CODEX ALIMENTARIUS COMMISSION E

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - Fax: (+39) 06 5705 4593 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda item 5 **CRD 2**

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

Thirty-seventh Session

Bad Soden a.T. – Germany

23 – 27 November 2015

PHYSICAL WORKING GROUP REPORT ON REVIEW OF THE *STANDARD FOR FOLLOW-UP FORMULA* (CODEX STAN 156-1987)

Prepared by New Zealand and France

1. The physical working group (pWG) was held on the 21st November 2015 prior to the 37th session of the CCNFSDU. The focus of the working group was on Section 2: Description and Section 3: Essential composition of follow-up formula for older infants.

2. The Scope and any reference to the WHA resolutions was not included in these discussions as it was not a part of the terms of reference of the pWG. There were fruitful discussions in the eWG and these have been captured in the Agenda paper. These discussions can be referred to by the Committee when it comes time to discuss the Scope and Labelling.

3. There was not sufficient time to discuss the essential composition of follow-up formula for young children aged 12-36 months. A proposed draft revised sections 2 and 3 of the *STANDARD FOR FOLLOW-UP FORMULA* (CODEX STAN 156-1987) is provided as Appendix 1 and summary of pWG essential composition recommendations in Appendix 2.

Section 2: Description

4. The Chairs noted that as the review of the full Standard progresses it is acknowledged that it may be necessary to continue to revise the definitions contained within the Standard to ensure that they remain relevant and provide sufficient clarity.

5. There was full support from the pWG to align the structure of Section 2 with that of the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981). This has resulted in two sub-headings: 2.1 Product definition; and 2.2 Other Definitions, and moving current definitions 2.2 to Section 3 Essential Composition; and definition 2.4 to Section 9.5 Information for Utilization of the Follow-up Formula standard.

pWG proposed text
Definition 2.1.1
2.1.1 **Follow-up formula** means a food intended for use as:
[a) ~~the~~ **a** 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.]

6. There was strong support to amend 'the' to 'a' and to retain the definition of older infant. There were mixed views as to whether a broad definition should be provided for both age groups or if the definition should be split into two parts to reflect the two age groups and as such this was left in square brackets.

Definition 2.1.2

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

7. There was agreement to the wording proposed for definition 2.1.2 in alignment with the Codex Standard for Infant Formula.

Definitions 2.2: Other Definitions

8. There was agreement to proceed with all definitions under sub-heading 2.2 with some minor grammatical changes. The agreed wording is:

pWG proposed text

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 infant** 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 a person from the age of more than 12 months up to the age of three years (36 months).

3.1. Essential Composition

9. After discussions on each option in square brackets presented in the Agenda paper the pWG agreed to the following text:

pWG proposed text

3.1.1 **Follow-up formula is** a food 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 shall be scientifically demonstrated to support growth and development of older infants and young children.

10. There was some discussion on the use of the term “food” or “product”. It was agreed to refer to “food” as this is defined in the Codex Procedural Manual and is used in definition 2.1.1. Some Codex Observers preferred to refer to “breastmilk substitutes”.

11. The pWG discussed the need for scientific demonstration to support growth and development for young children. There was some concern expressed on the feasibility of gathering scientific evidence for all age groups. However it was agreed to proceed with the text above.

Essential Composition

12. There has been a general agreement within the eWG and pWG to align the essential composition of follow up formula for older infants where possible with the Codex Infant Formula Standard. There are some nutrients that the eWG and pWG recognised should have a different requirement from the Codex Infant Formula standard. This was either based on the differing nutritional needs of the older aged infant; or, due to advances in scientific data on nutritional requirements and clinical trials in formula feeding for this age group since the Codex Infant Formula standard was finalised.

pWG response to Recommendation 1

Recommendation 1

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

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

13. The pWG agreed to revise the essential composition for follow-up formula for older infants to align with the requirements specified in the Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (CODEX STAN 72-1981) for all nutrients listed with the exception of the minimum requirements for vitamin C and vitamin K. It was highlighted that the EFSA Scientific Opinion has recommended substantially lowering the minimum content of vitamin C and K in both infant and follow-up formula.

