





EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10355/2015 ANNEX
(POOL/E4/2015/10355/10355-EN
ANNEX.doc)
[...](2015) XXX draft

ANNEXES 1 to 6

ANNEXES

to the

COMMISSION DELEGATED REGULATION (EU) .../...

**supplementing Regulation (EU) No 609/2013 of the European Parliament and of the
Council as regards the specific compositional and information requirements for
processed cereal-based food and baby food**

ANNEX I

COMPOSITIONAL REQUIREMENTS REFERRED TO IN ARTICLE 2(2)

1. CEREAL CONTENT

Processed cereal-based food shall be prepared primarily from one or more milled cereals and/or starchy root products.

The amount of cereal and/or starchy root shall not be less than 25 % of the final mixture on a dry weight for weight basis.

2. PROTEIN

- 2.1. For cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid and rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids, the protein content shall not exceed 1,3 g/100 kJ (5,5 g/100 kcal).
- 2.2. For cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid, the added protein shall not be less than 0,48 g/100 kJ (2 g/100 kcal).
- 2.3. For biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids, made with the addition of a high protein food, and presented as such, the added protein shall not be less than 0,36 g/100 kJ (1,5 g/100 kcal).
- 2.4. The chemical index of the added protein shall be equal to at least 80 % of that of the reference protein (casein as set out in Table 1), or the protein efficiency ratio (PER) of the protein in the mixture shall be equal to at least 70 % of that of the reference protein. In all cases, the addition of amino acids shall be permitted solely for the purpose of improving the nutritional value of the protein mixture, and only in the proportions necessary for that purpose.

Table 1
Amino acid composition of casein

	(g per 100 g of protein)
Arginine	3,7
Cystine	0,3
Histidine	2,9
Isoleucine	5,4
Leucine	9,5
Lysine	8,1
Methionine	2,8
Phenylalanine	5,2
Threonine	4,7
Tryptophan	1,6
Tyrosine	5,8
Valine	6,7

3. CARBOHYDRATES

3.1. If sucrose, fructose, glucose, glucose syrups or honey are added to simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids and rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids:

- the amount of added carbohydrates from these sources shall not exceed 1,8 g/100 kJ (7,5 g/100 kcal),
- the amount of added fructose shall not exceed 0,9 g/100 kJ (3,75 g/100 kcal).

3.2. If sucrose, fructose, glucose syrups or honey are added to cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid:

- the amount of added carbohydrates from these sources shall not exceed 1,2 g/100 kJ (5 g/100 kcal),
- the amount of added fructose shall not exceed 0,6 g/100 kJ (2,5 g/100 kcal).

4. LIPIDS

4.1. For simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids and rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids, the lipid content shall not exceed 0,8 g/100 kJ (3,3 g/100 kcal).

4.2. For cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid, the lipid content shall not exceed 1,1 g/100 kJ (4,5 g/100 kcal). If the lipid content exceeds 0,8 g/100 kJ (3,3 g/100 kcal):

- the amount of lauric acid shall not exceed 15 % of the total lipid content,
- the amount of myristic acid shall not exceed 15 % of the total lipid content,
- the amount of linoleic acid (in the form of glycerides = linoleates) shall not be less than 70 mg/100 kJ (300 mg/100 kcal) and shall not exceed 285 mg/100 kJ (1 200 mg/100 kcal).

5. MINERALS

5.1. Sodium

5.1.1. Sodium salts may only be added to processed cereal-based food for technological purposes.

5.1.2. The sodium content of processed cereal-based food shall not exceed 25 mg/100 kJ (100 mg/100 kcal).

5.2. Calcium

5.2.1. For cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid, the amount of calcium shall not be less than 20 mg/100 kJ (80 mg/100 kcal).

5.2.2. For rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids, manufactured with the addition of milk (milk biscuits) and presented as such, the amount of calcium shall not be less than 12 mg/100 kJ (50 mg/100 kcal).

6. VITAMINS

- 6.1. For processed cereal-based food, the amount of thiamin shall not be less than 25 µg/100 kJ (100 µg/100 kcal).
- 6.2. For cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid, the limits set out in Table 2 shall apply.

Those limits shall also apply where vitamins A and D are added to other processed cereal-based foods.

Table 2

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A (µg RE)⁽¹⁾	14	43	60	180
Vitamin D (µg)⁽²⁾	0,25	0,75	1	3

⁽¹⁾ RE = all trans retinol equivalents.

⁽²⁾ In the form of cholecalciferol, of which 10 µg = 400 i.u. of vitamin D.

7. MAXIMUM LIMITS FOR VITAMINS, MINERALS AND TRACE ELEMENTS, IF ADDED

The maximum limits set out in Table 3 shall apply. By way of derogation from Article 2(4), the limits for potassium and calcium refer to the product as sold.

