOR SPECIAL MEDICAL PURPOSES INTENDED FOR INFANTS** **(CODEX STAN 72 – 1981) (IF Standard)**
9. LABELLING In addition to the requirements of the General Standard for the Labelling of Prepackaged Foods (CODEX STAN 1-1985), the following specific provisions apply:	**9. LABELLING** The requirements of the *General Standard for the Labelling of Prepackaged Foods* (CODEX STAN 1-1985), the *Guidelines on Nutrition Labelling* (CAC/GL 2-1985) and the *Guidelines for Use of Nutrition and Health Claims* (CAC/GL 23-1997) apply to infant formula and formula for special medical purposes for infants. These requirements include a prohibition on the use of nutrition and health claims for foods for infants and young children except where specifically provided for in relevant Codex Standards or national legislation. In addition to these requirements the following specific provisions apply:
• Consider also including a statement referencing the applicability of the requirements of the *Codex Guidelines on Nutrition Labelling* (CAC/GL 2-1985) in the FUF Standard. • The eWG has not explored whether the FUF Standard should specifically allow for content, nutrition or health claims on follow-up formula for older infants, or for follow-up formula for young children.	
9.1 The Name of the Food **9.1.1** The name of the food shall be "Follow-up Formula". In addition thereto, any appropriate designation may be used in accordance with national usage. **9.1.2** Those products which are prepared from whole or skimmed milk in accordance with Section 3.3.1.2 and where 90% or more of the protein is derived from whole or skimmed milk as such, or with minor modification that does not substantially impair the vitamin and mineral content of the milk, may be labelled "Follow-up Formula based on milk". **9.1.3** All sources of protein shall be clearly shown on the label in close proximity to the name of the food in descending order of proportion by weight. **9.1.4** A product which contains neither milk nor any milk derivative may be labelled "contains no milk or milk products" or an equivalent phrase.	**9.1 The Name of the Food** **9.1.1** The text of the label and all other information accompanying the product shall be written in the appropriate language(s). **9.1.2** The name of the product shall be either "Infant Formula" or any appropriate designation indicating the true nature of the product, in accordance with national usage. **9.1.3** The sources of protein in the product shall be clearly shown on the label. **9.1.4** If cows' milk is the only source of protein, the product may be labelled "Infant Formula Based on Cows' Milk". **9.1.5** A product which contains neither milk or any milk derivative shall be labelled "contains no milk or milk products" or an equivalent phrase.
• Re-word 9.1 title to; The Name of the [Product] ~~Food,~~ in line with the decision made at CCNFSDU37 to use 'product' rather than 'food' as part of definition 2.1.1.	

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- There was widespread support for the name of product for young children to be distinguishable from follow-up formula for older infants so it is easily recognized that these are two distinct product categories. Suggestions made by the eWG members, which could be a starting point for discussion include: fortified milk for young children, processed milk for young children.
- Product for older infants to be called; Follow-up Formula for Older Infants

9.1.1: This requirement in the IF Standard could be adopted for both product categories within the FUF Standard.

9.1.2: This provision (as presented in the IF Standard) could be modified so that it is applicable to both product categories in the FUF Standard; *'The name of the product shall be either 'follow-up formula for older infants' or '[name of product] for young children, or any appropriate designation indicating the true nature of the product in accordance with national usage'.* 9.1.2 of the current FUF Standard will need to be considered by the Committee once the composition of the respective product categories is finalised.

9.1.3: There was support for adopting the IF Standard requirement for both product categories.

9.1.4/9.1.5: Yet to be determined – will depend on the outcome on the respective names and roles of products.
</td></tr>
<tr><td>9.2 List of Ingredients
The declaration of the list of ingredients shall be in accordance with Sections 4.2.1, 4.2.2 and 4.2.3 of the Codex General Standard for the Labelling of Prepackaged Foods except that in the case of added vitamins and added minerals, these ingredients shall be arranged as separate groups for vitamins and minerals, respectively, and within these groups the vitamins and minerals need not be listed in descending order of proportion.</td><td>9.2 List of Ingredients
9.2.1 A complete list of ingredients shall be declared on the label in descending order of proportion except that in the case of added vitamins and minerals, these ingredients may be arranged as separate groups for vitamins and minerals. Within these groups the vitamins and minerals need not be listed in descending order of proportion.
9.2.2 The specific name shall be declared for ingredients of animal or plant origin and for food additives. In addition, appropriate class names for these ingredients and additives may be included on the label.</td></tr>
<tr><td colspan="2">It was suggested that the provisions 9.2.1 and 9.2.2 of the IF Standard could be adopted for both product categories</td></tr>
<tr><td>9.3 Declaration of Nutritive Value
The declaration of nutrition information shall contain the following information in the following order:
(a)The amount of energy, expressed in Calories (kcal) and/or kilojoules (kJ) per 100 g of the food as sold as well as per specified quantity of the food as suggested for consumption.
(b) The number of grammes of protein, carbohydrate and fat per 100 g of the food as sold as well as per specified quantity of the food as suggested for consumption. In addition, the declaration per 100 calories (or per 100 kilojoules) is permitted.
(c) The total quantity of each vitamin, mineral and any optional ingredient, as listed in Section 3.3.2 of this standard per 100 g of the food as sold as well as per specified quantity of the food as suggested for consumption. In addition, the</td><td>9.3 Declaration of Nutritive Value
The declaration of nutrition information shall contain the following information which should be in the following order:
a) the amount of energy, expressed in kilocalories (kcal) and/or kilojoules (kJ), and the number of grammes of protein, carbohydrate and fat per 100 grammes or per 100 millilitres of the food as sold as well as per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.
b) the total quantity of each vitamin, mineral, choline as listed in paragraph 3.1.3 and any other ingredient as listed in paragraph 3.2 of this Standard per 100 grammes or per 100 millilitres of the food as sold as well as per 100 millilitres of the food ready for use, when prepared according to the instructions on the label.</td></tr>
</table>

declaration per 100 calories (or per 100 kilojoules) is permitted.	c) In addition, the declaration of nutrients in a) and b) per 100 kilocalories (or per 100 kilojoules) is permitted.
There was some support for adopting the 9.3 requirements of the IF Standard for both product categories so that both standards align.	
9.4 Date Marking and Storage Instructions In addition to the declaration of date marking and storage instructions in accordance with Sections 4.7.1 and 4.7.2 of the *General Standard for the Labelling of Prepackaged Foods*, the following provisions apply: **9.4.1** Storage of Opened Food Storage instructions of opened packages of a food for special dietary uses shall be included on the label if necessary to ensure that the opened product maintains its wholesomeness and nutritive value. A warning should be included on the label if the food is not capable of being stored after opening or is not capable of being stored in the container after opening.	**9.4 Date Marking and Storage Instructions** **9.4.1** The date of minimum durability (preceded by the words "best before") shall be declared by the day, month and year in uncoded numerical sequence except that for products with a shelf-life of more than three months, the month and year will suffice. The month may be indicated by letters in those countries where such use will not confuse the consumer. In the case of products requiring a declaration of month and year only, and the shelf-life of the product is valid to the end of a given year, the expression "end (stated year)" may be used as an alternative. **9.4.2** In addition to the date, any special conditions for the storage of the food shall be indicated if the validity of the date depends thereon. Where practicable, storage instructions shall be in close proximity to the date marking.
There was some support for adopting the 9.4 requirements of the IF Standard for both product categories.	
9.5 Information for Utilization **9.5.1** Directions as to the preparation and use of the food, and its storage and keeping after the container has been opened shall appear on the label. **9.5.2** The labelling of a Follow-up Formula shall include a statement that Follow-up Formula shall not be introduced before the 6th month of life. **9.5.3** Information that infants and children fed Follow-up Formula shall receive other foods in addition to the food shall appear on the label.	**9.5 Information for Use** **9.5.1** Products in liquid form may be used either directly or in the case of concentrated liquid products, must be prepared with water that is safe or has been rendered safe by previous boiling before feeding, according to directions for use. Products in powder form should be reconstituted with water that is safe or has been rendered safe by previous boiling for preparation. Adequate directions for the appropriate preparation and handling should be in accordance with Good Hygienic Practice. **9.5.2** Adequate directions for the appropriate preparations and use of the product, including its storage and disposal after preparation, i.e. that formula remaining after feeding should be discarded, shall appear on the label and in any accompanying leaflet. **9.5.3** The label shall carry clear graphic instructions illustrating the method of preparation of the product. **9.5.4** The directions should be accompanied by a warning about the health hazards of inappropriate preparation, storage and use.

	9.5.5 Adequate directions regarding the storage of the product after the container has been opened, shall appear on the label and in any accompanying leaflet.
• The Committee will need to consider if the FUF Standard requires the level of prescription contained within section 9.5 of the IF Standard, and whether different approaches might be required for the different product categories. Some have suggested that follow-up formula for older infants be aligned with the IF requirements. Comment was made that 'indication for use' was important to differentiate between products meant for older infants and those meant for young children, and labelling should avoid any risk of confusion between the two product categories. • Re-word 9.5 title to; Information for [Use] ~~Utilization,~~ to align with the IF Standard **9.5.2**: This provision within the FUF Standard continues to be appropriate for older infants. This provision for follow-up formula for young children could be amended so that it states that product should not be introduced before 12 months of age. **9.5.3**: This provision within the FUF Standard continues to be appropriate for older infants. There was some eWG support for retaining this provision for follow-up formula for young children.	
9.6 Additional Requirements The products covered by this standard are not breast-milk substitutes and shall not be presented as such.	**9.6 Additional Labelling Requirements** **9.6.1** Labels should not discourage breastfeeding. Each container label shall have a clear, conspicuous and easily readable message which includes the following points: a) the words "important notice" or their equivalent; b) the statement "Breast milk is the best food for your baby" or a similar statement as to the superiority of breastfeeding or breast milk; c) a statement that the product should only be used on advice of a independent health worker as to the need for its use and the proper method of use. **9.6.2** The label shall have no pictures of infants and women nor any other picture or text which idealizes the use of infant formula. **9.6.3** The terms "humanized", "maternalized" or other similar terms shall not be used. **9.6.4** Information shall appear on the label to the effect that infants should receive complementary foods in addition to the formula, from an age that is appropriate for their specific growth and development needs, as advised by an independent health worker, and in any case from the age over six months. **9.6.5** The products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula, and formula for special medical purposes.
• Of those eWG members who commented on this section, most supported classifying follow-up formula for older infants as a breast-milk substitute, whereas two thirds of respondents were of the view that follow-up formula for young children is not a breast-milk substitute, but rather a substitute or supplement for cows' milk. Most eWG members who were of the view that both product categories are breast-milk substitutes supported the	

incorporation of the labelling requirements in 9.6 of the IF Standard in to the FUF Standard as a direct consequence of WHA 69.9.