14. Vitamin C: One Codex Member had questioned whether EFSA had taken into consideration the food matrix when recommending the minimum level of 4 mg/100 kcal in comparison to the Codex Infant Formula Standard level of 10 mg/100 kcal. They raised issues of nutrient availability and stability in formula and whether this was accounted for. The minimum level for vitamin C remains to be discussed in the Plenary.

15. Vitamin K: One Codex Observer expressed concerns regarding the evidence underpinning the EFSA Scientific Opinion for reducing vitamin K levels in formula based on theoretical considerations of nutrient requirement values. It was stated that one study in the Netherlands with formula containing lower levels of vitamin K had shown vitamin K deficiency and the occurrence of bleeding in infants. The minimum level for vitamin K remains to be discussed in the Plenary.

16. The US requested to record their disagreement with modifying the values and supported removing the square brackets around the minimum requirements for vitamin C and vitamin K.

Recommendation 2 agreed

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

17. During the review the eWG it was noted that there were some inconsistencies in the conversion of the essential compositional requirements of the Codex Standard for Infant Formula from kilocalories to kilojoules. At times rounding inconsistencies occurred when using the international standard unit (ISU) conversion factors. The conversion factors for kilojoules and kilocalories are: 1 kJ = 0.239 kcal; and 1 kcal = 4.184 kJ. This is currently specified in the Codex Standard for Follow-up Formula under the definition for kilocalorie.

18. There was agreement within the pWG to amend these inconsistencies, these are recorded in Appendix 2 of the Agenda paper. The Secretariat informed the pWG that once the corrections were finalised in this standard then consequential amendments can be made for Codex Infant Formula Standard.

Recommendations agreed to in the PWG

19. There were several recommendations which received full support from the pWG. These included:

Recommendation 4: Total fat

Recommendation 11: Folic acid

Recommendation 12: Iron

Recommendation 14: Manganese

Recommendation 15: Iodine

Recommendation 16: Selenium

Recommendation 20: Myo-inositol

Recommendation 21: L-Carnitine

20. As there was full support for these recommendations as presented in the agenda paper these are recommendations are not discussed further in this CRD.The agreed upon values are presented in Appendix 2 and the draft standard.

Recommendation 3

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

Protein[2), 3), 4)]

Unit	**Minimum**	**Maximum**	**GUL**
g /100 kcal	[1.8] or [1.65][5)]	[3.5] or [3.0] or [2.5]	-
g /100 kJ	[0.43][5)]	[0.84]	-

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

3) For an equal energy value the formula must contain an available quantity of each essential and semi-essential amino acid at least equal to that contained in the reference protein (breast-milk as defined in Annex I of the *Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants* (CODEX STAN 72-1981)); nevertheless for calculation purposes the 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 ~~Infant F~~ follow-up formula only to improve its nutritional value for infants. Essential and semi-essential amino acids may be added to improve protein quality, only in amounts necessary for that purpose. Only L-forms of amino acids shall be used. agreed

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

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

Minimum Protein composition

21. The pWG discussed but could not come to agreement on the minimum composition of protein in follow-up formula for older infants. Two proposals were considered, to align with the Codex Infant Formula standard value of 1.8 g/100 kcal; or to lower this value to 1.65 g/100 kcal.

22. It was stated that a minimum value of 1.65 g/100 kcal was based on WHO report on protein needs for older infants. This was supported by some pWG members. However it was also noted by other pWG members that although there were some studies looking at protein intakes and growth outcomes, there was very limited research on developmental outcomes. As such it was considered premature to lower the minimum protein requirement further than 1.8 g/100 kcal. This view was supported by the EFSA opinion and some delegations. This issue will be discussed further in the Plenary.

Maximum protein composition

23. The Chairs stated that the current maximum value for follow-up formula in the Codex standard is 5.5 g/100 kcal whereas the infant formula standard is 3.0g/100 kcal. It was explained that many eWG members supported lowering the protein maximum to at least the level in the Codex Infant Formula standard. In doing so, this would result in a scenario where all follow-up formula currently produced under the existing standard would be non-compliant with the revised codex standard. It was noted that this could cause issues for trade, unless it was possible to establish a transition period. The Chairs had explained that no transition periods were possible within Codex Standards as advised by the Codex Secretariat. Any transitioning to lower protein follow-up formulas would need to be catered for at the national legislation level.