Table 3

Nutrient	Maximum per 100 kcal
Vitamin A (µg RE)	180
Vitamin E (mg α-TE) ⁽¹⁾	3
Vitamin D (µg)	3
Vitamin C (mg)	12,5/25 ⁽²⁾
Thiamin (mg)	0,5
Riboflavin (mg)	0,4
Niacin (mg NE) ⁽³⁾	4,5
Vitamin B6 (mg)	0,35
Folic acid (µg)	50
Vitamin B12 (µg)	0,35
Pantothenic acid (mg)	1,5
Biotin (µg)	10
Potassium (mg)	160
Calcium (mg)	80/180 ⁽⁴⁾ /100 ⁽⁵⁾
Magnesium (mg)	40
Iron (mg)	3

Zinc (mg)	2
Copper (µg)	40
Iodine (µg)	35
Manganese (mg)	0,6
<p>⁽¹⁾ α-TE = d-α-tocopherol equivalent.</p> <p>⁽²⁾ Limit applicable to products fortified with iron.</p> <p>⁽³⁾ NE = Niacin equivalents = mg nicotinic acid + mg tryptophan/60.</p> <p>⁽⁴⁾ Limit applicable to simple cereals which are or have to be reconstituted with milk or other appropriate nutritious liquids, and cereals with an added high protein food which are or have to be reconstituted with water or other protein-free liquid.</p> <p>⁽⁵⁾ Limit applicable to rusks and biscuits which are to be used either directly or, after pulverisation, with the addition of water, milk or other suitable liquids.</p>	

ANNEX II

COMPOSITIONAL REQUIREMENTS REFERRED TO IN ARTICLE 2(3)

1. PROTEIN

- 1.1. If meat, poultry, fish, offal or other traditional source of protein are the only ingredients mentioned in the name of the product:
 - the named meat, poultry, fish, offal or other traditional protein source, in total, shall constitute not less than 40 % by weight of the total product,
 - each named meat, poultry, fish, offal or other traditional source of protein shall constitute not less than 25 %, by weight, of total named protein sources,
 - the total protein from the named sources shall not be less than 1,7 g/100 kJ (7 g/100 kcal).
- 1.2. If meat, poultry, fish, offal or other traditional source of protein, singularly or in combination, are mentioned first in the name of the product, whether or not the product is presented as a meal:
 - the named poultry, fish, offal or other traditional protein source, in total, shall constitute not less than 10 % by weight of the total product,
 - each named meat, poultry, fish, offal or other traditional source of protein shall constitute not less than 25 % by weight, of total named protein sources,
 - the protein from the named sources shall not be less than 1 g/100 kJ (4 g/100 kcal).
- 1.3. If meat, poultry, fish, offal or other traditional source of protein, singularly or in combination are mentioned, but not first, in the name of the product, whether or not the product is presented as a meal:
 - the named meat, poultry, fish, offal or other traditional protein source, in total, shall constitute not less than 8 % by weight of the total product,
 - each named meat, poultry, fish, offal or other traditional source of protein shall constitute not less than 25 %, by weight, of total named protein sources,
 - the protein from the named sources shall not be less than 0,5 g/100 kJ (2,2 g/100 kcal),
 - the total protein in the product from all sources shall not be less than 0,7 g/100 kJ (3 g/100 kcal).
- 1.4. If cheese is mentioned together with other ingredients in the name of a savoury product, whether or not the product is presented as a meal:
 - the protein from the dairy sources shall not be less than 0,5 g/100 kJ (2,2 g/100 kcal),
 - the total protein in the product from all sources shall not be less than 0,7 g/100 kJ (3 g/100 kcal).
- 1.5. If the product is designated on the label as a meal, but does not mention meat, poultry, fish, offal or other traditional source of protein in the name of the product, the total protein in the product from all sources shall not be less than 0,7 g/100 kJ (3 g/100 kcal).

- 1.6. Sauces presented as an accompaniment to a meal shall be exempt from the requirements of points 1.1 to 1.5.
- 1.7. Sweet dishes that mention dairy products as the first or only ingredient in the name shall contain not less than 2,2 g dairy protein/100 kcal. All other sweet dishes shall be exempt from the requirements in 1.1 to 1.5.
- 1.8. The addition of amino acids shall be permitted solely for the purpose of improving the nutritional value of the protein present, and only in the proportions necessary for that purpose.

2. **CARBOHYDRATES**

The quantities of total carbohydrates present in fruit and vegetable juices and nectars, fruit-only dishes, and desserts or puddings shall not exceed:

- 10 g/100 ml for vegetable juices and drinks based on them,
- 15 g/100 ml for fruit juices and nectars and drinks based on them,
- 20 g/100 g for fruit-only dishes,
- 25 g/100 g for desserts and puddings,
- 5 g/100 g for other non-milk-based drinks.