- The Committee will need to consider if section 9.6 of the FUF Standard should be retained for follow-up formula for young children. Alternatively, rather than classifying the product, the Standard could refer to the presentation only and require that follow-up formula for young children shall not be presented as a breast-milk substitute, or presented in a way that may cause confusion and have a negative impact on breastfeeding.
- Re-word title 9.6 to Additional [Labelling] Requirements to align with the IF Standard.

9.6.1/9.6.2/9.6.3: Several eWG members were of the view that these provisions within the IF Standard should also be contained within the FUF Standard, with most who supported this approach being of the view that both product categories should be considered breast-milk substitutes and therefore these provisions would be applicable to both. It was also the view of some that this would align with Recommendation 4 of the WHO Technical Guidance on ending the inappropriate promotion of foods for infants and young children. Others expressed concern with adopting these provisions for follow-up formula for young children. It was thought this could confuse consumers especially if this product is not considered a breast-milk substitute and would therefore not require all provisions in the IF for this product category. There was some support from those who view follow-up formula for young children to be alternative or substitute for cows' milk, that labelling should be presented in a way that does not undermine breastfeeding. The Committee will need to consider this labelling aspect further, as a clear approach was not presented by the eWG.

9.6.4: Whilst this provision within the IF Standard is relevant, particularly for older infants, it is also covered under section 9.5.3 – please see comments above.

9.6.5: It has been suggested that a similar modified statement to that required for IF be modified for the FUF Standard to account for the different names of product categories. Such a statement could read; '*products shall be labelled in such a way as to avoid any risk of confusion between infant formula, follow-up formula for older infants, [name of product] for young children, and formula for special medical purposes'* and would be applicable to all products covered by this Standard. It was suggested that this inclusion in the FUF Standard would assist in meeting Recommendation 5 of the WHO Technical Guidance on ending the inappropriate promotion of foods for infants and young children relating to cross promotion.

Based on the 2016 eWG comments received to the two consultation papers, the Chairs recommend that the Follow-up Formula Standard be divided in to two separate parts, similar to the approach used in the Standard for Infant Formula and Formula for Special Medical Purposes Intended for Infants where Section A refers to Infant Formula, and Section B deals with Formulas for Special Medical Purposes (CODEX STAN 72 – 1981). This recommendation is based on comments from the eWG that product for older infants and product for young children are distinctly different from one another, with the proposal for product for young children to contain a limited number of mandatory nutrients, compared to follow-up formula for older infants which mandates the addition of 32 nutrients. It was considered therefore that product for young children needs to be easily distinguishable from product for older infants so as to avoid confusion about the suitability of individual products for different age groups. Two separate parts to the Standard would allow for different composition and labelling approaches to the two different product categories, and this would possibly assist in being able to easily distinguish the different products and consequent roles in the diet from one another.

Recommendation 20:

That CCNFSDU agree to divide the Standard for Follow-up Formula in to two separate parts as presented in Appendix 5. Section A will refer to the essential composition and labelling of follow-up formula for older infants, and Section B will deal with the essential composition and labelling of product for young children.

6.5 Further evidence to inform the Scope and Labelling Sections

Electronic working group members were asked to provide further evidence that could be used to inform the review of the Scope and Labelling sections. Comment was made that Codex needs to address the issue of consumer confusion as to the appropriate age for introduction of different formula products, and this could be achieved through consideration of distinctly different labelling to be able to easily differentiate between the two products under discussion.

Research from the Helen Keller International Assessment and Research in Child Feeding (ARCH) Project was cited as evidence showing that infant formulas, follow-up formula and growing- up milk products are often labelled with the similar names, labels, designs and colours. The survey by Pereira and colleagues highlights that cross-promotion between three product categories (Infant Formula, Follow-up Formula and Growing Up Milks) is common in four low and middle income countries[84]. On this basis and given strong market growth in low and middle income countries, the authors support global guidance that specifically prohibits their cross-promotion[84]. Further results of the ARCH project have been published in an open access supplement of the Maternal and Child Nutrition Journal (April 2016 – Volume12, Supplement 2).

In addition to the ARCH Project, the following research was provided as evidence of consumer confusion when choosing appropriate formula products for infants and young children. The Infant Feeding Survey 2010 (UK) was cited as evidence that the use of the term 'follow-up formula' in the name, scope, and definition of product implies that both products could be used for infants. The Survey reports that *'most mothers followed the recommendation of not giving their baby follow-on formula before the age of six months (16% had given follow-on formula when their baby was four months old, increasing to 50% at six months). Mothers from routine and manual occupations and mothers who had never worked were more likely than average to say they had given their baby follow-on formula at an earlier age (18% and 27% respectively at four months)'* [85].

Cattaneo et al undertook to assess how follow-on formula milks for older infants are presented to and understood by mothers[86]. The results showed that irrespective of level of education, the majority of pregnant women and mothers *'have little knowledge of the different types of formula for different ages that are available on the market'.* The authors concluded that *'advertisements of follow-on formula are perceived by pregnant women and mothers as promoting infant formula'* [86].

Concerns were expressed by members of the eWG that consumer confusion over the appropriate age and product to feed to infants and young children could potentially lead to significant nutritional consequences (such as nutritional deficiencies) if an inappropriate product was consumed at the wrong age.

A review of role and use of fortified milk-based products in the diets of older infants and young children reported that *'there is some evidence that recommendations for the minimum age of follow-up formula introduction are not always followed'*[87]. The literature review reports that *'Rates of follow-up formula consumption at or before six months of age were reported by eight developed countries and three developing countries. The mean proportion consuming follow-up formula in developed countries was 50% (four to six months), range 11% at five months in Ireland to 90% at six months in Sweden. Developing countries had a mean 18% of children (from birth to six months) consuming follow-up formula, with a range of <10% in Guatemala before six months up to 33% in Ghana at six months'*[87]*.*

7 Definitions

Consideration of the name of the food and definition 2.1.1 has up until now been deferred until sufficient clarity on the composition of product for young children is reached. It is clear from eWG feedback that the majority preference is for two very distinctly different product names to clearly distinguish follow-up formula for older infants from follow-up formula for young children. It has also become apparent that the Name of the Standard, the Name of the Product, Definitions, the Scope and the Labelling sections are all interlinked. It is therefore proposed that definition 2.1.1 is refined as per the ToR, based on information and comments gained from the 2016 eWG.

The ToR ask for the eWG to refine definition 2.1.1 based on the outcomes of the review of the compositional requirements for 6-36 months with a point of differentiation at 12 months.

Definition 2.1.1 of the Follow-up Formula currently reads:

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.

Based on the collective comments of the 2015 eWG, the following draft definition 2.1.1 was proposed for consideration and discussion by the Committee:

> ***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.]*

The majority preference of the 2015 eWG was to have one broad definition for follow-up formula which separated out the different purpose and role of the product in the diet of older infants compared to that of young children (as presented above). It is now proposed that separate definitions for the respective product categories are used as it has become apparent that there is majority support for distinctively different names which are easily distinguishable, based on the diverse roles in the diet that these products play. Many members of the 2016 eWG commented that product for young children should not be considered a 'formula' as this confuses product for young children with formula marketed and suitable for use by infants in the first year of life. It was also proposed that product for young children have a distinctly different name to follow-up formula for older infants, with 'fortified milk product for young children' or 'processed milk for young children' suggested as options for consideration (see Table 2 of 6.4.2 for further detail). The decision made at CCNFSDU37 to use 'product' rather than 'food' as part of definition 2.1.1 has been included in the modified definition below. The title of the Standard should also be changed accordingly, depending on the outcome of discussions relating to product name(s) and definitions.

As a starting point for discussion, the following draft definition 2.1.1 is proposed for Committee's consideration:

> ***[Follow-up formula for older infants*** *means a product intended for use as the liquid part of the diet for older infants when complementary feeding is introduced, and*
>
> ***Fortified milk product/processed milk product for young children/follow-up formula for young children*** *means a product intended for use as a liquid part of the progressively diversified diet when nutrient intakes may not be adequate to meet the nutritional requirements of young children.]*

Other suggestions provided by eWG members for defining product for young children 12 – 36 months included:

- *A supplement to the diet to support adequacy of intakes for nutrients of key global concern for young children.*
- *A liquid part of the diversified complementary diet [to contribute to the nutritional needs of young children] [to address global nutrient inadequacies].*
- *A cows' milk alternative beverage formulated to address global nutritional inadequacies in young children.*

Once a decision about the name of product(s) is agreed to, consequential amendments throughout the Standard will need to be made to reflect this. For example, the definition in section 2.1.2 as presented in REP16/NFSDU (Appendix III Part I) will most likely require modification. At CCNFSDU37, the Committee agreed to retain the definitions in section 2.1.2 and 2.2 at Step 4 until the revision of the other sections were agreed.

Recommendation 21:

The Committee will need to finalise the product definitions (section 2.1.1).

The following definitions have been proposed by the Chairs, taking into account the need to differentiate between product for older infants and young children

***[Follow-up formula for older infants** means a product intended for use as the liquid part of the diet for older infants when complementary feeding is introduced, and* ***[Fortified milk product]** OR **[Processed milk product for young children]** OR **[Follow-up formula for young children]** [means a product intended for use as a liquid part of the progressively diversified diet when nutrient intakes may not be adequate to meet the nutritional requirements of young children.]*

8 Recommendations and work for further consideration

The Agenda paper contains 21 recommendations on the essential composition of follow-up formula for older infants and young children, in addition to the format of the standard and Definitions section.

The Chairs of the eWG are of the view that the Committee has been provided with a significant amount of data to finalise their decisions on the essential composition of follow-up formula for older infants and assist with their decisions on the approach to and essential composition of follow-up formula for young children. The Committee is also in a position to finalise the structure of the standard and refine the definition of 2.1.1.

Based on discussions on the recommendations presented in this paper, the Committee is in a position to agree to key elements of a draft Standard. The Chairs have provided a draft Standard to support discussions at Appendix 5.

8.1 Work for further consideration

8.1.1 Scope and Labelling

With regard to Scope and Labelling the eWG was tasked with:

- *Explore issues for further consideration by CCNFSDU38 on Section 9 (Labelling) to inform the revision of the Sections of the Standard on Scope and Labelling.*

Section 6 of this agenda paper presents the issues raised by members of the eWG regarding Scope and Labelling. The eWG did not undertake an assessment of these issues. It is the task of the Committee to consider the issues raised in the eWG and identify if there are elements regarding Scope and Labelling that can be agreed to in the Committee at CCNFSDU38. The Committee will also need to identify those elements that require further assessment before the Committee is in a position to finalise this section of the standard.

9 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 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.

10 References

1. WHO/FAO/UNU. *Protein and amino acid requirements in human nutrition. Report of a joint WHO/FAO/UNU expert consultation. WHO technical report series, no. 935.* Geneva, Switzerland: WHO; 2007.