24. The pWG discussed but could not come to agreement on the maximum composition of protein in follow-up formula for older infants. Three proposals were considered: to align with the Codex Infant Formula standard value of 3.0 g/100 kcal; or to lower this value to 2.5 g/100 kcal as recommended by EFSA and the international working group coordinated by ENA; or to set a level at 3.5 g/100 kcal as proposed in the Agenda Paper.

25. Some eWG members expressed concern that maximum limits would be set based on trade considerations. Others stated that there was no scientific justification to establish a maximum limit at 3.5 g/100 kcal, or 3.0 g/100 kcal. It was stated by some that formula containing more than 2.5 g/100 kcal would result in more than protein than is required by this age group.

26. It was noted that a reduction of protein from 5.5g /100 kcal to 3.5 g/100 kcal was already a substantial reduction in protein content of follow-up formula. Some members also highlighted issues with their domestic regulation and the issue of non-compliance with the current Codex standard as being an issue. Further to this, there were some concerns that lowering the maximum could result in additions of carbohydrate which could be significant.

27. As no agreement could be reached in the pWG this will be discussed in the Plenary.

Footnote 2: Nitrogen conversion factors

28. The Chairs outlined that the majority of eWG members had supported calculating the protein content of formula using the same approach outlined in the Codex Standard for Infant Formula. To calculate the protein content using the nitrogen conversion factor of 6.25 unless a scientific justification is provided for the use of different conversion factor.

29. The pWG noted that CCMAS were considering the issue of nitrogen conversion factors for soy products and that CCNFSDU could request that they consider soy protein isolate specific to infant formula. It was recommended to put some the value of 5.71 as a specific conversion factor for nitrogen to in protein in other soy products in square brackets then write an addendum to CCMAAS to consider soy protein isolate and more specific to infant formula. It was stated that some soy formulas have methionine added this would not to be taken into consideration when evaluating the nitrogen of soy protein isolate with and without the methionine added. The drafted addendum is provided below.

pWG Proposal

[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.

Request to CCMAS

CCNFSDU requests CCMAS to provide advice on the accuracy and appropriateness of 5.71 as the nitrogen conversion factor for soy protein isolate used in formula for infants and young children and taking account of the amino acid profile of the isolate

Footnote 3:

30. The physical working group supported adoption of a modified version of footnote 3 as presented below. The justification for removing the text contained within the Codex Infant Formula Standard on the ratios methionine and cysteine and tyrosine and methionine was discussed. It was explained that EFSA Scientific Opinion had recommended that no restrictions regarding amino acid ratios were required for from the sixth month onwards as complementary foods will contribute to amino acid intakes and the metabolism of older infants is more mature with respect to the capacity to convert methionine to cysteine and phenylalanine to tyrosine. The physical working group supported removal of the square brackets around this footnote.

[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 1); nevertheless for calculation purposes the ~~sum~~ **concentrations** of tyrosine and phenylalanine and the ~~sum~~ **concentrations** of methionine and cysteine may be ~~used~~ **added together**.

Footnote 4

31. The footnote has been supported by the pWG and square brackets removed.

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

Footnote 5

32. Footnote 5 was supported by the physical working group with minor modification. These minor modifications were related to the inclusion of reference to “goats’ milk”. This is reflected below.

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

Footnote 6

33. There was full support for removing footnote 6 by the pWG. One Codex Observer presented some draft alternative wording however it was noted that the inclusion of any footnote was related to the outcome of discussions on the maximum limit which is yet to be confirmed.

Recommendation 5

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

Linoleic acid

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

α-Linolenic acid

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

*N.S. = not specified

[Ratio linoleic acid/ α-Linolenic acid]

to be discussed after Recommendation 6: DHA

Min	**Max**
[5:1]	[15:1]

34. Recommendation 5 on the essential composition of linoleic and alpha-linolenic acid received some discussions by the pWG. There were no objections to retaining the current minimum level for linoleic acid of 300 mg/100 kcal.

35. At the time of establishing the Codex Infant Formula standard a GUL of 1400 mg/100 kcal was adopted based on a history of safe use. The pWG supported this value.

36. The minimum alpha-linolenic acid was agreed to by the pWG and is recommended to be aligned with the Codex Standard for Infant Formula at 50 mg/100 kcal.

