

# CODEX ALIMENTARIUS COMMISSION



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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON NUTRITION AND FOODS FOR SPECIAL DIETARY USES

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#### Editorial and technical amendments to the Essential Composition Requirements for Follow-up Formula for older infants and [Name of Product] for young children

*(Prepared by the Chair of the EWG of the review of the Standard for Follow-Up Formula)*

The following issues have been identified by the Chairs of the electronic working group as requiring minor technical or editorial amendments and corrections to the Sections relating to the Essential Composition Requirements for Follow-up Formula for older infants (Section A) and [Name of Product] for young children (Section B) within the *Standard for Follow-up Formula* (CXS 156-1987).

All of the amendments discussed below have been included in the draft standard (Annex).

#### Section A and Section B: Conversion and rounding issues

During the 2015 electronic working group, it was noted that there were some inconsistencies in the conversion of the essential compositional requirements from kilocalories to kilojoules, partly due to rounding inconsistencies in the development of the Codex Standard for Infant Formula. It was agreed in the [PWG at CCNFSDU38](#) (recommendation 2) to amend the conversion factors in line with the International Standard Unit conversion factors and conventional rounding.

It is now considered to be imperative that any final inconsistencies are addressed to ensure that the conversion of nutrient values per 100 kcal to kJ for all essential composition requirements are technically correct given that the values have largely been agreed to.

A systematic approach that is consistent for all essential composition requirements has been done for each essential composition requirement presented per 100 kJ and is presented in the attached amended standard.

#### *Composition per 100 kcal*

Within the Committee, discussions are primarily based on the values for the composition per 100 kcal, and subsequently converted to per 100 kJ. As such it is not considered appropriate to propose any amendments to the requirements per 100 kcal as they are not considered editorial issues.

#### *Composition per 100 kJ*

Regarding the conversion to kJ, a level of specificity is required to ensure that the same minimum and maximum levels are specified as for those presented per 100 kcal. This is of particular importance for compliance purposes in those national or regional authorities which use kJ in their regulation.

Our proposal is to ensure that the converted nutrient requirements values per 100 kcal to per 100 kJ are nutritionally equivalent to a reasonable level of specificity. Furthermore, a systematic approach that is consistent for all essential composition requirements is necessary. The rounding logic that has been applied aligns fairly well with the current drafting and also with other international regulations for follow-up formula.

Rounding logic	
Values >5	round to nearest whole number
Values 1-5	report to 1 decimal point
Values <1	Report to 2 decimal points

### Section A and Section B: Consistent use of terminology

Consistent use of terminology for ‘follow-up formula for older infants’ is required. It is important to be explicit about which product is being referred and spell out the full product name each time in order to avoid any misunderstanding. Amendments have been made throughout to refer to the full term “follow-up formula for older infants” with correct use of capitalisation.

### Section B: [Name of product] for young children

#### *Order of vitamins and minerals requirements*

For the Essential Composition Requirements for Section B: [Name of Product] for young children, the vitamins and minerals are not presented in groups and are in a random order. It is proposed that the sequential order of vitamins, minerals and trace elements is presented in the same manner as in the section on follow-up formula for older infants.

Vitamins: vitamin A, vitamin D, riboflavin, vitamin B12, vitamin C

Minerals and trace elements: iron, calcium, zinc

#### *Footnote 4: Available carbohydrates*

At [CCNFSDU39](#) it was agreed that the percentage limit for mono- and disaccharides would be converted to an absolute amount based on the energy density of the product. The percentage limit that was agreed to was 20% of available carbohydrates. Given that the maximum level of available carbohydrates was agreed at 12.5g/100 kcal, 20% of this should be 2.5g/100 kcal. When the conversion was done, it was overlooked that the words ‘of available carbohydrate’ should have been deleted as part of the conversion:

#### **a) Carbohydrates**

##### **Available carbohydrates <sup>4)</sup>**

Unit	Minimum	Maximum <sup>5)</sup>	GUL
g /100 kcal	-	12.5	-
g /100 kJ	-	3.0	-

<sup>4)</sup> [Lactose should be the preferred carbohydrates in [name of product] based on milk protein. For products not based on milk protein, carbohydrate sources (like starch) that have no contribution to the sweet taste should be preferred. Mono- and disaccharides, other than lactose, either added as ingredients, or constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means, should not exceed 2.5 g/100kcal (0.60 g/100kJ) ~~of available carbohydrate~~. National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ). Sucrose and/or fructose or other carbohydrates contributing to the sweet taste of [name of product] should not be added, unless needed as a carbohydrate source. Other non-carbohydrate ingredients should not be added with the purpose of imparting or enhancing a sweet taste. ]

It is noted that the whole footnote is still in square brackets but this is a drafting error that should be corrected before the discussions on the footnote commence.