2. EFSA (European Food Safety Authority). Scientific opinion on dietary reference values for protein. *EFSA Journal*. 2012;10(2).

3. IOM (Institute of Medicine). *Dietary reference intakes for energy, carbohydrate, fibre, fat, fatty acids, cholesterol, protein and amino acids. food and nutrition board, institute of medicine.* National Academies Press; 2002.

4. Koletzko B, Bhutta ZA, Cai W, et al. Compositional requirements of follow-up formula for use in infancy: Recommendations of an international expert group coordinated by the early nutrition academy. *Ann Nutr Metab*. 2013;62:44-54.

5. EFSA (European Food Safety Authority). Scientific opinion on the essential composition of infant and follow-on formulae. *EFSA Journal*. 2014;12(7):3760.

6. EFSA (European Food Safety Authority). Opinion of the scientific panel on dietetic products, nutrition and allergies (NDA panel) on a request from the commission related to the safety and suitability for particular nutritional use by infants of formula based on whey protein partial hydrolysates with a protein content of at least 1.9 g/100 kcal. *EFSA Journal*. 2005;280(1-16).

7. Abrams SA, Hawthorne KM, Pammi M. A systematic review of controlled trials of lower-protein or energy-containing infant formulas for use by healthy full-term infants. *Adv Nutr*. 2015;6(2):178-188.

8. Patro-Golab B, Zalewski BM, Kouwenhoven SM, et al. Protein concentration in milk formula, growth, and later risk of obesity: A systematic review. *J Nutr*. 2016;146(3):551-564.

9. Koletzko B, von Kries R, Closa R, et al. Lower protein in infant formula is associated with lower weight up to age 2 y: A randomized clinical trial. *Am J Clin Nutr*. 2009;89(6):1836-1845.

10. Weber M, Grote V, Closa-Monasterolo R, et al. Lower protein content in infant formula reduces BMI and obesity risk at school age: Follow-up of a randomized trial. *Am J Clin Nutr*. 2014;99(5):1041-1051.

11. Escribano J, Luque V, Canals-Sans J, et al. Mental performance in 8-year-old children fed reduced protein content formula during the 1st year of life: Safety analysis of a randomised clinical trial. *Br J Nutr*. 2016:1-9.

12. Inostroza J, Haschke F, Steenhout P, Grathwohl D, Nelson SE, Ziegler EE. Low-protein formula slows weight gain in infants of overweight mothers. *J Pediatr Gastroenterol Nutr*. 2014;59(1):70-77.

13. Ziegler EE, Fields DA, Chernausek SD, et al. Adequacy of infant formula with protein content of 1.6 g/100 kcal for infants between 3 and 12 months. *J Pediatr Gastroenterol Nutr*. 2015;61(5):596-603.

14. WHO/FAO. Vitamin and mineral requirements in human nutrition: Report of a joint FAO/WHO expert consultation, Bangkok, Thailand, 21-30 September 1998. . 2004;World Health Organisation and Food and Agriculture Organization of the United Nations.

15. Shearer MJ. Vitamin K deficiency bleeding (VKDB) in early infancy. *Blood Rev*. 2009;23(2):49-59.

16. EFSA (European Food Safety Authority). Scientific opinion on nutrient requirements and dietary intakes of infants and young children in the European Union. *EFSA Journal*. 2013;11(10).

17. MacLean WC, Van Dael P, Clemens R, et al. Upper levels of nutrients in infant formulas: Comparison of analytical data with the revised codex infant formula standard. *Journal of food composition and analysis*. 2010;23(1):44-53.

18. Brenna JT, Varamini B, Jensen RG. Docosahexaenoic acid and arachidonic acid concentrations in human breast milk worldwide. *Am J Clin Nutr*. 2007;85:1457-1464.

19. FAO. Fats and fatty acids in human nutrition: Report of an expert consultation. *Food and Nutrition Paper 91*. 2010.

20. Simmer K, Patole SK, Rao SC. Long-chain polyunsaturated fatty acid supplementation in infants born at term. *Cochrane Database Syst Rev*. 2011;12.

21. Sun H, Como P, Downey L, Murphy D, Ariagno R, Rodriguez W. Infant formula and neurocognitive outcomes: Impact of study end-point selection. *Journal of Perinatology*. 2015.

22. Qawasmi A, Landeros-Weisenberger A, Leckman JF, Bloch MH. Meta-analysis of long-chain polyunsaturated fatty acid supplementation of formula and infant cognition. *Pediatrics*. 2012;129(6):1141-1149.

23. Michaelsen KF, Dewey KG, Perez-Exposito AB, Nurhasan M, Lauritzen L, Ross N. Food sources and intake of n-6 and n-3 fatty acids in low-income countries with emphasis on infants, young children (6–24

months), and pregnant and lactating women.

. *Maternal and Child Nutrition*. 2011;7:S124-S140.

24. Szajewska H, Skórka A, Piescik-Lech M. Fermented infant formulas without live bacteria: A systematic review. *Eur J Pediatr*. 2015;174(11):1413-1420. Accessed 12 June 2016.

25. Labuschagne I, van Niekerk E, Lombard MJ. Acidified infant formula explained. *S Afr Fam Pract*. 2013;55(4):354-356. Accessed 12 June 2016.

26. WHO/FAO. Probiotics in food: Health and nutritional properties and guidelines for evaluation. Report of a joint FAO/WHO working group on drafting guidelines for the evaluation of probiotics in food. *FAO Food and Nutrition Paper 85*. 2006.

27. Mugambi MN, Musekiwa A, Lombard M, Young T, Blaauw R. Synbiotics, probiotics or prebiotics in infant formula for full term infants: A systematic review. *Nutrition journal*. 2012;11(1):1.

28. Braegger C, Chmielewska A, Decsi T, et al. Supplementation of infant formula with probiotics and/or prebiotics: A systematic review and comment by the ESPGHAN committee on nutrition. *J Pediatr Gastroenterol Nutr*. 2011;52(2):238-250.

29. Thomas DW, Greer FR, American Academy of Pediatrics Committee on Nutrition, American Academy of Pediatrics Section on Gastroenterology, Hepatology, and Nutrition. Probiotics and prebiotics in pediatrics. *Pediatrics*. 2010;126(6):1217-1231.

30. The Norwegian Scientific Committee for Food Safety. Assessment of infant formula and follow-on formula supplemented with lactobacillus fermentum CECT 5716. *VKM Report 2014: 03*. 2014.

31. European Commission. Report from the commission to the European parliament and the council on young child formulae. 2016; Brussels 31.3.2016 COM(2016) 169 final; SWD(2016) 99 final.

32. WHO. *Guiding principles for feeding non-breastfed children 6-24 months of age.* Geneva: World Health Organization; 2005.

33. FAO. *Milk and dairy products in human nutrition.* Rome: Food and Agriculture Organization; 2013.

34. Butte N, Cobb K, Dwyer J, Graney L, Heird W, Rickard K. The start healthy feeding guidelines for infants and toddlers. *J Am Diet Assoc*. 2004;104(3):442-454.

35. Suthutvoravut U, Abiodun PO, Chomtho S, et al. Composition of follow-up formula for young children aged 12-36 months: Recommendations of an international expert group coordinated by the nutrition association of Thailand and the Early Nutrition Academy. *Ann Nutr Metab*. 2015;67(2):119-132.

36. WHO. *Guideline: Sugars intake for adults and children.* Geneva: World Health Organization; 2015.

37. FAO. Dietary protein quality evaluation in human nutrition: Report of an FAO expert consultation. *FAO Food and Nutrition Paper 92*. 2013.

38. FAO. Protein quality evaluation: Report of a joint FAO/WHO expert consultation. *FAO Food and Nutrition Paper 51*. 1989.

39. Lewis JL. The regulation of protein content and quality in national and international food standards. *Br J Nutr*. 2012;108(S2):S212-S221.

40. Gibson RS. *Principles of nutritional assessment.* 2nd ed. Oxford University Press; 2005.

41. Huffman SL, Harika RK, Eilander A, Osendarp SJ. Essential fats: How do they affect growth and development of infants and young children in developing countries? A literature review. *Maternal & child nutrition*. 2011;7(s3):44-65.

42. Uauy R, Aro A, Clarke R. WHO scientific update on trans fatty acids: Summary and conclusions. *Eur J Clin Nutr*. 2009;63:S68-S75.

43. de Souza RJ, Mente A, Maroleanu A, et al. Intake of saturated and trans unsaturated fatty acids and risk of all cause mortality, cardiovascular disease, and type 2 diabetes: Systematic review and meta-analysis of observational studies. *BMJ*. 2015;351:h3978.

44. Brouwer IA. *Effects of trans fatty acid intake on blood lipids and lipoproteins: A systematic review and meta-regression analysis.* Geneva: World Health Organization; 2016.

45. Kliem KE, Shingfield KJ, Livingstone KM, Givens DI. Seasonal variation in the fatty acid composition of milk available at retail in the United Kingdom and implications for dietary intake. *Food Chem*. 2013;141(1):274-281.

46. Månsson HL. Fatty acids in bovine milk fat. *Food & nutrition research*. 2008;52.

47. Aro A, Antoine J, Pizzoferrato L, Reykdal O, Van Poppel G. Transfatty acids in dairy and meat products from 14 European countries: The TRANSFAIR study. *Journal of Food Composition and Analysis*. 1998;11(2):150-160.

48. EFSA (European Food Safety Authority). Scientific opinion on dietary reference values for carbohydrates and dietary fibre. *EFSA Journal*. 2010;8(3):1462.

49. European Union. Commission delegated regulation (EU) 2016/127 of 25 september 2015 supplementing regulation (EU) no 609/2013 of the european parliament and of the council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding. *Official Journal of the European Union L25*. 2 February 2016;59:1-29.

50. Black RE, Victora CG, Walker SP, Bhutta ZA. Maternal and child undernutrition and overweight in low-income and middle-income countries. *Lancet*. 2013;382:427-451.

51. WHO. Information concerning the use and marketing of follow-up formula. http://www.who.int/nutrition/topics/WHO_brief_fufandcode_post_17July.pdf.

52. Hernell O, Fewtrell MS, Georgieff MK, Krebs NF, Lönnerdal B. Summary of current recommendations on iron provision and monitoring of iron status for breast-fed and formula fed infants in resource-rich and resource-constrained countries. *The Journal of pediatrics*. 2015;167(4):S40-S47.

53. Walter T, Pino P, Pizarro F, Lozoff B. Prevention of iron-deficiency anemia: Comparison of high-and low-iron formulas in term healthy infants after six months of life. *J Pediatr*. 1998;132(4):635-640.

54. Gill D, Vincent S, Segal D. Follow-on formula in the prevention of iron deficiency: A multicentre study. *Acta Paediatrica*. 1997;86(7):683-689.