37. It was noted that the discussions on the alpha-linolenic acid maximum and ratio of LA and ALA are dependent on outcome of DHA which was not resolved during the pWG. It is recommended that we discuss the square brackets under recommendation 5 once we have agreed on the optional or mandatory status of the addition of DHA.

Recommendation 6

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

38. The pWG discussed at length whether the addition of DHA should be optional or mandatory. The EFSA recommendation for the mandatory addition of DHA to both infant and follow up formula was discussed. It was noted that this recommendation was based on its structural role in the nervous tissue and retina, and its involvement in normal brain and visual development. However it was also noted that the EFSA conclusion was that there was no convincing evidence that the addition of DHA to formula had benefits beyond infancy and that there was a lack of long term data on benefit.

39. Many Codex Members noted that the evidence was not yet strong enough to justify establishing mandatory requirements, and that there was no justification to vary from the Codex Infant Formula standard, or to require mandatory requirements for this age group prior to the Codex Infant Formula standard.

40. This will be discussed further in the Plenary, in addition to any requirements for ARA and EPA. It was noted that the addition of EPA should be removed from recommendation 6, which was adopted by the group.

Recommendation 7

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

Total OR [Available] Carbohydrates [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 animal milk protein or 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, and provided the sum of these does not exceed 20% of total carbohydrate.]

41. The pWG agreed to establish minimum and maximum limits for carbohydrate as aligned with the Codex Infant Formula standard.

42. There was substantial discussion on the title of “total carbohydrate” and that this should be revised to state either “digestible” or “available” to take into account that these requirements refer to digested and absorbed carbohydrates as oligosaccharides are considered under these requirement levels. The term “available” was included in square brackets for the plenary to consider further.

Footnote 9

43. There was a lot of discussion on the inclusion of the text from Codex Infant Formula standard that lactose and glucose polymers should be the preferred carbohydrate in formula. It was noted glucose polymers were only preferred for formulas based on protein hydrolysates and soy protein isolates. After a lot of discussion it was determined that alignment with the Codex Infant Formula standard was the recommended approach and the text was retained.

44. Regarding reference to sucrose and fructose in the standard, some eWG members preferred the Codex Infant Formula standard wording which is that “sucrose, unless needed, and the addition of fructose as an ingredient should be avoided in infant formula”. Editorial changes were suggested to state that “Sucrose and/or fructose should not be added, unless needed, and provided the sum of these does not exceed 20% of total carbohydrate”. This wording reflects the Scientific Opinion of EFSA and the international expert working group coordinated by ENA that sucrose and fructose may be added to follow-up formula.

Recommendation 8

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

Vitamin A

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

[10] expressed as retinol equivalents (RE)

1 µg RE = 3.33 IU Vitamin A = 1 µg 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.

45. The pWG supported minimum of 75 ug Retinol equivalents and footnote 10. There was some discussion on aligning with Codex infant formula standard to set a minimum of 60 ug RE/100 kcal. However it was noted that the EFSA recommendation supported elevating the minimum level to 70 ug RE/100 kcal based on dietary requirements for infants. Using the same logic and the revised dietary requirements established by WHO/FAO this would equate to a minimum level of 75 ug RE/100 kcal required to fulfil the dietary requirements for infants. The outcome of the discussion was to remove the square brackets around the minimum compositional requirements for vitamin A.

46. Regarding the maximum value for vitamin A there were several proposals including the EU draft directive which has a maximum limit of 114 ug RE/100 kcal and retaining the current maximum of the follow-up formula of 225 ug RE/100 kcal. There were concerns that consumption of formula (at 500 kcal/day) containing 180 ug RE/100 kcal and 225 ug RE/100 kcal would lead to intakes in excess of the WHO/FAO UL of 600 ug/day for young children.

47. The maximum level remains in square brackets for discussion at the Committee.

Recommendation 9

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

Vitamin D

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

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

48. There was some discussion on the minimum level established by EFSA of 2 ug/100 kcal. Due to regional differences and supplementation programmes, the majority of the pWG supported alignment with the Codex Infant Formula standard and there was overall agreement to remove the square bracket for the minimum vitamin D content of follow-up formula.

49. Some members supported establishing a maximum level of 4.5 ug/100 kcal due to vitamin D deficiency in many regions. It was also noted that this maximum limit could lead to excessive intakes above the upper limit. As such the majority pWG agreed to remove the square brackets and recommend a maximum limit of 3 ug/100 kcal.