### *Optional ingredients*

The framework for optional addition for [name of product] for young children was discussed at the physical working group immediately prior to CCNFSDU38 ([NFSDU/38 CRD/2](#)) as well as at the Committee meeting ([REP17/NFSDU Appendix I, para 76-79](#)). It was agreed that additional *nutrients* should be permitted within the range specified for follow-up formula for older infants taking into account any inherent levels of nutrients in cow's milk as is indicated in 3.2.3 which was amended and agreed to at the Committee meeting.

Currently 3.2.1 and 3.2.2 include '*nutrients*' as well '*ingredients*' and '*substances*' and are thus in conflict with 3.2.3 which specifically covers the addition of additional *nutrients*. To reflect the decision of the Committee at CCNFSDU38, 'or nutrients' within 3.2.1 and 3.2.2 should be deleted as shown below.

Furthermore for consistency in terminology 'essential' in 3.2.1 should be deleted as it is not used in the equivalent clause in the infant formula standard or for follow-up formula for older infants. The name of the product should replace 'formula' in 3.2.2.

## **3.2 Optional Ingredients**

**3.2.1** In addition to the ~~essential~~ compositional requirements listed under 3.1.3 Section B, other ingredients, ~~or substances or nutrients~~ may be added to [name of the product] for young children where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated by national and/or regional authorities and demonstrated by generally accepted scientific evidence. Optional ingredients listed in 3.2.3 Section A are also permitted.

**3.2.2** When any of these ingredients, ~~or substances or nutrients~~ is added the ~~formula~~ **[name of the product] for young children** shall contain sufficient amounts to achieve the intended effect.

**3.2.3** Additional nutrients may also be added to [name of the product] 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 (3.1.3 Section A) and take into account the inherent levels of nutrients in cows' milk; or amended by national and/or regional authorities if the nutritional needs of the local population and scientific justification warrants such deviation.

**DRAFT REVIEW OF STANDARD FOR FOLLOW-UP FORMULA (CXS 156-1987)****- ESSENTIAL COMPOSITION -**

(All changes are in bold and underlined)

**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. The nutritional safety and adequacy of follow-up formula for older infants shall be scientifically demonstrated to support growth and development of older infants.
- 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~~ **251** kJ) and not more than 70 kcal (~~295~~ **293** kJ) of energy.
- 3.1.3 Follow-up formula **for older infants** 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) <sup>1</sup> as appropriate.

**a) Protein** <sup>2), 3), 4)</sup>

Unit	Minimum	Maximum	GUL
g/100 kcal	1.8 <sup>5), 6)</sup>	3.0	-
g/100 kJ	0.43 <sup>5), 6)</sup>	0.72	-

<sup>2)</sup> 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. For information the value of 6.38 is used as a specific factor appropriate for conversion of nitrogen to protein in other Codex standards for milk products.

<sup>3)</sup> 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* (CXS 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.

<sup>4)</sup> Isolated amino acids may be added to follow-up formula **for older infants** 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.

<sup>5)</sup> The minimum value applies to cows' and goats' milk protein. For follow-up formula **for older infants** based on non-cows' 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.

<sup>6)</sup> A lower minimum protein level between 1.6 and 1.8 g/100 kcal (0.38 and 0.43 g/100 kJ) in follow-up formula **for older infants** based on non-hydrolysed milk protein can be accepted. Such follow-up formula and follow-up formula **for older infants** based on hydrolysed protein should be evaluated for their safety and suitability and assessed by a competent national and/or regional authority based on clinical evidence.

