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[...] (2015) **XXX** draft

ANNEXES 1 to 4

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 food for special medical purposes

ANNEX I

COMPOSITIONAL REQUIREMENTS REFERRED TO IN ARTICLE 2(3)

Part A

Food for special medical purposes developed to satisfy the nutritional requirements of infants

1. Products referred to in Article 2(1)(a) developed to satisfy the nutritional requirements of infants shall contain the vitamins and mineral substances as specified in Table 1.
2. Products referred to in Article 2(1)(b) developed to satisfy the nutritional requirements of infants shall contain the vitamins and mineral substances as specified in Table 1, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.
3. Maximum levels of vitamins and mineral substances present in products referred to in Article 2(1)(c) developed to satisfy the nutritional requirements of infants shall not exceed those specified in Table 1, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.
4. Where this is not contrary to the requirements dictated by the intended use, food for special medical purposes developed to satisfy the nutritional requirements of infants shall comply with the provisions relating to other nutrients applicable to infant formula and follow-on formula, as the case may be, laid down in Commission Delegated Regulation (EU) [.../...]¹.

TABLE 1

Values for vitamins and minerals in food for special medical purposes developed to satisfy the nutritional requirements of infants

		Per 100 kJ		Per 100 kcal	
		Minimum	Maximum	Minimum	Maximum
Vitamins					
	Vitamin A (µg-RE) ⁽¹⁾	16,7	43	70	180
	Vitamin D (µg)	0,48	0,72	2	3
	Vitamin K (µg)	0,24	6	1	25
	Vitamin C (mg)	0,96	7,2	4	30
	Thiamin (µg)	9,6	72	40	300
	Riboflavin (µg)	14,3	107	60	450
	Vitamin B ₆ (µg)	4,8	72	20	300
	Niacin (mg) ⁽²⁾	0,1	0,72	0,4	3
	Folate (µg-DFE) ⁽³⁾	3,6	11,4	15	47,6

¹ COMMISSION DELEGATED REGULATION (EU) .../... of XXX supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding, OJ ..., XXX.

	Vitamin B ₁₂ (µg)	0,02	0,12	0,1	0,5
	Panthenic Acid (mg)	0,1	0,48	0,4	2
	Biotin (µg)	0,24	4,8	1	20
	Vitamin E (mg α-tocopherol) ⁽⁴⁾	0,14	1,2	0,6	5
Minerals					
	Sodium (mg)	6	14,3	25	60
	Chloride (mg)	14,3	38,2	60	160
	Potassium (mg)	19,1	38,2	80	160
	Calcium (mg) ⁽⁵⁾	12	60	50	250
	Phosphorus (mg) ⁽⁶⁾	6	24	25	100
	Magnesium (mg)	1,2	3,6	5	15
	Iron (mg)	0,07	0,6	0,3	2,5
	Zinc (mg)	0,12	0,6	0,5	2,4
	Copper (µg)	14,3	29	60	120
	Iodine (µg)	3,6	8,4	15	35
	Selenium (µg)	0,72	2	3	8,6
	Manganese (µg)	0,24	24	1	100
	Chromium (µg)	-	2,4	-	10
	Molybdenum (µg)	-	3,3	-	14
	Fluoride (µg)	-	47,8	-	200
<p>⁽¹⁾ Preformed vitamin A; RE = all trans retinol equivalent.</p> <p>⁽²⁾ Preformed niacin.</p> <p>⁽³⁾ Dietary folate equivalent: 1 µg DFE = 1 µg food folate = 0.6 µg folic acid from formula.</p> <p>⁽⁴⁾ Based on vitamin E activity of RRR-α-tocopherol.</p> <p>⁽⁵⁾ The calcium:available phosphorus molar ratio shall not be less than 1 nor greater than 2.</p> <p>⁽⁶⁾ Total phosphorus.</p>					

Part B

Food for special medical purposes other than that developed to satisfy the nutritional requirements of infants

1. Products referred to in Article 2(1)(a) other than those developed to satisfy the nutritional requirements of infants shall contain the vitamins and mineral substances as specified in Table 2.
2. Products referred to in Article 2(1)(b) other than those developed to satisfy the nutritional requirements of infants shall contain the vitamins and mineral substances as specified in Table 2, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.
3. Maximum levels of vitamins and mineral substances present in products referred to in Article 2(1)(c) other than those developed to satisfy the nutritional requirements of infants shall not exceed those specified in Table 2, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

TABLE 2

Values for vitamins and minerals in food for special medical purposes other than that developed to satisfy the nutritional requirements of infants