50. Footnote 11 was supported by the pWG.

Recommendation 10

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

Vitamin B_6

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

51. There was full support in the pWG for the minimum and GUL for vitamin B6 to align with the Codex Infant Formula Standard.

52. Alignment resulted in removing the footnote that is currently in the Codex Follow-up Formula Standard.

53. Chile wished to record that they supported retaining a modified footnote to reflect that vitamin B6 is linked to protein metabolism. As no other pWG members supported inclusion of a footnote it was not included in the draft standard.

Recommendation 13

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

Calcium

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

Phosphorus

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

.

*This GUL should accommodate higher needs with soy formula

Ratio calcium/phosphorus

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

54. It was noted by the Chairs that calcium and phosphorus are interlinked and should be discussed together. The eWG were split between those that wished to align with the Codex Std for IF and those that wished to retain the current higher provisions within the Codex Std for FUF. The eWG recommendation took into consideration the eWG's range of views regarding the calcium content of follow-up formula for older infants and recommended a more flexible range to enable consistency but also allow for slightly higher levels of addition to reflect the increase in dietary calcium requirements for older infants.

55. Some members supported a higher minimum level, but this was not widely supported by the pWG and as a result it was agreed to remove the square brackets from the minimum level of calcium and phosphorus.

56. Some concerns to have a GUL for the Codex Follow-up Formula standard 180 mg/100 kcal) that was higher than that in the Codex Infant Formula Standard (140 mg/100 kcal). It was mentioned that the upper limit for calcium is higher than in the second half of the first year of life. It is 1500 mg in 6-12 month and 100 mg in the first 6 months based on the fact that older infants have a greater degree of renal maturation. As the majority view was to retain a higher GUL for calcium it was recommended that the square brackets were removed.

57. Footnote 18 was fully supported by the pWG. This states that "This GUL should accommodate higher needs with soy formula".

Recommendation 17

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

Copper[19)]

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

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

58. The physical working fully supported the minimum copper composition of follow-up formula of 35 ug/100 kcal in alignment with the Codex Infant Formula standard.

59. One Codex Observer stated that they have data on technical feasibility up to 150 ug/100 kcal and would prefer that the GUL was set at 250 ug/100 kcal based on the recommendations of the international expert working group coordinated by ENA.

60. It was further explained that the ENA recommendation is based on the fact that the WHO safe levels for copper is 2000 ug per day and a controlled trial in Chile that had been performed demonstrating no adverse effects.

61. There was no further support in the pWG to elevate the GUL to 250 ug/100 kcal. It was stated that there could be issues related to the absorption of zinc and iron at this elevated level as copper is known to interact. As there was majority support for establishing a GUL of 120 ug/100 kcal, aligned with the Codex Infant Formula Standard, the square brackets were removed.

62. Footnote 19 of the Codex Infant Formula Standard was supported by the pWG after clarification that this meant if there is high content of copper in the water supply the GUL could be lowered.

Recommendation 18

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

Zinc[20)]

Unit	**Minimum**	**Maximum**	**GUL**
mg/100 kcal	0.5	-	[1.0] or [1.5]
mg/100 kJ	0.12	-	[0.24]

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

63. There was consensus within the pWG to retain a minimum requirement for zinc in FUF for older infants at 0.5 mg/100 kcal. The minimum zinc composition of 0.5 mg per 100 kcal is consistent with the requirements of the Codex Std for IF, and the recommendations of EFSA and the international expert working group coordinated by ENA.

64. There were diverging views on the level at which the GUL for zinc should be set. Many pWG members wished to adopt the GUL specified in the Codex Infant Formula Standard of 1.5 mg/100 kcal, however it was highlighted that consumption of 500 kcal per day containing 1.5 mg/100 kcal would lead to intakes exceeding the tolerable upper level established by EFSA and the IOM. It was also highlighted that there are technical constraints in manufacturing formula within the narrow range of 0.5 to 1.0 mg/100 kcal.

65. As there were diverging views on this it was proposed to retain the maximum limit in square brackets for further discussion at the Plenary.

66. Footnote 20 was fully supported by the pWG. The Chairs note that the maximum level of zinc in soy protein isolate may need to be reviewed depending on the GUL established and has placed this in square brackets.