**b) Lipids****Total Fat** <sup>7), 8)</sup>

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

<sup>7)</sup> Partially hydrogenated oils and fats shall not be used in follow-up formula for older infants.

<sup>8)</sup> Lauric acid and myristic acids are constituents of fats, but combined shall not exceed 20% of total fatty acids. The content of trans fatty acids shall not exceed 3% of total fatty acids. Trans fatty acids are endogenous components of milk fat. The acceptance of up to 3% of trans fatty acids is intended to allow for the use of milk fat in **follow-up formula for older infants** 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

 **$\alpha$ -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/  $\alpha$ -Linolenic acid**

Min	Max
5:1	15:1

**c) Carbohydrates****Available carbohydrates <sup>9)</sup>**

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

<sup>9)</sup> Lactose and glucose polymers should be the preferred carbohydrates in **follow-up** formula **for older infants** based on cow's 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
$\mu$ g RE <sup>10)</sup> /100 kcal	75	180	-
$\mu$ g RE <sup>10)</sup> /100 kJ	18	43	-

<sup>10)</sup> expressed as retinol equivalents (RE)

1  $\mu$ g RE = 3.33 IU Vitamin A = 1  $\mu$ g 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
$\mu$ g <sup>11)</sup> /100 kcal	1.0	3.0	-
$\mu$ g <sup>11)</sup> /100 kJ	0.24	0.72	-

<sup>11)</sup> Calciferol. 1  $\mu$ g calciferol = 40 IU vitamin D.**Vitamin E**

Unit	Minimum	Maximum	GUL
mg $\alpha$ -TE <sup>12)</sup> /100 kcal	0.5 <sup>13)</sup>	-	5
mg $\alpha$ -TE <sup>12)</sup> /100 kJ	0.12 <sup>13)</sup>	-	<b>1.20</b>

<sup>12)</sup> 1 mg  $\alpha$ -TE (alpha-tocopherol equivalents) = 1 mg d- $\alpha$ -tocopherol

<sup>13)</sup> Vitamin E shall be at least 0.5 mg  $\alpha$ -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  $\alpha$ -TE /g linoleic acid (18:2 n-6); 0.75  $\alpha$ -TE/g  $\alpha$ -linolenic acid (18:3 n-3); 1.0 mg  $\alpha$ -TE/g arachidonic acid (20:4 n-6); 1.25 mg  $\alpha$ -TE/g eicosapentanoic acid (20:5 n-3); 1.5 mg  $\alpha$ -TE/g docosahexaenoic acid (22:6 n-3).

**Vitamin K**

Unit	Minimum	Maximum	GUL
µg /100 kcal	4	-	27
µg /100 kJ	<del>4.0</del> <b>0.96</b>	-	<del>6.5</del>

**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	-	<del>119</del> <b>120</b>

**Niacin** <sup>14)</sup>

Unit	Minimum	Maximum	GUL
µg /100 kcal	300	-	1500
µg /100 kJ	72	-	<del>360</del> <b>359</b>

<sup>14)</sup> Niacin refers to preformed niacin

**Vitamin B<sub>6</sub>**

Unit	Minimum	Maximum	GUL
µg /100 kcal	35	-	175
µg /100 kJ	8.4	-	<del>41.8</del> <b>42</b>

**Vitamin B<sub>12</sub>**

Unit	Minimum	Maximum	GUL
µg /100 kcal	0.1	-	1.5
µg /100 kJ	<del>0.024</del> <b>0.02</b>	-	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** <sup>15)</sup>

Unit	Minimum	Maximum	GUL
mg /100 kcal	10	-	70 <sup>16)</sup>
mg /100 kJ	2.4	-	17 <sup>16)</sup>

<sup>15)</sup> expressed as L-ascorbic acid

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

### Biotin

Unit	Minimum	Maximum	GUL
µg /100 kcal	1.5	-	10
µg /100 kJ	<del>0.4</del> <b>0.36</b>	-	2.4

### e) Minerals and Trace Elements

#### Iron <sup>17)</sup>

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

<sup>17)</sup> For follow-up formula for older infants 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

#### Phosphorus

Unit	Minimum	Maximum	GUL
mg /100 kcal	25	-	100 <sup>18)</sup>
mg /100 kJ	6	-	24 <sup>18)</sup>

<sup>18)</sup> This GUL should accommodate higher needs with follow-up formula for older infants based on soy protein isolate.