		Per 100 kJ		Per 100 kcal	
		Minimum	Maximum	Minimum	Maximum
Vitamins					
	Vitamin A (µg-RE)	8,4	43	35	180
	Vitamin D (µg)	0,12	0,65/0,75 ⁽¹⁾	0,5	2,5/3 ⁽¹⁾
	Vitamin K (µg)	0,85	5	3,5	20
	Vitamin C (mg)	0,54	5,25	2,25	22
	Thiamin (mg)	0,015	0,12	0,06	0,5
	Riboflavin (mg)	0,02	0,12	0,08	0,5
	Vitamin B ₆ (mg)	0,02	0,12	0,08	0,5
	Niacin (mg NE)	0,22	0,75	0,9	3
	Folic Acid (µg)	2,5	12,5	10	50
	Vitamin B ₁₂ (µg)	0,017	0,17	0,07	0,7
	Panhotenic Acid (mg)	0,035	0,35	0,15	1,5
	Biotin (µg)	0,18	1,8	0,75	7,5
	Vitamin E (µg α-TE)	0,5 / g of polyunsaturated fatty acids expressed as linoleic acid but in	0,75	0,5 / g of polyunsaturated fatty acids expressed as linoleic acid but in	3

		no case less than 0,1 mg per 100 available kJ		no case less than 0,5 mg per 100 available kcal	
Minerals					
Sodium (mg)	7,2	42	30	175	
Chloride (mg)	7,2	42	30	175	
Potassium (mg)	19	70	80	295	
Calcium (mg)	8,4/12 ⁽¹⁾	42/60 ⁽¹⁾	35/50 ⁽¹⁾	175/250 ⁽¹⁾	
Phosphorus (mg)	7,2	19	30	80	
Magnesium (mg)	1,8	6	7,5	25	
Iron (mg)	0,12	0,5	0,5	2	
Zinc (mg)	0,12	0,36	0,5	1,5	
Copper (µg)	15	125	60	500	
Iodine (µg)	1,55	8,4	6,5	35	
Selenium (µg)	0,6	2,5	2,5	10	
Manganese (mg)	0,012	0,12	0,05	0,5	
Chromium (µg)	0,3	3,6	1,25	15	
Molybdenum (µg)	0,72	4,3	3,5	18	
Fluoride (mg)	-	0,05	-	0,2	
⁽¹⁾ For products intended for children of 1 to 10 years of age.					

ANNEX II

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 III

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
Haloxypop (sum of haloxypop, its salts and esters including conjugates, expressed as haloxypop)
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 IV

NAME REFERRED TO IN ARTICLE 4

The name of food for special medical purposes shall be respectively:

- in Bulgarian: ‘Храни за специални медицински цели’,
- in Spanish: ‘Alimento para usos médicos especiales’,
- in Czech: ‘Potravinami pro zvláštní lékařské účely’,
- in Danish: ‘Fødevare til særlige medicinske formål’,
- in German: ‘Lebensmittel für besondere medizinische Zwecke (bilanzierte Diät)’,
- in Estonian: ‘Meditsiinilisel näidustusel kasutamiseks ettenähtud toit’,
- in Greek: ‘Τρόφιμα για ειδικούς ιατρικούς σκοπούς’,
- in English: ‘Food for special medical purposes’,
- in French: ‘Denrée alimentaire destinée à des fins médicales spéciales’,
- in Croatian: ‘Hrana za posebne medicinske potrebe’,
- in Italian: ‘Alimento a fini medici speciali’,
- in Latvian: ‘Īpašiem medicīniskiem nolūkiem paredzēta pārtika’,
- in Lithuanian: ‘Specialios medicininės paskirties maisto produktai’,
- in Hungarian: ‘Speciális gyógyászati célra szánt élelmiszer’,
- in Maltese: ‘Ikel għal skopijiet mediċi speċjali’,
- in Dutch: ‘Voeding voor medisch gebruik’,
- in Polish: ‘Żywność specjalnego przeznaczenia medycznego’,
- in Portuguese: ‘Alimento para fins medicinais específicos’,
- in Romanian: ‘Alimente destinate unor scopuri medicale speciale’,
- in Slovak: ‘Potraviny na osobitné lekárske účely’,
- in Slovenian: ‘Živila za posebne zdravstvene namene’,
- in Finnish: ‘Erityisiin lääkinällisiin tarkoituksiin tarkoitettu elintarvike (kliininen ravintovalmiste)’,
- in Swedish: ‘Livsmedel för speciella medicinska ändamål’.