55. Morley R, Abbott R, Fairweather-Tait S, MacFadyen U, Stephenson T, Lucas A. Iron fortified follow on formula from 9 to 18 months improves iron status but not development or growth: A randomised trial. *Arch Dis Child*. 1999;81(3):247-252.

56. Daly A, MacDonald A, Aukett A, et al. Prevention of anaemia in inner city toddlers by an iron supplemented cows' milk formula. *Arch Dis Child*. 1996;75(1):9-16.

57. Sazawal S, Dhingra U, Dhingra P, et al. Micronutrient fortified milk improves iron status, anemia and growth among children 1–4 years: A double masked, randomized, controlled trial. *PloS one*. 2010;5(8):e12167.

58. Singhal A, Morley R, Abbott R, Fairweather-Tait S, Stephenson T, Lucas A. Clinical safety of iron-fortified formulas. *Pediatrics*. 2000;105(3):e38-e38.

59. Rivera JA, Shamah T, Villalpando S, Monterrubio E. Effectiveness of a large-scale iron-fortified milk distribution program on anemia and iron deficiency in low-income young children in mexico. *Am J Clin Nutr*. 2010;91(2):431-439.

60. Villalpando S, Shamah T, Rivera JA, Lara Y, Monterrubio E. Fortifying milk with ferrous gluconate and zinc oxide in a public nutrition program reduced the prevalence of anemia in toddlers. *J Nutr*. 2006;136(10):2633-2637.

61. Szymlek-Gay EA, Ferguson EL, Heath AL, Gray AR, Gibson RS. Food-based strategies improve iron status in toddlers: A randomized controlled trial12. *Am J Clin Nutr*. 2009;90(6):1541-1551.

62. IOM (Institute of Medicine). *Dietary reference intakes for vitamin A, vitamin K, arsenic, boron, chromium, copper, iodine, iron, manganese, molybdenum, nickel, silicon, vanadium, and zinc.* Washington DC, USA: National Academies Press; 2001.

63. Hotz C, Brown KH. International zinc nutrition consultative group (IZiNCG) technical document #1: Assessment of the risk of zinc deficiency in populations and options for its control. . 2004;25(1):S91-S202.

64. Butte NF, Fox MK, Briefel RR, et al. Nutrient intakes of US infants, toddlers, and pre-schoolers meet or exceed dietary reference intakes. *J Am Diet Assoc*. 2010;110(12, Supplement):S27-S37.

65. Lind T, Lonnerdal B, Stenlund H, et al. A community-based randomized controlled trial of iron and zinc supplementation in Indonesian infants: Interactions between iron and zinc. *Am J Clin Nutr*. 2003;77::883-90.

66. Benedich A, Langseth L. Safety of vitamin-A. *Am J Clin Nutr*. 1989;49:358-371.

67. Allen LH, Haskell M. Estimating the potential for vitamin A toxicity in women and young children. *Journal of Nutrition*. 2002;132(S2907-S2919).

68. Coghlan D, Cranswick NE. Complementary medicine and vitamin A toxicity in children. *Medical Journal of Australia*. 2001;175(223-224).

69. Hathcock JN, Hattan DG, Jenkins MY, McDonald JT, Sundaresan PR, Wilkening VL. Evaluation of vitamin A toxicity. *Am J Clin Nutr*. 1990;52:183-202.

70. Fomon SJ. *Nutrition of normal infants.* St. Louis, MO, USA: Mosby; 1993.

71. Sandjaja S, Budiman B, Harahap H, et al. Food consumption and nutritional and biochemical status of 0· 5–12-year-old indonesian children: The SEANUTS study. *Br J Nutr*. 2013;110(S3):S11-S20.

72. Poh BK, Ng BK, Haslinda MDS, et al. Nutritional status and dietary intakes of children aged 6 months to 12 years: Findings of the nutrition survey of Malaysian children (SEANUTS Malaysia). *Br J Nutr*. 2013;110(S3):S21-S35.

73. Rojroongwasinkul N, Kijboonchoo K, Wimonpeerapattana W, et al. SEANUTS: The nutritional status and dietary intakes of 0.5-12-year-old Thai children. *Br J Nutr*. 2013;110(S3):S36.

74. Flores M, Macias N, Lozada A, Sanchez LM, Díaz E, Barquera S. Serum 25-hyrdroyvitamin D levels among mexican children aged 2y to 12 y: A national survey. *Nutrition*. 2013;29:802-804.

75. Olang B, Naghavi M, Bastani D, Yngve A. Optimal vitamin A and suboptimal vitamin D status are common in Iranian infants. *Acta Paediatricia*. 2012;15(9):1603-1610.

76. Abdul-Razzak KK, Ajlony MA, Khoursheed AM, Obeidat BA. Vitamin D deficiency among healthy infants and toddlers: A prospective study from Irbid, Jordan. *Pediatrics International*. 2011;53:839-845.

77. WHO. *International code of marketing of breast-milk substitutes.* Geneva: World Health Organization; 1981.

78. WHA. *World health assembly resolution 39.28.* Geneva: World Health Organization; 16 May 1986.

79. WHA. *Fifty-fourth world health assembly (WHA54.2): Agenda item 13.1 infant and young child nutrition.* Geneva: World Health Organization; 18 May 2001.

80. WHA. *Sixty-third world health assembly Agenda item 11.6: Infant and young child nutrition (WHA63.23).* Geneva: World Health Organization; 21 May 2010.

81. WHA. *Sixty-fifth world health assembly: Resolutions and decisions annexes (WHA65/2012/REC/1).* Geneva: World Health Organization; 21-26 May 2012.

82. WHO. Discussion paper: Clarification and guidance on inappropriate promotion of foods for infants and young children. http://www.who.int/nutrition/events/inappropriate-food-promotion-consultation/en/. Updated 2015. Accessed 05/25, 2016.

83. WHO. *Scientific and technical advisory group on inappropriate promotion of foods for infants and young children: Meeting report, 24-25 june 2013, geneva, switzerland.*

http://www.who.int/nutrition/publications/STAGmeeting_report/en/ ed. Geneva: World Health Organization; 2013.

84. Pereira C, Ford R, Feeley AB, Sweet L, Badham J. Cross-sectional survey shows that follow-up formula and growing-up milks are labelled similarly to infant formula in four low and middle income countries. Maternal & Child Nutrition. 2016:12(S2: 91-105).

85. McAndrew F, Thompson J, Fellows L, Large A, Speed M, Renfrew MJ. Infant Feeding Survey 2010. IFF Research. 2012. Accessed online: http://digital.nhs.uk/catalogue/PuB08694/Infant-Feeding-Survey-2010-Consolidated-Report.pdf

86. Cattaneo A, Pani O, Carletti C, Guidetti M, Mutti V, Guidetti C, Knowles A. *Advertisements of follow-on formula and their perception by pregnant women and mothers in Italy.* Arch Dis Child 2014;0:1-6.

87. Watson E, Heath A-L. The role and use of fortified milk-based products in the diets of older infants and young children prepared for the New Zealand Ministry of Primary Industries. 2013. MPI Technical Paper No: 2013/40. Accessed online: http://www.foodsafety.govt.nz/elibrary/industry/fortified-milk-products-children.pdf

APPENDIX 1: Nutrient composition of cows' milk

The nutrient composition of cows' milk has been calculated by the Chairs of the eWG in accordance with the approach used by the FAO in their report *Milk and Dairy Products in Human Nutrition*[3]

The Chairs have extended the calculation to present the nutrient composition of the full range of nutrients per 100 kcal to inform the eWG using the density of cows' milk specified in FAO/INFOODS (Milk, liquid, whole 1.030 g/mL)[4]. The Chairs have used the updated food composition values, where applicable, from the references used in the FAO report[1] and stated in italics below.

In addition to this, as some eWG members have referred to the nutrient composition of both breast milk and semi-skimmed milk in relation to some nutrients, the Chairs have also calculated the contribution of nutrients from semi-skimmed cows' milk, and breast milk.

The FAO report presents the composition of selected nutrients in whole cows' milk per 100 g of milk using data from a range of food composition databases. These food composition databases include:

Full fat cows' milk:

USDA	Food code 01211 "milk, whole, 3.25 percent milk fat, without added vitamin A and vitamin D[5]
UK food composition table (FCT)	Food code 12-316 "whole milk, pasteurized, average (average of summer and winter milk)". *Revised food code 12-596: Milk, whole, pasteurised, average. Average of summer/autumn and winter/spring standardised milk. Analytical data, 1995-1996; and industry data*[6]
Danish FCT	Food code 0156 "milk, whole, conventional (not organic), 3.5 percent fat"[7]. *Revised food code 6* "milk, whole, conventional (not organic), 3.5 percent fat".[8]
New Zealand FCT	food code F1028 "whole milk, pasteurized, average (average of summer and winter milk)" [9]

Reduced fat cows' milk:

USDA	01174 "milk, reduced fat, fluid, 2% milkfat, without added vitamin A and vitamin D"[3]
UK food composition table (FCT)	Food code 12-316 "whole milk, pasteurized, average (average of summer and winter milk)". *Revised food code 12-596: Milk, whole, pasteurised, average. Average of summer/autumn and winter/spring standardised milk. Analytical data, 1995-1996; and industry data*[4]
Danish FCT	Food code 33: "milk, partly skimmed, conventional (not organic), 1.5 % fat[5,6]

[3] FAO. *Milk and dairy products in human nutrition.* Rome: Food and Agriculture Organization; 2013.
[4] FAO/INFOODS. FAO/INFOODS: Density database (version 2.0). http://www.fao.org/infoods/infoods/tables-and-databases/faoinfoods-databases/en/. Updated 2012. Accessed 31 May, 2016.
[5] USDA. USDA national nutrient database for standard reference (release 28, released September 2015, slightly revised May 2016). https://ndb.nal.usda.gov/. Updated 2015. Accessed 31 May, 2016.
[6] Public Health England. McCance and widdowson's composition of foods integrated dataset. . https://www.gov.uk/government/publications/composition-of-foods-integrated-dataset-cofid. Updated March 2015. Accessed 31 May, 2016.
[7] NFI. The official Danish food composition database. Søborg, Denmark, National Food Institute (version 7.01). http://www.foodcomp.dk/v7/fcdb_default.asp. Updated March 2009. Accessed 31 May, 2016.
[8] NFI. Fooddata: Danish food composition database: Fødevaredatabanken, 2015. http://frida.fooddata.dk/index.php?lang=en. Updated 4 December 2015. Accessed 31 May, 2016.
[9] The New Zealand Institute for Plant & Food Research Limited and the Ministry of Health (New Zealand). New Zealand food composition database: FOODfiles 2014 version 01. http://www.foodcomposition.co.nz/foodfiles. Updated 2015. Accessed 31 May, 2016.

New Zealand FCT	Food code F1042. “milk, cow, lite 1.5% fat, fluid, composite[7]

Breast milk: USDA, food code 01107 “milk, human, mature, fluid”[3].