Recommendation 19

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

Choline

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

67. The addition of choline is not currently specified in the FUF Std, however its addition is mandatory under the current IF Std. Choline can be synthesised endogenously, and therefore many considered that the diversified diet of older infants would provide this nutrient. Others were of the view that the complementary diet may not provide adequate choline.

68. There were mixed views in the pWG as to need for choline to be mandatory in follow-up formula. However it was decided that if the outcome of the discussions were to mandate the addition of choline this should be at a minimum of 7 mg/100 kcal. The minimum and two options for the GUL are left in square brackets for consideration by the Committee.

Recommendation 22

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

69. The pWG did not discuss any detail regarding the optional ingredients due to available time but focussed on the text provided in 3.3.2.1. Of the two proposed options there was support in the pWG for the second option with minor modifications. The reference to generally accepted scientific evidence was challenged by one Codex Observer as to its meaning. One Codex Member reminded the pWG that generally accepted scientific evidence is described in the Codex text on Nutrition Labelling Guidelines where such a term is described as synonymous with convincing evidence. The pWG supported this clarification.

70. The pWG supported inclusion of the text safe and suitable. It was then discussed that the concept of nutritional adequacy also needed to be included and draft wording was provided, as below. This wording was supported by the pWG. In the Plenary further discussions will be had on the remainder of the Optional Ingredients section.

pWG Proposed text

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.

APPENDIX 1

PROPOSED DRAFT REVISED STANDARD FOR FOLLOW-UP FORMULA

CODEX STAN 156-1987

1. [SCOPE]

2. DESCRIPTION

2.1 Product Definition

2.1.1 **Follow-up formula** means a food intended for use as

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

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

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

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 infant** 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).

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

3.1 Essential composition

3.1.1 **Follow-up formula** is a food 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 to support growth and development] for older infants and young children. The nutritional safety and adequacy of follow-up formula shall be scientifically demonstrated to support growth and development of older infants and young children.

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)]	[3.5] or [3.0] or [2.5]	-
g/100 kJ	[0.43] or [0.39][5)]	[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); 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 or non-goats' 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 (0.54 g/100 kJ)] applies.

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] *will be discussed after (DHA)*

Min	Max
[5:1]	[15:1]

c) Carbohydrates

Total OR [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, and provided the sum of these does not exceed 20% of total carbohydrate.]

d) Vitamins

Vitamin A

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

[10)] expressed as retinol equivalents (RE)

1 µg RE = 3.33 IU Vitamin A = 1 µg 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[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	[4]	-	27
µg /100 kJ	[1]	-	6.5

Thiamin

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

Riboflavin

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

Niacin[14)]

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

[14)] Niacin refers to preformed niacin

Vitamin B_6

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

Vitamin B_{12}

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

Pantothenic acid

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

Folic acid

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

Vitamin C[15)]

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

15) expressed as ascorbic acid

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

Biotin

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

e) Minerals and Trace Elements

Iron[17)]

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

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

Calcium

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

Phosphorus

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/phosphorus

Min	Max
1:1	2:1

Magnesium

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

Sodium

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

Chloride

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

Potassium

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

Manganese

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

Iodine

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

Selenium

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

Copper[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 [0.36]

[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

3.3.2 **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 ~~The usefulness of these nutrients shall be scientifically shown.~~ *[The suitability for the particular nutritional uses [**in products for**] ~~of~~ [**older**] infants and the safety of these [**ingredients and**] substances shall be scientifically demonstrated. [**When any of these ingredients or substances is***

***added**] ~~I~~ the formula shall contain sufficient amounts o~~f these substances~~ to achieve the intended effect~~, taking into account levels in human milk~~.]*

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

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

[Taurine]

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

[Total nucleotides

Levels may need to be determined by national authorities.]

[Docosahexaenoic acid[20)]

Unit	**Minimum**	**Maximum**	**GUL**
% of fatty acids	-	-	[0.5]

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

[Choline]

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

Myo-inositol

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

L-Carnitine
Levels may need to be determined by national authorities.