#### 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	<del>5</del> <b>4.8</b>	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	-	<del>44.3</del> <b>14</b>

**Selenium**

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

**Copper** <sup>19)</sup>

Unit	Minimum	Maximum	GUL
µg /100 kcal	35	-	120
µg /100 kJ	<del>8.4</del> <b>8</b>	-	29

<sup>19)</sup> Adjustment may be needed in these levels for follow-up formula **for older infants** made in regions with a high content of copper in the water supply.

**Zinc** <sup>20)</sup>

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

<sup>20)</sup> For follow-up formula **for older infants** based on soy protein isolate a minimum value of 0.75 mg/100 kcal (0.18 mg/100 kJ).

**3.2 Optional Ingredients**

- 3.2.1** In addition to the compositional requirements listed under 3.1.3 Section A, 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.
- 3.2.2** 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.
- 3.2.3** 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 **for older infants** 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	-	<del>3</del> <b>2.9</b>	-

**Total nucleotides**

Levels may need to be determined by national authorities.

**Docosahexaenoic acid** <sup>21)</sup>

Unit	Minimum	Maximum	GUL
mg /100 kcal	-	-	30
mg /100 kJ	-	-	<del>7.2</del> <b>7</b>

<sup>21)</sup> If docosahexaenoic acid (22:6 n-3) is added to follow-up formula **for older infants**, a minimum level of 20 mg/100 kcal (4.8 mg/100 kJ) should be reached, and 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	-	-	<del>9.6</del> <b>10</b>

**L-carnitine**

Levels may need to be determined by national authorities.

**L (+) lactic producing cultures**

Only L (+) lactic producing cultures may be used for the purpose of producing acidified follow-up formula for older infants. The acidified final formula product should not contain significant amounts of viable L (+) lactic acid-producing cultures, and residual amounts should not represent any health risk.

The safety and suitability of the addition of specific strains of L(+) lactic acid producing cultures for particular beneficial physiological effects, at the level of use, must be demonstrated by clinical evaluation and generally accepted scientific evidence. When added for this purpose, the final product ready for consumption shall contain sufficient amounts of viable cultures 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.

3.1.4 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~~ **251** kJ) and not more than 70 kcal (~~295~~ **293** kJ) of energy. 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.

3.1.2 (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. The general principles for establishing these levels are identified in Annex I of this standard.

**a) Protein** <sup>1), 2)</sup>

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

<sup>1)</sup> 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. For information the value of 6.38 is used as a specific factor appropriate for conversion of nitrogen to protein in other Codex standards for milk products.

<sup>2)</sup> When determined by PER methodology, 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** <sup>3)</sup>**Total fat**

Unit	Minimum	Maximum	GUL
g /100 kcal	3.5	-	-
g /100 kJ	0.84	-	-

**α-Linolenic acid**

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

**Linoleic acid**

Unit	Minimum	Maximum	GUL
mg /100 kcal	300	-	-
mg /100 kJ	72	-	-

<sup>3)</sup> Partially hydrogenated oils and fats shall not be used in [name of product] for young children.

\* Guidance upper levels are for nutrients without sufficient information for a science-based risk assessment. These levels are values derived on the basis of meeting nutritional requirements of young children and an established history of apparent safe use. They may be adjusted based on relevant scientific or technological progress. The purpose of the GULs is to provide guidance to manufacturers and they should not be interpreted as goal values. Nutrient contents in [name of product] for young children should usually not exceed the GULs unless higher nutrient levels cannot be avoided due to high or variable contents in constituents of [name of product] for young children or due to technological reasons. When a product type or form has ordinarily contained lower levels than the GULs, manufacturers should not increase levels of nutrients to approach the GULs.

**c) Carbohydrates****Available carbohydrates <sup>4)</sup>**

Unit	Minimum	Maximum <sup>5)</sup>	GUL
g /100 kcal	-	12.5	-
g /100 kJ	-	3.0	-

<sup>4)</sup> [Lactose should be the preferred carbohydrates in [name of product] based on milk protein. For products not based on milk protein, carbohydrate sources (like starch) that have no contribution to the sweet taste should be preferred.