Table 1: Average nutrient composition of breast milk, whole cows’ milk and semi-skimmed milk presented per 100 kcal

Nutrients	**Breast milk**	**Whole cows’ milk (~3.5% fat)**		**Semi-skimmed cows’ milk (1.5-2% fat)**	
	Average	Average	Range	Average	Range
Energy (kcal/100 mL)	70	60	57-61	46	44-49
Protein (g/100kcal)	1.4	5.4	5.2-5.6	7.3	6.6-7.6
Total Fat (g/100kcal)	6.1	5.5	5.2-5.7	3.5	3.1-4.0
SAFA (g/100kcal)	2.8	3.4	3.1-3.7	2.3	1.9-2.5
Lauric acid (g/100kcal)	0.35	0.18	0.13-0.22	0.13	0.11-0.15
Myristic acid (g/100kcal)	0.45	0.53	0.49-0.60	0.35	0.31-0.39
Lauric & myristic acid (% fat)	13	12.8	11.4-14.4	13.1	11.6-14.7
MUFA (g/100kcal)	2.3	1.4	1.3-1.6	0.87	0.66-1.12
Erucic acid (g/100kcal)	-	0	0	0	0
PUFA (g/100kcal)	0.7	0.19	0.13-0.32	0.11	0.07-0.15
LA (mg/100kcal)	-	78	51-106	64	51-72
ALA (mg/100kcal)	-	21	16-26	18	8-23
DHA mg/100kcal)**	0	0	0	0	0
Trans fat (g/100kcal)	-	0.21	0.19-0.24	0.14	0.11-0.15
Trans fat (% fat)	-	3.8	3.5-4.3	2.2	0.1-6.5
Carbohydrates (g/100kcal)	9.6	7.5	7.3-7.8	10.1	9.6-10.5
Total sugar (g/100kcal)	9.6	7.6	7.3-8.3	10.2	9.8-10.5
Lactose (g/100kcal)	-	7.6	7.3-8.3	10.1	9.8-10.5
Vitamins					
Vitamin A (µg RE/100 kcal)	85	60	48-75	44	29-61
Vitamin D (µg /100 kcal)	0.14	0.27	0-0.81	0.18	0-0.72
Vitamin E (mg α-TE/100 kcal)	0.11	0.11	0.10-0.14	0.08	0.06-0.09
Vitamin K (µg/100 kcal)	0.42	0.5	0-1.0	0.13	0-0.4
Thiamin (µg/100 kcal)	19	51	17-75	66	22-98

Riboflavin (µg/100 kcal)	50	342	273-456	451	366-546
Niacin (µg/100 kcal)	245	133	118-146	205	184-218
Vitamin B_6 (µg/100 kcal)	17	67	46-93	68	59-93
Vitamin B_{12} (µg/100 kcal)	0.07	0.8	0.5-1.4	1.2	0.7-2.0
Pantothenic acid (µg/100 kcal)	309	690	540-920	966	708-1478
Folate (µg DFE/100 kcal)	6.9	13	8-17	20	10-25
Vitamin C (mg/100 kcal)	6.9	1.4	0-3.1	1.95	0.4-4.4
Biotin (µg/100 kcal)	-	3.1	2.2-4.0	4.6	2.9-6.3
Minerals					
Iron (mg/100 kcal)	0.04	0.04	0.03-0.06	0.05	0.04-0.06
Calcium (mg/100 kcal)	44	190	184-201	259	240-280
Phosphorous (mg/100 kcal)	19	148	138-153	199	184-210
Magnesium (mg/100 kcal)	4	17	16-18	24	22-25
Sodium (mg/100 kcal)	24	68	64-72	91	85-94
Chloride (mg/100 kcal)	-	145	141-148	194	189-199
Potassium (mg/100 kcal)	70	236	216-251	319	280-339
Manganese (mg/100 kcal)	0.04	0	0	0	0
Iodine (µg/100 kcal)	-	31	9-46	31	10-45
Selenium (µg/100 kcal)	2.5	2.9	1.6-6.1	3.0	1.4-5
Copper (µg/100 kcal)	0.07	0.01	0-0.04	0	0
Zinc (mg/100 kcal)	0.24	0.66	0.56-0.79	0.86	0.76-0.96

APPENDIX 2: Modelling macronutrient content of formula products with an energy density of 65 kcal/100 mL

Table1: Residual carbohydrate content of higher fat products with varying protein levels

Higher fat level		Product 1			Product 2			Product 3			Product 4			Product 5		
	Unit	100 kcal	300 mL	% E	100 kcal	300 mL	% E	100 kcal	300 mL	% E	100 kcal	300 mL	% E	100 kcal	300 mL	% E
Fat	g	5.5	10.7	48	5.5	10.7	48	5.5	10.7	48	5.5	10.7	48	5.5	10.7	48
Protein	g	1.5	2.9	6	2.5	4.9	10	3.5	6.8	14	4.5	8.8	18	5.5	10.7	22
Carbohydrate	g	11.5	22.5	46	10.5	20.5	42	9.5	18.6	38	8.5	16.6	34	7.5	14.7	30

Table 2: Residual carbohydrate content of moderate fat products with varying protein levels

Moderate fat level		Product 6			Product 7			Product 8			Product 9			Product 10		
	Unit	100 kcal	300 mL	% E	100 kcal	300 mL	% E	100 kcal	300 mL	% E	100 kcal	300 mL	% E	100 kcal	300 mL	% E
Fat	g	4.5	8.8	39	4.5	8.8	39	4.5	8.8	39	4.5	8.8	39	4.5	8.8	39
Protein	g	1.5	2.9	6	2.5	4.9	10	3.5	6.8	14	4.5	8.8	18	5.5	10.7	22
Carbohydrate	g	13.7	26.7	55	12.7	24.8	51	11.7	22.8	47	10.7	20.9	43	9.7	18.9	39

Table 3: Residual carbohydrate content of low fat products with varying protein levels

Lower fat level		Product 11			Product 12			Product 13			Product 14			Product 15		
	Unit	100 kcal	300 mL	% E	100 kcal	300 mL	% E	100 kcal	300 mL	% E	100 kcal	300 mL	% E	100 kcal	300 mL	% E
Fat	g	3.5	6.8	30	3.5	6.8	30	3.5	6.8	30	3.5	6.8	30	3.5	6.8	30
Protein	g	1.5	2.9	6	2.5	4.9	10	3.5	6.8	14	4.5	8.8	18	5.5	10.7	22
Carbohydrate	g	15.9	31.0	64	14.9	29.0	60	13.9	27.1	56	12.9	25.1	52	11.9	23.2	48

Table 4: Residual fat content of formula with varying protein levels and a maximum carbohydrate level of 12 mg/100 kcal

High carbohydrate		Product 16			Product 17			Product 18			Product 19			Product 20		
	Unit	100 kcal	300 mL	% E	100 kcal	300 mL	% E	100 kcal	300 mL	% E	100 kcal	300 mL	% E	100 kcal	300 mL	% E
Fat	g	5.3	10.3	46	4.8	9.4	42	4.4	8.5	38	3.9	7.6	34	3.4	6.7	30
Protein	g	1.5	2.9	6	2.5	4.9	10	3.5	6.8	14	4.5	8.8	18	5.5	10.7	22
Carbohydrate	g	12.0	23.4	48	12.0	23.4	48	12.0	23.4	48	12.0	23.4	48	12.0	23.4	48

Table 5: Residual fat content of formula with varying protein levels and a low carbohydrate level of 7.5 mg/100 kcal

Low carbohydrate		Product 21			Product 22			Product 23			Product 24			Product 25		
	Unit	100 kcal	300 mL	% E	100 kcal	300 mL	% E	100 kcal	300 mL	% E	100 kcal	300 mL	% E	100 kcal	300 mL	% E
Fat	g	7.4	14.3	64	6.9	13.4	60	6.4	12.6	56	6.0	11.7	52	5.5	10.8	48
Protein	g	1.5	2.9	6	2.5	4.9	10	3.5	6.8	14	4.5	8.8	18	5.5	10.7	22
Carbohydrate	g	7.5	14.6	30	7.5	14.6	30	7.5	14.6	30	7.5	14.6	30	7.5	14.6	30

APPENDIX 3: Summary of Scientific Evidence used to inform the WHO Technical Guidance Document on Ending the Inappropriate Promotion of Foods for Infants and Young Children

The STAG reviewed a number of scientific reports as part of their deliberations. Key documents and a synopsis of some of the most relevant findings are below:

1. Assessment & Research on Child Feeding (ARCH) Project[10]

In 2013-2014, Helen Keller International investigated how food products for infants and young children are promoted in Cambodia, Nepal, Senegal, and Tanzania. Key results from the ARCH studies included:

- Snack foods (including cookies, candy, chips, or cakes):
    - Consumption of snack foods was high in Nepal (74%), Senegal (59%), and Cambodia (55%), based on 24-hour recall.
    - Reported exposure to promotion of snack foods was very high—46% in Tanzania, above 80% in the other three countries.
- Breast-milk substitutes:
    - Consumption of breast-milk substitutes among one-year old children was high in Cambodia (24%) and Senegal (19%), based on 24-hour recall.
    - Mothers' reported exposure to promotion of breast-milk substitutes was high in Cambodia (86%), Senegal (41%), and Nepal (28%).
    - Of all television ads for foods for infants and young children in Cambodia, 96% were for breast-milk substitutes—most of these were for growing-up milks.
    - About one-third of stores in Cambodia and Senegal had promotions of breast-milk substitutes, with more promotions for growing up milks than any other BMS. Promotions were typically displays or posters and were created by the manufacturer/distributer rather than the store itself.
    - Cross-promotion of infant formula was common. Of all the products labelled for children over 12 months of age in all four countries:
        - 51% used the word "formula" on the label.
        - 38% used images of bottles with teats
        - 84% used similar or same colour schemes or designs as the manufacturer's infant formula
        - 84% used a similar or same name as the manufacturer's infant formula
        - 67% used similar or the same slogans, mascots or symbols as the manufacturer's infant formula
- Commercially produced complementary foods:
    - Over a quarter of mothers reported seeing promotions for commercial complementary foods on television in Cambodia and Senegal. Promotions in stores or health facilities were less common.
    - Two-thirds of stores in Senegal had promotions of commercially produced complementary foods.
    - Labels for commercially produced complementary foods with recommended introduction earlier than 6 months were common in Senegal (20%), Nepal (13%), and Tanzania (12%). Lack of information on age of introduction was also common in Cambodia (30%) and Tanzania (19%).