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

APPENDIX 2

PHYSICAL WORKING GROUP SUMMARY OF ESSENTIAL COMPOSITION DISCUSSIONS

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

The following table provides an overview of the compositional requirements in the current Follow-up Formula Standard (CODEX STAN 156-1987) in column 2, the requirements of the Infant Formula Standard (CODEX STAN 72-1981) in column 3, the results of the 2015 eWG consultations (column 4) and results of the 2015 pWG in column 5. Alternative proposals discussed in the pWG for further consideration are presented in column 6. Where there was support to remove the square brackets from the draft standard this is presented in bold. The remainder of the values presented in column 5 represent the recommendations proposed in the Agenda Paper.

1. Nutrient	2. FUF standard CODEX STAN 156-1987		3. IF standard CODEX STAN 72-1981			4. 2015 eWG report recommendations			5. 2015 pWG report recommendations			6. Alternative proposals
	Min	Max	Min	Max	GUL	Min	Max	GUL	Min	Max	GUL	
Energy kcal/100 ml kJ/100 ml	 60 250	 85 355	 60 250	 70 295	-	 **60** **250***	 **70** **293***	-	 **60** **250***	 **70** **293***		
Protein g/100 kcal g/100 kJ	 3.0 0.7	 5.5 1.3	 1.8 0.45	 3.0 0.7	-	 1.8 0.43*	 3.5 0.84*	-	 1.8 0.43*	 3.5 0.84*	-	Min: 1.65 Max: 3.0 2.5
Total fat g/100 kcal g/100 kJ	 3.0 0.7	 6.0 1.4	 4.4 1.05	 6.0 1.4	-	 **4.4** **1.1***	 **6.0** **1.4**	-	 **4.4** **1.1***	 **6.0** **1.4**	-	
LA mg/100 kcal mg/100 kJ	 300 71.7	 -	 300 70	 -	 1400 330	 300 72*	 -	 1400 335*	 **300** **72***	 **-**	 **1400** **335***	
ALA mg/100 kcal mg/100 kJ	 - 	 - 	 50 12	 N.S. 	 - 	 **50** **12**	 N.S. 	 - 	 **50** **12**	 TBD 	 	
Total CHO g/100 kcal g/100 kJ	 - 	 - 	 9.0 2.2	 14.0 3.3	 - 	 **9.0** **2.2**	 **14.0** **3.3**	 	 **9.0** **2.2**	 **14.0** **3.3**	 	
Vitamins												
Vitamin A µg RE/100 kcal µg RE/100 kJ	 75 18	 225 54	 60 14	 180 43	-	 75 18	 180 43	-	 **75** **18**	 180 43	-	Max: 114 OR 225

1. Nutrient	2. FUF standard CODEX STAN 156-1987		3. IF standard CODEX STAN 72-1981			4. 2015 eWG report recommendations			5. 2015 pWG report recommendations			6. Alternative proposals
Vitamin D µg/100 kcal µg /100 kJ	1 0.25	3 0.75	1 0.25	2.5 0.6	-	1.0 0.24*	3.0 0.72*	-	**1.0** **0.24***	**3.0** **0.72***	-	
Vitamin E mg /100 kcal mg /100 kJ	0.7 IU 0.15IU	-	0.5 0.12	-	5 1.2	0.5 0.12	-	**5** **1.2**	**0.5** **0.12**	-	**5** **1.2**	
Vitamin K µg/100 kcal µg /100 kJ	4 1	NS	4 1	-	27 6.5	4 1	-	**27** **6.5**	4 1	-	**27** **6.5**	Min: 1
Thiamin µg/100 kcal µg /100 kJ	40 10	NS	60 14	-	300 72	60 14	-	**300** **72**	**60** **14**	-	**300** **72**	
Riboflavin µg/100 kcal µg /100 kJ	60 14	NS	80 19	-	500 119	80 19	-	**500** **119**	**80** **19**	-	**500** **119**	
Niacin µg/100 kcal µg /100 kJ	250 60	NS	300 70	-	1500 360	300 72	-	**1500** **360**	**300** **72**	-	**1500** **360**	
Vitamin B6 µg/100 kcal µg /100 kJ	45 11	NS	35 8.5	-	175 45	35 8.4	-	**175** **41.8**	**35** **8.4**	-	**175** **41.8**	
Vitamin B12 µg/100 kcal µg /100 kJ	0.15 0.04	NS	0.1 0.025	-	1.5 0.36	**0.1** **0.024**	-	**1.5** **0.36**	**0.1** **0.024**	-	**1.5** **0.36**	
Pantothenic µg/100 kcal µg /100 kJ	300 70	NS	400 96	-	2000 478	**400** **96**	-	**2000** **478**	**400** **96**	-	**2000** **478**	
Folic acid µg/100 kcal µg /100 kJ	4 1	NS	10 2.5	-	50 12	10 2.4	-	50 12	**10** **2.4**	**-**	**50** **12**	
Vitamin C mg/100 kcal mg /100 kJ	8 1.9	NS	10 2.5	-	70 17	10 2.4	-	**70** **17**	10 2.4	-	**70** **17**	Min: 4