Mono- and disaccharides, other than lactose, either added as ingredients, or constituents of ingredients and/or increased above the amount contributed by the ingredients by some other means, should not exceed 2.5 g/100kcal (0.60 g/100kJ) of available carbohydrate. National and/or regional authorities may limit this level to 1.25 g/100 kcal (0.30 g/100 kJ). Sucrose and/or fructose or other carbohydrates contributing to the sweet taste of [name of product] should not be added, unless needed as a carbohydrate source. Other non-carbohydrate ingredients should not be added with the purpose of imparting or enhancing a sweet taste. ]

<sup>5)</sup> For [Name of the product] for young children with a protein level below 3.0 g/100 kcal a maximum level of available carbohydrates up to 14 g/100 kcal (3.3 g/100 kJ) may be permitted by competent national and/or regional authorities.

**d) Vitamins****Vitamin A**

Unit	Minimum	Maximum	GUL
µg RE <sup>6)</sup> /100 kcal	60	180	-
µg RE <sup>6)</sup> /100 kJ	14	43	-

<sup>6)</sup> 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<sub>3</sub><sup>7)</sup>**

Unit	Minimum	Maximum	GUL
µg <sup>8)</sup> /100 kcal	[1.5]	[4.5]	-
µg <sup>8)</sup> /100 kJ	[0.36]	[ <del>4.08</del> ] [1.1]	-

<sup>7)</sup> Competent national and/or regional authorities may deviate from the conditions as appropriate for the nutritional needs of their population.]

<sup>8)</sup> Calciferol. 1 µg calciferol = 40 IU vitamin D.

**Riboflavin**

Unit	Minimum	Maximum	GUL
µg /100 kcal	80	-	650
µg /100 kJ	19	-	155

**Vitamin B<sub>12</sub>**

Unit	Minimum	Maximum	GUL
µg /100 kcal	0.1	-	2.0
µg /100 kJ	<del>0.024</del> <b>0.02</b>	-	0.48

**Vitamin C <sup>9)</sup>**

Unit	Minimum	Maximum	GUL
mg /100 kcal	10	-	70
mg /100 kJ	2.4	-	17

<sup>9)</sup> expressed as L-ascorbic acid

## e) Minerals and Trace Elements

### Iron <sup>10)</sup>

Unit	Minimum	Maximum	GUL
mg /100 kcal	1.0	3.0	-
mg /100 kJ	0.24	0.72	-

<sup>10)</sup> For [name of product] based on soy protein isolate a minimum value of 1.5 mg/100 kcal (0.36 mg/100 kJ) applies.

### Calcium

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

### Zinc

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

**Sodium chloride** should not be added to [name of the product] for young children.

**3.1.4** National and/or regional authorities may add mandatory requirements for essential nutrients listed under 3.1.3, Section B. Any additional mandatory nutrients should be chosen from the essential composition of follow-up formula for older infants under 3.1.3 Section A. If additional mandatory nutrients are added, the nutrient levels must be based on the nutrient composition of follow-up formula for older infants (3.1.3 Section A) which is informed by the composition of breast milk, and take into account the inherent levels of nutrients in cows' milk.

All nutrient levels may be amended if the nutritional needs of the local population and scientific justification warrants such deviation.

## 3.2 Optional Ingredients

**3.2.1** In addition to the ~~essential~~ compositional requirements listed under 3.1.3 Section B, other ingredients, or substances ~~or nutrients~~ may be added to [name of the product] for young children where the safety and suitability of the optional ingredient for particular nutritional purposes, at the level of use, is evaluated by national and/or regional authorities and demonstrated by generally accepted scientific evidence. Optional ingredients listed in 3.2.3 Section A are also permitted.

**3.2.2** When any of these ingredients, or substances ~~or nutrients~~ is added the **formula [name of product] for young children** shall contain sufficient amounts to achieve the intended effect.

**3.2.3** Additional nutrients may also be added to [name of the product] 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 (3.1.3 Section A) and take into account the inherent levels of nutrients in cows' milk; or amended by national and/or regional authorities if the nutritional needs of the local population and scientific justification warrants such deviation.