2. Euromonitor International Consulting studies on global marketing of breast-milk substitutes[11]

To understand the market for breast-milk substitutes, WHO commissioned analyses from Euromonitor International Consulting to analyse data from 16 large high- and middle-income countries in the Global Infant Formula Data File. Key findings included:

[10] See http://www.hki.org/assessment-research-child-feeding-arch-project#.VuBZGyvF8-I. (accessed 9 March 2016)
[11] Rollins N, et al. Why invest, and what it will take to improve breastfeeding practices? *Lancet* 2016; 387: 491–504 and accompanying online appendices http://www.thelancet.com/cms/attachment/2047468707/2057986230/mmc1.pdf .

- In 2014, total sales of all breast-milk substitutes were about US$44·8 billion.
- By 2019, the market value is projected to reach $70·6 billion.
- Growth of the breast-milk substitutes market in Western Europe, Australasia, and North America from 2014 to 2019 is projected to be about 1%. The corresponding increase in the Middle East and Africa is expected to be more than 7% and in the Asia Pacific it is expected to be more than 11%.
- In 2014, the total volume of toddler milks sold in 2014 (1.19 million tonnes) exceeded the total volume of infant formula (0.59 million tonnes) and follow-up formula (0.55 million tonnes) combined.
- Toddler milks is the fastest growing category of breast-milk substitutes, with 8.6% growth per year (measured as kg per capita).

3. Euromonitor International Consulting studies in Europe and Latin America[12]

To expand upon the results from Helen Keller International in Africa and Asia specifically related to marketing of commercially produced complementary foods (not including breast-milk substitutes), WHO contracted with Euromonitor International Consulting to analyse data from seven countries in Latin America and 19 countries in western Europe. The analysis included three type of food products: dried baby food (mostly cereals), prepared baby food (including pureed food, yoghurts, desserts, or soup), and other baby food (including rusks, teething biscuits, and baby fruit juices). Euromonitor then conducted store audits in Brazil and Norway to identify baby food products being sold and selected 20 products for in-depth evaluation of marketing strategies. Brazil and Norway were selected for these in-depth evaluations on the basis of having large markets, relatively fast projected growth rates, and a mixture of both dried and prepared baby foods. Key findings included:

- Per capita sales of baby foods varied greatly by country, with sales per child 0-36 months ranging from over $500 annually in Norway, Sweden and Italy to less than $40 annually in Mexico, Argentina, and Peru. Sales were lower in nearly all the Latin American countries compared to the European countries.
- In a majority of countries, sales of prepared baby foods dominated the market with more than half of sales, although in some countries sales of prepared baby foods were greater (Bulgaria, Croatia, Greece, Denmark, Venezuela, Brazil, Chile, and Argentina).
- In most countries, over 80% of the market share of baby food sales is controlled by three or fewer companies.
- The baby food market is projected to grow by 14.6% per year in the next five years in Brazil and by 16.7% in Norway.
- In Brazil:
    - Social Media is used to reach consumers because restrictions on promotion do not cover social media. TV and radio are not widely used for promotion.
    - Health claims are common, including aiding digestion, helping baby to grow and learn and strengthening the immune system.
    - Many products do not specify age of use. Complementary foods are sometimes marketed for use before 6 months.
    - Leading company (with 92% market share) invests heavily on merchandising, brand coverage within a display or presence in different aisles of an outlet and premium positioning.
- In Norway:
    - Social media is a growing platform for promotion and discussion of products.
    - Products exist which market complementary food to infants less than 6 months.
    - Health and structural claims on products are uncommon, but some examples include claims of aiding digestion and helping infant's get a good night's sleep.
    - Recommendation that breast-milk is best for children is inconsistently used across all complementary food types aimed at 0-2 year olds.

[12] See http://www.who.int/nutrition/topics/CF_babyfood_trends_brazilandnorway_euromonitor.pdf?ua=1 (accessed 11 March 2016).

- Manufacturers regularly promote campaigns in supermarkets for baby and children food products, particularly when it comes to the launch of new products.

4. Systematic review on the health effects of commercially-available complementary foods[13]

WHO commissioned a systematic literature review to determine what health and dietary effects (both positive and negative) could be attributed to the consumption or marketing of commercially-available complementary foods. Researchers at the University of North Carolina examined questions on replacement of breast-milk intake, risk of obesity and chronic diseases, nutrient composition of the diet, portion sizes, and nutritional status. Both randomized control trials and observational studies were included. Study quality was examined using the GRADE framework. Key findings included:

- Commercially-available complementary foods are highly heterogeneous, being formulated in different ways to meet needs of different target consumers and their predominant nutritional and health risks. They vary substantially in energy and nutrient density. Differences may reflect whether a product is designed to be the main weaning food consumed or to be part of a highly varied diet with numerous products included.
- There is low quality evidence that commercially-available complementary foods do not displace breast-milk after 6 months of age, but their consumption is associated with shorter duration of breastfeeding. However, studies suggest that breast-milk intake is sensitive to energy density and feeding frequency of the complementary foods used.
- There is moderate quality evidence that high protein intake is associated with increased child BMI in an industrialized setting.
- There is moderate quality evidence that animal source food does not increase fat mass in a LMIC setting.
- There is very low quality evidence suggesting that milk cereal drink is associated with child overweight status.
- There is little evidence of either the inferiority or superiority of commercially-available complementary foods owing to high heterogeneity in the types of foods compared, and low quality methods of infant dietary assessment. Some commercially-available complementary foods were nutritionally superior to home-prepared or local foods, while the converse was true for others.
- No evidence was found on whether the portion sizes of commercially-available complementary foods are appropriate.
- While there has been extensive research on how complementary feeding relates to infant nutritional status, there is no evidence that commercially available products specifically reduce the risk of stunting, anemia, or micronutrient deficiencies.

5. Review of the effects of marketing of commercially available complementary foods on infant and young child feeding[14]

WHO commissioned a literature review on the effects of marketing of commercially available complementary food and drink products on the feeding attitudes and behaviours of their caregivers. The review also included analysis of previous reviews on the effects of marketing of other products, including child-oriented food products, pharmaceutical products, breast-milk substitutes, alcohol, and tobacco or tobacco-related products. Researchers at the Australian National University conducted the reviews. Studies from academia (75 studies) and industry (22 studies) were examined, but kept separate in the analyses. The reviewers assessed quality of the studies examined but did not apply the GRADE framework because of the diverse nature of the literature. Key findings included:

- Out of 53 academic studies that assessed the influence of marketing on infant and young child feeding (IYCF), 34 studies found effects classified as 'harmful' (i.e. moving away from optimal IYCF), 11 studies

[13] Tzioumis E, Kay M, Wright M, Adair L. Health effects of commercially-available complementary foods: a systematic review, 2015. See http://www.who.int/nutrition/topics/CF_health_effects_commercially_systematicreview.pdf?ua=1 (accessed 11 March 2016)

[14] Smith JP, Sargent GM, Mehta K, James J, Berry N, Koh C, Salmon L, Blake M. A rapid evidence assessment: Does marketing of commercially available complementary foods affect infant and young child feeding? 2015. See http://www.who.int/nutrition/topics/CF_anu_effects_marketingcommercial.pdf?ua=1 (accessed 11 March 2016).

found positive effects (i.e. moving towards optimal IYCF), and eight were classified as mixed or ambiguous.

- "Harmful" effects included:
    - Reduction in exclusive breastfeeding (25 studies vs. 4 studies showing no harmful effects or ambiguous result)
    - Reduction in the duration of breastfeeding (22 studies vs. 1 study showing no harmful effect)
    - Excessive nutrients, particularly excessive sugar, salt, or fats (5 studies vs. 4 studies showing no harmful effect or ambiguous result)
- Positive effects included:
    - Timely introduction good quality complementary foods (2 studies vs. 3 studies showing no positive effect or ambiguous result)
    - More nutrients in complementary previously inadequate in the diet (10 studies vs. 4 with no positive effect or ambiguous result)
- Fifty studies examined the effect of marketing on attitudinal outcomes. Of these, 37 demonstrated effects that were categorized as "harmful," 5 studies found positive effects, and eight were classified as mixed or ambiguous. Effects included:
    - Confusion among caregivers about nutrition- and health-related qualities of commercially available complementary foods.
    - Confusion about age-appropriate and safe use
    - Concerns among mothers about the comparative nutritional value of breast-milk and breastfeeding or home-prepared CF foods.
- Examination of 16 systematic reviews of studies describing the impact of marketing of tobacco, alcohol, pharmaceutical products, food and beverage marketing to children, and breast-milk substitutes yielded several relevant findings:
    - Product packaging is an important component of marketing communications and is invested in highly by marketers.
    - Sponsorship activities in schools and sport settings are dominated by food corporations.
    - Endorsement by celebrities and children's characters is a prevalent technique used to market foods and beverages.

Marketing of pharmaceutical products largely uses visits by sales representative, journal advertisements, sponsorship of professional meetings and clinical trials, mailed information, and provision of prescribing software.

APPENDIX 4: SIXTY-NINTH WORLD HEALTH ASSEMBLY WHA69.9

Agenda item 12.1 **28 May 2016**

Ending inappropriate promotion of foods for infants and young children

The Sixty-ninth World Health Assembly,

Having considered the reports on maternal, infant and young child nutrition;[1]

Recalling resolutions WHA33.32 (1980), WHA34.22 (1981), WHA35.26 (1982), WHA37.30 (1984), WHA39.28 (1986), WHA41.11 (1988), WHA43.3 (1990), WHA45.34 (1992), WHA46.7 (1993), WHA47.5 (1994), WHA49.15 (1996), WHA54.2 (2001), WHA55.25 (2002), WHA58.32 (2005), WHA59.21 (2006), WHA61.20 (2008) and WHA63.23 (2010) on infant and young child nutrition, appropriate feeding practices and related questions;

Further recalling resolution WHA65.6 (2012) on maternal, infant and young child nutrition, in which the Health Assembly requested the Director-General to provide guidance on the inappropriate promotion of foods for infants and young children cited in resolution WHA63.23;

Convinced that guidance on ending the inappropriate promotion of foods for infants and young children is needed for Member States, the private sector, health systems, civil society and international organizations;

Reaffirming the need to promote exclusive breastfeeding practices in the first 6 months of life, and the continuation of breastfeeding up to 2 years and beyond, and recognizing the need to promote optimal complementary feeding practices for children from ages 6−36 months based on WHO[2] and FAO dietary guidelines and in accordance with national dietary guidelines;

Recognizing that the Codex Alimentarius Commission is an intergovernmental body which is the principal organ of the joint FAO/WHO food standards programme and that it is the appropriate body for establishing international standards on food products, and that reviews of Codex standards and guidelines should give full consideration to WHO guidelines and recommendations, including the International Code of Marketing of Breast-milk Substitutes and relevant Health Assembly resolutions,

1. WELCOMES with appreciation the technical guidance on ending the inappropriate promotion of foods for infants and young children;

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[1] Documents A69/7 and A69/7 Add.1.

[2] Pan American Health Organization, World Health Organization. Guiding principles for complementary feeding of the breastfed child. Washington (DC): Pan American Health Organization; 2003; Guiding principles for feeding non-breastfed children 6−24 months of age. Geneva: World Health Organization; 2005.