3. **FAT**

- 3.1. For products referred to in point 1.1:

If meat or cheese are the only ingredients or are mentioned first in the name of a product, the total fat in the product from all sources shall not exceed 1,4 g/100 kJ (6 g/100 kcal).

- 3.2. For all other products, the total fat in the product from all sources shall not exceed 1,1 g/100 kJ (4,5 g/100 kcal).

4. **SODIUM**

- 4.1. The final sodium content in the product shall be either not more than 48 mg/100 kJ (200 mg/100 kcal) or not more than 200 mg per 100 g. However if cheese is the only ingredient mentioned in the name of the product, the final sodium content in the product shall not be more than 70 mg/100 kJ (300 mg/100 kcal).
- 4.2. Sodium salts may not be added to products based on fruit, nor to desserts, puddings except for technological purposes.

5. **VITAMINS**

Vitamin C

In a fruit juice, nectar, or vegetable juice the final content of vitamin C in the product shall be either not less than 6 mg/100 kJ (25 mg/100 kcal) or not less than 25 mg per 100 g.

Vitamin A

In vegetable juices, the final content of vitamin A in the product shall be not less than 25 µg RE/100 kJ (100 µg RE/100 kcal).

Vitamin A shall not be added to other baby food.

Vitamin D

Vitamin D shall not be added to baby food.

6. MAXIMUM LIMITS FOR VITAMINS, MINERALS AND TRACE ELEMENTS, IF ADDED

The maximum limits set out in Table 1 shall apply. By way of derogation from Article 2(4), the limits for potassium and calcium refer to the product as sold.

Table 1

Nutrient	Maximum per 100 kcal
Vitamin A ($\mu\text{g RE}$)	180 ⁽¹⁾
Vitamin E (mg $\alpha\text{-TE}$)	3
Vitamin C (mg)	12,5/25 ⁽²⁾ /125 ⁽³⁾
Thiamin (mg)	0,25
Riboflavin (mg)	0,4
Niacin (mg NE)	4,5
Vitamin B6 (mg)	0,35
Folic acid (μg)	50
Vitamin B12 (μg)	0,35
Pantothenic acid (mg)	1,5
Biotin (μg)	10
Potassium (mg)	160
Calcium (mg)	80
Magnesium (mg)	40
Iron (mg)	3
Zinc (mg)	2
Copper (μg)	40
Iodine (μg)	35
Manganese (mg)	0,6

⁽¹⁾ In accordance with point 5.
⁽²⁾ Limit applicable to products fortified with iron.
⁽³⁾ Limit applicable to fruit-based dishes, fruit juices, nectars and vegetable juices.

ANNEX III

ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 3(3)

Chemical name of the substance	Maximum residue level (mg/kg)
Cadusafos	0,006
Demeton-S-methyl/demeton-S-methyl sulfone/oxydemeton-methyl (individually or combined, expressed as demeton-S-methyl)	0,006
Ethoprophos	0,008
Fipronil (sum of fipronil and fipronil-desulfinyl, expressed as fipronil)	0,004
Propineb/propylenethiourea (sum of propineb and propylenethiourea)	0,006

ANNEX IV

ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 3(4)

Chemical name of the substance (residue definition)
Aldrin and dieldrin, expressed as dieldrin
Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone expressed as disulfoton)
Endrin
Fensulfothion (sum of fensulfothion, its oxygen analogue and their sulfones, expressed as fensulfothion)
Fentin, expressed as triphenyltin cation
Haloxyfop (sum of haloxyfop, its salts and esters including conjugates, expressed as haloxyfop)
Heptachlor and <i>trans</i> -heptachlor epoxide, expressed as heptachlor
Hexachlorobenzene
Nitrofen
Omethoate
Terbufos (sum of terbufos, its sulfoxide and sulfone, expressed as terbufos)

ANNEX V

REFERENCE INTAKES REFERRED TO IN ARTICLE 5(6)

Nutrient	Reference intake
Vitamin A	(µg) 400
Vitamin D	(µg) 7
Vitamin E	(mg TE) 5
Vitamin K	(µg) 12
Vitamin C	(mg) 45
Thiamin	(mg) 0,5
Riboflavin	(mg) 0,7
Niacin	(mg) 7
Vitamin B6	(mg) 0,7
Folate	(µg) 125
Vitamin B12	(µg) 0,8
Pantothenic acid	(mg) 3
Biotin	(µg) 10
Calcium	(mg) 550
Phosphorus	(mg) 550
Potassium	(mg) 1 000
Chloride	(mg) 500
Iron	(mg) 8
Zinc	(mg) 5
Iodine	(µg) 80
Selenium	(µg) 20
Copper	(mg) 0,5
Magnesium	(mg) 80
Manganese	(mg) 1,2