CODEX ALIMENTARIUS COMMISSION

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CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECCIAL DIETARY USES

Thirty-eighth Session

Hamburg, Germany, 5 – 9 December 2016

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

Physical Working Group Report

Prepared by the New Zealand and France

Additional information for the report from physical working group on the review of follow up formula

This CRD is to be read in combination with CRD 2- the report of the physical working group (PWG) on follow up formula. This paper includes the response to recommendation 11 Protein Quality (which was inadvertently left out of CRD2) and a clean copy of the updated drafting for the revised standard for follow up formula, following the discussions at the PWG.

Recommendation. 11: 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.]

[*the protein quality shall be determined provisionally using the PER or PDCAAS and other methods that come available in the future.]

The Chair introduced this section stating that there was almost full support in the eWG to specify requirements for protein quality in product for young children. Formula for infants and cows' milk are a source of high quality protein in the diets of young children, containing a source of highly digestible amino acids. 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.

There were mixed views as to whether cows' milk should be used as the reference protein or if reference to the amino acid requirements for this age group should be the point of reference. In addition to this the method used to derive these protein quality parameters was also mixed and no conclusions could be made.

In 2013 the FAO released a report from an expert consultation on protein quality evaluation. The conclusions of which were that a new method, the digestible indispensable amino acid score (DIAAS). It was also stated that this method should be used to evaluate protein quality and that this method is used in regulation, specifically Codex texts. However, it was also noted that there are limitations associated with its use, mainly related to the limited data available on ileal amino acid digestibly of foods and that the FAO would in future need to review the recommended use of this method if work was not sufficiently progressed in a timely manner.

The Chair noted that despite the recommended use of amino acid scoring patterns to assess protein quality using PDCAAS since 1989, there are very few references to this method in Codex texts. Several Codex documents continue to refer to the use of the protein efficiency ratio which has not been recommended by FAO or WHO for some time.

There was uncertainty within the eWG and Codex in general as to the appropriate manner in which either the PDCAAS or DIAAS scoring patterns could be applied to standards, particularly for foods for which they are not the sole source of nutrition.

To open up the discussions the Chair requested that FAO provide an update on measurement of protein quality

FAO stated that in relation to DIAAS, FAO convened an expert consultation on the best way to score protein quality and the experts concluded that DIASS is better conceptually. However there is insufficient data available for human foods, and lacking data on clinical studies. For this reason 2014, FAO convened another working group in Bangalore. The outcomes of this meeting were published in the Journal of Nutrition[1] paper to encourage scientists to do more research in this area. FAO clarified that the DIAAS score is not ready for use at this stage as there is not sufficient data to support its use. Until sufficient accumulation of good quality data can this be used then we can ask that national authorities use this method. So we need to use PDCAAS at this point in time.

One Codex observer stated that PDCAAS is currently widely used but only applicable to children over 2 years and requested that the standard reference the reference pattern recommended by FAO in 2013. FAO responded that the method has not been tested in children even with DIAAS so are not in a position to use this FAO report scoring pattern and restated the need for more human data.

It was recommended that there was a footnote stating that protein quality would be determined provisionally using PER or PDCAAS. It was further recommended that the footnote should also state that other methods could be used once they come available in the future.

One Codex observer supported the footnote, but preferred that PDCAAS method is used not PER as it was outdated

Proposed footnote: the protein quality shall be determined provisionally using the PER or PDCAAS and other methods that come available in the future.

It was noted that protein quality would need further discussion in the Plenary.

[1] Lee, W. et al (2016) Research approaches and methods for evaluating the protein quality of human foods proposed by an FAO expert working group in 2014. Journal of Nutrition 146:929-32

Proposed revised draft standard for Follow-up Formula

Amendments from the Physical Working Group

3rd December 2016

CODEX 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

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	-

1. **Total nucleotides**

2. 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

3.

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

4. [3.3.2.4 Only L(+) lactic producing cultures may be used **for the purpose of producing acidified follow-up formula for older infants**.]

5. [**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)]~~ **National and/or regional authorities can deviate from the minimum energy content in line with national/regional dietary guidelines taking into account the nutritional needs of the local population.**

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[*), **)]

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

[*) 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.]

[**) 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.]

[*the protein quality shall be determined provisionally using the PER or PDCAAS and other methods that come available in the future]

b) Lipids[*)]

[Total fat]

Unit	Minimum	Maximum	GUL
g/100 kcal	[**3.5**] or [4.0] or [**4.4**]	-	-
g/100 kJ	[**0.84**] or [0.96] or [**1.1**]	-	-

α-linolenic acid

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

[Linoleic acid*]	Minimum	Maximum	GUL
Unit	**300**	-	-

mg/100	kJ	**12**	-	-

[*This can be decided by national or regional authorities]

) ~~Commercially~~ **Partially and fully hydrogenated oils and fats shall not be used in (name of product) for young children.]

OR

) **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% trans fatty acids is intended to allow for the use of milk fat in follow-up formula.]

c) Carbohydrates

[Available cabohydrates[4)]

Unit	Minimum	Maximum	GUL
g/100 kcal	-	[**12.0**] or [**12.5**]	-
g/100 kJ	-	[**2.9**] or [**3.0**]	-

[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 [**in the absence of lactose**]. Sugars, other than lactose, should not exceed [**20%**] 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.]

***National and/or regional authorities can deviate from the maximum iron taking into account the nutritional needs of the population.**

Vitamin C[6)]

Unit	Minimum	Maximum	GUL
mg/100 kcal	[~~**10**~~]**align with FUF-OI**	-	~~[~~**70**~~]~~
mg/100 kJ	[~~**1.0**~~] **align with FUF-OI**	-	~~[~~**17**~~]~~

[6) expressed as ascorbic acid]

Calcium

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**~~]~~ **650**
µg/100 kJ	~~[~~**19**~~]~~	-	~~[~~**119**~~]~~ **155**

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**]	-

[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] or [**1.0**]	[4.5] or [**3.0**]	-
µg[9)] /100 kJ	[0.36] or [**0.24**]	[1.08] or [**0.72**]	-

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

3.1.4 For national **and/or regional** authorities may **lay down additional** ~~require the~~ mandatory **requirements** ~~addition of~~ **for** other essential nutrients in addition to those listed under 3.1.3, Section B, for their specific population, these nutrients should be chose from the essential composition of follow-up formula for older infants 3.1.3 Section A. The nutrient levels must be:

- based on the nutrient composition of follow-up formula for older infants or;
- **[based on key nutrients from cows' milk];**
- amended if the nutritional needs of the local population and scientific justification warrants deviating from the level stipulated for older infants.
-

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.]~~ *(Draft text moved to 3.1.4)*

3.2.1 [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**~~ **young children** 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 **by national and/or regional authorities** 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].

(Noted in the physical working group that drafting text is required to clarify that the optional ingredients and substances already permitted for follow-up formula for older infants in Section 3.3.2 Section A apply to this section.)

~~**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.]~~