WHA69.9

2. URGES Member States[1,2,3] in accordance with national context;

(1) to take all necessary measures in the interest of public health to end the inappropriate promotion of foods for infants and young children, including, in particular, implementation of the guidance recommendations while taking into account existing legislation and policies, as well as international obligations;

(2) to establish a system for monitoring and evaluation of the implementation of the guidance recommendations;

(3) to end inappropriate promotion of food for infants and young children, and to promote policy, social and economic environments that enable parents and caregivers to make well informed infant and young child feeding decisions, and further support appropriate feeding practices by improving health and nutrition literacy;

(4) to continue to implement the International Code of Marketing of Breast-milk Substitutes and WHO recommendations on the marketing of foods and non-alcoholic beverages to children;

3. CALLS UPON manufacturers and distributors of foods for infants and young children to end all forms of inappropriate promotion, as set forth in the guidance recommendations;

4. CALLS UPON health care professionals to fulfil their essential role in providing parents and other caregivers with information and support on optimal infant and young child feeding practices and to implement the guidance recommendations;

5. URGES the media and creative industries to ensure that their activities across all communication channels and media outlets, in all settings and using all marketing techniques, are carried out in accordance with the guidance recommendations on ending the inappropriate promotion of foods for infants and young children;

6. CALLS UPON civil society to support ending inappropriate promotion of foods for infants and young children, including activities to advocate for, and monitor, Member States' progress towards the guidance's aim;

7. REQUESTS the Director-General:

(1) to provide technical support to Member States in implementing the guidance recommendations on ending the inappropriate promotion of foods for infants and young children and in monitoring and evaluating their implementation;

(2) to review national experiences with implementing the guidance recommendations in order to build the evidence on their effectiveness and consider changes, if required;

(3) to strengthen international cooperation with relevant United Nations funds, programmes and specialized agencies and other international organizations, in promoting national action to

(4) to report on implementation of the guidance recommendations on on ending the inappropriate promotion of foods for infants and young children as part of the report on progress in implementing the comprehensive implementation plan on maternal, infant and young child nutrition to the Seventy-first and Seventy-third World Health Assemblies in 2018 and 2020, respectively.

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[1] And, where applicable, regional economic integration organizations.

[2] Taking into account the context of federated States.

[3] Member States could take additional actions to end inappropriate promotion of foods for infants and young children.

end the inappropriate promotion of foods for infants and young children, taking into consideration the WHO guidance recommendations;

Eighth plenary meeting, 28 May 2016
A69/VR/8

SIXTY-NINTH WORLD HEALTH ASSEMBLY **A69/7 Add.1**
Provisional agenda item 12.1 **13 May 2016**

Maternal, infant and young child nutrition
Guidance on ending the inappropriate promotion of foods for infants and young children

Report by the Secretariat

PURPOSE

8. The purpose of this document is to provide guidance on ending the inappropriate promotion of foods for infants and young children, with the aim to promote, protect and support breastfeeding, prevent obesity and noncommunicable diseases, promote healthy diets, and ensure that caregivers receive clear and accurate information on feeding.

SCOPE

9. The term "foods" is used in this guidance to refer to both foods and beverages (including complementary foods). Guidance on the inappropriate promotion of breast-milk substitutes is contained in the Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions. The current document does not replace any provisions in the Code but clarifies the inclusion of certain products that should be covered by the Code and subsequent resolutions.

10. This guidance applies to all commercially produced foods that are marketed as being suitable for infants and young children from the age of 6 months to 36 months. Products are considered to be marketed as being suitable for this age group if they (a) are labelled with the words "baby", "infant," "toddler" or "young child"; (b) are recommended for introduction at an age of less than 3 years;

(c) have a label with an image of a child who appears to be younger than 3 years of age or feeding with a bottle; or (d) are in any other way presented as being suitable for children under the age of 3 years. This approach is in line with the relevant Codex guidelines and standards on foods for infants and young children that refer to young children up to the age of 3 years.[1]

11. This guidance is not applicable to vitamin and mineral food supplements and home-fortification products such as micronutrient powders and small-quantity lipid-based nutrient supplements. Although such supplements and products are often classified as foods for regulatory purposes, they are

[1] Codex guidelines on formulated complementary foods for older infants and young children (CAC/GL-8-1991, revised in 2013); Codex standard for processed cereal-based foods for infants and young children (Codex/STAN 074-1981, revised in 2006); Codex standard for canned baby foods (CODEX STAN 73-1981); and Codex standard for follow-up formula (CODEX STAN 156-1987). not foods per se, but fortification products. Many of the principles contained in this guidance, including those concerning adherence to national and global standards for nutrient levels, safety and quality and to prohibitions on any messages indicating their use for infants under 6 months of age, should nevertheless be applied to such products.

12. The promotion of foods for infants and young children occurs through government programmes, non-profit organizations and private enterprises. This guidance is applicable in all these settings, as the principles it contains are important regardless of who is responsible for the promotion.

DEFINITIONS

13. Foods for infants and young children are defined as commercially produced food or beverage products that are specifically marketed as suitable for feeding children up to 36 months of age.

14. Marketing means product promotion, distribution, selling, advertising, product public relations and information services.

15. Promotion is broadly interpreted to include the communication of messages that are designed to persuade or encourage the purchase or consumption of a product or raise awareness of a brand. Promotional messages may be communicated through traditional mass communication channels, the Internet and other marketing media using a variety of promotional methods. In addition to promotional techniques aimed directly at consumers, measures to promote products to health workers or to consumers through other intermediaries are included. There does not have to be a reference to a brand name of a product for the activity to be considered as advertising or promotion.

16. Cross-promotion (also called brand crossover promotion or brand stretching) is a form of marketing promotion where customers of one product or service are targeted with promotion of a related product. This can include packaging, branding and labelling of a product to closely resemble that of another (brand extension). In this context, it can also refer to use of particular promotional activities for one product and/or promotion of that product in particular settings to promote another product.

RECOMMENDATIONS

17. **Recommendation 1.** Optimal infant and young child feeding should be promoted based on the Guiding principles for complementary feeding of the breastfed child[1] and the Guiding principles for feeding non-breastfed children 6–24 months of age.[2] Emphasis should be placed on the use of suitable, nutrient-rich, home-prepared, and locally available foods that are prepared and fed safely.[3]

18. **Recommendation 2.** Products that function as breast-milk substitutes should not be promoted. A breast-milk substitute should be understood to include any milks (or products that could be used to not foods per se, but fortification products. Many of the principles contained in this guidance, including replace milk, such as fortified soy milk), in either liquid or powdered form, that are specifically marketed for feeding infants and young children up to the age of 3 years (including follow-up formula and growing-up milks). It should be clear that the implementation of the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions covers all these products.

19. **Recommendation 3.** Foods for infants and young children that are not products that function as breast-milk substitutes should be promoted only if they meet all the relevant national, regional and global standards for composition, safety, quality and nutrient levels and are in line with national dietary guidelines. Nutrient profile models should be developed and utilized to guide decisions on which foods are inappropriate for promotion. Relevant Codex standards and guidelines[1] should be updated and additional guidelines developed in line with WHO's guidance to ensure that products are appropriate for infants and young children, with a particular focus on avoiding the addition of free sugars and salt.

20. **Recommendation 4.** The messages used to promote foods for infants and young children

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[1] PAHO and WHO. Guiding principles for complementary feeding of the breastfed child. 2003. http://www.who.int/maternal_child_adolescent/documents/a85622/en/ (accessed 25 November 2015).

[2] WHO. Guiding principles for feeding non-breastfed children 6–24 months of age. 2005 http://www.who.int/maternal_child_adolescent/documents/9241593431/en/ (accessed 25 November 2015).

[3] See WHO/UNICEF. Global strategy for infant and young child feeding, Geneva. 2003. http://apps.who.int/iris/bitstream/10665/42590/1/9241562218.pdf?ua=1&ua=1 (accessed 25 November 2015).

should support optimal feeding and inappropriate messages should not be included. Messages about commercial products are conveyed in multiple forms, through advertisements, promotion and sponsorship, including brochures, online information and package labels. Irrespective of the form, messages should always:

(1) include a statement on the importance of continued breastfeeding for up to two years or beyond and the importance of not introducing complementary feeding before 6 months of age;

(2) include the appropriate age of introduction of the food (this must not be less than 6 months);

(3) be easily understood by parents and other caregivers, with all required label information being visible and legible.

21. Messages should not:

(1) include any image, text or other representation that might suggest use for infants under the age of 6 months (including references to milestones and stages);

(2) include any image, text or other representation that is likely to undermine or discourage breastfeeding, that makes a comparison to breast-milk, or that suggests that the product is nearly equivalent or superior to breast-milk;

(3) recommend or promote bottle feeding;

(4) convey an endorsement or anything that may be construed as an endorsement by a professional or other body, unless this has been specifically approved by relevant national, regional or international regulatory authorities.

22. **Recommendation 5.** There should be no cross-promotion to promote breast-milk substitutes indirectly via the promotion of foods for infants and young children.

(1) The packaging design, labelling and materials used for the promotion of complementary foods must be different from those used for breast-milk substitutes so that they cannot be used in a way that also promotes breast-milk substitutes (for example, different colour schemes, designs, names, slogans and mascots other than company name and logo should be used).

(2) Companies that market breast-milk substitutes should refrain from engaging in the direct or indirect promotion of their other food products for infants and young children by establishing relationships with parents and other caregivers (for example through baby clubs, social media groups, childcare classes and contests).

23. **Recommendation 6.** Companies that market foods for infants and young children should not create conflicts of interest in health facilities or throughout health systems. Health workers, health systems, health professional associations and nongovernmental organizations should likewise avoid such conflicts of interest. Such companies, or their representatives, should not:

(1) provide free products, samples or reduced-price foods for infants or young children to families through health workers or health facilities, except:

- as supplies distributed through officially sanctioned health programmes. Products distributed in such programmes should not display company brands;

(2) donate or distribute equipment or services to health facilities;

(3) give gifts or incentives to health care staff;

(4) use health facilities to host events, contests or campaigns;

(5) give any gifts or coupons to parents, caregivers and families;

(6) directly or indirectly provide education to parents and other caregivers on infant and young child feeding in health facilities;

(7) provide any information for health workers other than that which is scientific and factual;

(8) sponsor meetings of health professionals and scientific meetings.

24. Likewise, health workers, health systems, health professional associations and nongovernmental

organizations should not:

(1) accept free products, samples or reduced-price foods for infants or young children from companies, except:

- as supplies distributed through officially sanctioned health programmes. Products distributed in such programmes should not display company brands;

(2) accept equipment or services from companies that market foods for infants and young children;

(3) accept gifts or incentives from such companies;

(4) allow health facilities to be used for commercial events, contests or campaigns;

(5) allow companies that market foods for infants and young children to distribute any gifts or coupons to parents, caregivers and families through health facilities;

(6) allow such companies to directly or indirectly provide education in health facilities to parents and other caregivers;

(7) allow such companies to sponsor meetings of health professionals and scientific meetings.