1. Nutrient	2. FUF standard CODEX STAN 156-1987		3. IF standard CODEX STAN 72-1981			4. 2015 eWG report recommendations			5. 2015 pWG report recommendations			6. Alternative proposals
Biotin µg/100 kcal µg /100 kJ	1.5 0.4	NS	1.5 0.4	-	10 2.4	1.5 0.4	-	**10** **2.4**	**1.5** **0.4**	-	**10** **2.4**	
Minerals and Trace Elements												
Iron mg/100 kcal mg /100 kJ	1 0.25	2 0.5	0.45 0.1	-	-	1.0 0.24*	2.0 0.48*	-	**1.0** **0.24***	**2.0** **0.48***	-	
Calcium mg/100 kcal mg /100 kJ	90 22	NS	50 12	-	140 35	50 12	-	180 43*	**50** **12**	**-**	**180** **43***	
Phosphorous mg/100 kcal mg /100 kJ	60 14	NS	25 6	-	100 24	25 6	-	100 24	**25** **6**	**-**	**100** **24**	
Ratio	-	-	1:1	2:1	-	1:1	2:1	-	1:1	2:1	-	
Magnesium mg/100 kcal mg /100 kJ	6 1.4	NS	5 1.2	-	15 3.6	**5** **1.2**	**-**	**15** **3.6**	**5** **1.2**	**-**	**15** **3.6**	
Sodium mg/100 kcal mg /100 kJ	20 5	85 21	20 5	60 14	-	20 5	60 14	-	**20** **5**	**60** **14**	-	
Chloride mg/100 kcal mg /100 kJ	55 14	NS	50 12	160 38	-	50 12	**160** **38**	-	**50** **12**	**160** **38**	-	
Potassium mg/100 kcal mg /100 kJ	80 20	NS	60 14	180 43	-	60 14	**180** **43**	-	**60** **14**	**180** **43**	-	
Manganese µg/100 kcal µg /100 kJ	-	-	1 0.24	-	100 24	1 0.24*	-	100 24	**1** **0.24***	**-**	**100** **24**	
Iodine µg/100 kcal µg /100 kJ	5 1.2	NS	10 2.5	-	60 14	10 2.4*	-	60 14.3*	**10** **2.4***	**-**	**60** **14.3***	
Selenium µg/100 kcal	-	-	1	-	9	2		**9**	**2**		**9**	

1. Nutrient	2. FUF standard CODEX STAN 156-1987		3. IF standard CODEX STAN 72-1981			4. 2015 eWG report recommendations			5. 2015 pWG report recommendations			6. Alternative proposals
µg /100 kJ			0.24		2.2	0.48*		**2.2**	**0.48***		**2.2**	
Copper µg/100 kcal µg /100 kJ	- 	- 	35 8.5	-	120 29	35 8.4*	-	120 29	**35** **8.4***	**-**	**120** **29**	
Zinc mg/100 kcal mg /100 kJ	0.5 0.12	NS 	0.5 0.12	-	1.5 0.36	**0.5** **0.12**	-	1.0 0.24	**0.5** **0.12**	-	1.0 0.24	GUL: 1.5
Choline mg/100 kcal mg/100 kJ	NS	NS	7 1.7	-	50 12	Optional			7 1.7	-	50 12	Optional or mandatory GUL 50 or 150
Myo-Inositol mg/100 kcal mg/100 kJ	NS	NS	4 1	-	40 9.5	Optional			**Optional**			
L-carnitine mg/100 kcal mg/100 kJ	NS	NS	1.2 0.3	NS	-	Optional			**Optional**			

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

TBD: To be determined