Recommendation 7. The WHO set of recommendations on the marketing of foods and non- alcoholic beverages to children[1] should be fully implemented, with particular attention being given to ensuring that settings where infants and young children gather are free from all forms of marketing of foods high in saturated fats,[2] *trans*-fats, free sugars or salt. While foods marketed to children may not be specifically intended for infants and young children, they may, nevertheless, be consumed by them. A range of strategies should be implemented to limit the consumption by infants and young children of foods that are unsuitable for them.

APPENDIX 5: Proposed revised draft standard for Follow-up Formula

STANDARD FOR FOLLOW-UP FORMULA [FOR OLDER INFANTS] AND [(NAME OF PRODUCT) FOR YOUNG CHILDREN]

CODEX STAN 156-1987

(Un-bracketed text at Step 4, text in square brackets for further discussion)

[**PREAMBLE**

This Standard is divided into two sections. Section A refers to Follow-up Formula for Older Infants, and Section B deals with (Name of Product) for Young Children.]

[1. SCOPE *(Sections 1.1 and 1.2 to be tailored as appropriate for the two product categories)*

1.1 Section A of this Standard applies to the compositional, safety and labelling requirements of follow-up formula for older infants.

1.1.1 The application of Section A of this Standard should take in to account the recommendations made in the …….. *(Include WHO documents, and WHA resolutions – if deemed relevant and appropriate)*

1.1.2

1.2 Section B of this Standard applies to the compositional, safety and labelling of (name of product) for young children.

1.2.1 The application of Section B of this Standard should take in to account the recommendations made in the …….. *(Include WHO documents, and WHA resolutions – if deemed relevant and appropriate)*

1.2.2]

2. DESCRIPTION

2.1 Product Definition

2.1.1 **[*Follow-up formula for older infants*** *means a product intended for use as the liquid part of the diet for older infants when complementary feeding is introduced.]*

[*Follow-up formula for young children*] OR **[*Fortified milk product*]** OR **[*Processed milk product*] *for young children for young children*** *means a product intended for use as a liquid part of the progressively diversified diet when nutrient intakes may not be adequate to meet the nutritional requirements of young children.]*

2.1.2 **Follow-up formula [for older infants and (name of product) for young children** [~~is~~] [are] 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.

2.2 Other Definitions

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

2.2.2 The term **older infants** means a person 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).

SECTION A: FOLLOW-UP FORMULA FOR OLDER INFANTS

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

3.1 Essential composition

3.1.1 **Follow-up formula [for older infants** is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be safe and suitable for the feeding of older infants [~~and young children~~.]

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

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**] or [1.65][5),6)]	[3.5] or [**3.0**] or [2.5]	-
g/100 kJ	[**0.43**] or [0.39] [5),6)]	[0.84] or [**0.72**] or [0.60]	-

[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 Codex Standard for Infant Formula (CODEX STAN 72-1981)]**); nevertheless for calculation purposes the concentrations of tyrosine and phenylalanine may be added together and the concentrations of methionine and cysteine may be added together.

[4)] Isolated amino acids may be added to 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 follow-up formula based on non-cows' milk protein other minimum values may need to be applied. For follow-up formula based on soy protein isolate, a minimum value of [2.25 g/100 kcal (0.5 g/100 kJ)] applies.

[[6)] ~~Follow-up formula based on non-hydrolysed milk protein containing less than [2 g protein/100 kcal] and]~~ follow-up [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 infant 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/ α-Linolenic acid

Min	Max
5:1	15:1

c) Carbohydrates

Available 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. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source, and provided the sum of these does not exceed 20% of available 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[12] /100 kcal	0.5 [13]	-	5
mg α-TE[12] /100 kJ	0.12 [13]	-	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	[1] or **[4]**	-	27
µg /100 kJ	[0.24] or **[1.0]**	-	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	[4] or **[10]**	-	70[16)]
mg /100 kJ	[1] or **[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	-

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

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[18)]
mg /100 kJ	6	-	24[18)]

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	1.0	-	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[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 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] or **[1.5]**
mg /100 kJ	0.12	-	[0.24] or **[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 to follow-up formula for older infants where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.

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

3.3.2.3 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 competent national and/or regional 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. Competent national and/or regional authorities may deviate from the above conditions, as appropriate for the nutritional needs.

Choline

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	-	50
mg /100 kJ	-	-	12

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 **for the purpose of producing acidified follow-up formula for older infants**.]

[**3.3.2.5 The safety and suitability of the addition of specific strains of L(+) lactic acid producing cultures for particularly nutritional purposes, at the level of use, shall be demonstrated by generally accepted scientific evidence. When added for this purpose, the final product ready for consumption shall contain sufficient amounts of viable bacteria to achieve the intended effect**.]

SECTION B: (NAME OF PRODUCT) FOR YOUNG CHILDREN

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Essential composition

3.1.1 **(Name of product) for young children** is a product based on milk of cows or other animals or a mixture thereof and/or other ingredients which have been proven to be safe and suitable for the feeding of young children.

The nutritional safety and adequacy of (Name of Product) for young children shall be scientifically demonstrated to support growth and development of young children.

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**.] [For products formulated for young children of more than 24 months of age, the product when prepared ready for consumption shall contain per 100 mL not less than 45 kcal (kJ)]

3.1.3 (Name of product) for young children 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[1), 2)]

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

[1) 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.]

[2) The quality of protein shall not be less than 85% of that of casein.]

OR

a) Protein

[The quality of protein shall not be less than 85% of that of casein.]

b) Lipids3)

[Total fat]

[Unit	**Minimum**	**Maximum**	**GUL]**
[g/100 kcal	[4.0]	-	-]
[g/100 kJ	[0.96]	-	-]

[α-linolenic acid]

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

[3)Commercially hydrogenated oils and fats shall not be used in (name of product) for young children.]

OR

b) Lipids

[α-linolenic acid]

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

[Commercially hydrogenated oils and fats shall not be used in (name of product) for young children.]

c) Carbohydrates

[Available cabohydrates4)

Unit	**Minimum**	**Maximum**	**GUL**
g/100 kcal	-	[**12.0**]	-
g/100 kJ	-	[**2.9**]	-

[4) Lactose should be the preferred carbohydrates in [name of product] based on milk protein. Only precooked and/or gelatinised starches gluten-free by nature may be added. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source. Sugars, other than lactose, should not exceed 10% of available carbohydrate].

OR

[Available cabohydrates[4)]

Unit	Minimum	Maximum	GUL
g/100 kcal	-	[**12.0**]	-
g/100 kJ	-	[**2.9**]	-

[4)Lactose should be the preferred carbohydrates in [name of product] based on milk protein [and should provide not less than 50% of total carbohydrates]. Only precooked and/or gelatinised starches gluten-free by nature may be added. Sucrose and/or fructose should not be added, unless needed as a carbohydrate source. Sugars, other than lactose, should not exceed 10% of available carbohydrate].

Iron[5)]

Unit	Minimum	Maximum	GUL
mg/100 kcal	[**1.0**]	[**3.0**]	-
mg/100 kJ	[**0.25**]	[**0.7**]	-

[5)For [name of product] based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36 mg/100 kJ) applies.]

Vitamin C[6)]

Unit	Minimum	Maximum	GUL
mg/100 kcal	[**10**]	-	[**70**]
mg/100 kJ	[**1.0**]	-	[**17**]

[6) expressed as ascorbic acid]

Calcium

Unit	Minimum	Maximum	GUL
mg/100 kcal	[**90**]	-	[**280**]
mg/100 kJ	[**22**]	-	[**67**]

OR

Calcium[7)]

Unit	Minimum	Maximum	GUL
mg/100 kcal	[**90**]	-	[**280**]
mg/100 kJ	[**22**]	-	[**67**]

[7)Ratio calcium/phosphorous]

Min	Max
[1:1]	[2:1]

Riboflavin

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

Vitamin B12

Unit	**Minimum**	**Maximum**	**GUL**
µg/100 kcal	[**0.1**]	-	[**2.0**]
µg/100 kJ	[**0.024**]	-	[**0.48**]

Sodium

Unit	**Minimum**	**Maximum**	**GUL**
mg /100 kcal	-	[**85**]	-
mg /100 kJ	-	[**20**]	-

(Additional options for consideration)

[Zinc]

[Unit	**Minimum**	**Maximum**	**GUL]**
[mg /100 kcal	[0.5]	-	[1.8]
[mg /100 kJ	[0.12]	-	[0.43]

[Vitamin A]

Unit	**Minimum**	**Maximum**	**GUL**
µg RE[8)] /100 kcal	[60]	[180]	-
µg RE[8)] /100 kJ	[14]	[43]	-

[[8)] expressed as retinol equivalents (RE)

1 µg RE = 3.33 IU Vitamin A = 1 µg all-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[9)] /100 kcal	[1.5]	[4.5]	-
[µg[9)] /100 kJ	[0.36]	[1.08]	-

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

3.2 Optional Ingredients

3.2.1 [National authorities may require the mandatory addition of other essential nutrients to address the nutritional needs of the local population than those listed under 3.1.3, Section B. These nutrients should be chosen from the essential composition of follow-up formula for older infants, 3.1.3 Section A. The nutrient levels must be as per the minimum, maximum and GULs stipulated for follow-up formula for older infants (3.1.3 Section A); or amended if the nutritional needs of the local population and scientific justification warrants deviating from the level stipulated.]

3.2.2 [In addition to the [essential] compositional requirements listed under 3.1.3 Section B, other ingredients or substances may be added to follow-up formula for older infants where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.]

3.2.3 [When any of these ingredients or substances is added the formula shall contain sufficient amounts to achieve the intended effect.]

3.2.4 [Additional nutrients may also be added to follow-up formula for young children provided these nutrients are chosen from the essential composition of follow-up formula for older infants and levels are as per the minimum, maximum, GULs stipulated for follow-up formula for older infants; or amended if the nutritional needs of the local population and scientific justification warrants deviating from the level stipulated for older infants. All footnotes relevant to these listed essential nutrients for older infants, would also apply when added to [name of product] for young children].

OR

3.2.2 **[**In addition to the essential compositional requirements listed under 3.1.3 Section B, other [nutrients,] ingredients or substances may be added to [name of product] for young children where the safety and suitability of the optional [nutrient,] ingredient [or substance] for particular nutritional purposes, at the level of use, is evaluated and demonstrated by generally accepted scientific evidence.]

3.2.3 [When any of these [nutrients,] ingredients or substances is added, the [name of product for young children] shall contain sufficient amounts to achieve the intended effect.]