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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
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Subject:	ANNEX to the COMMISSION DELEGATED REGULATION (EU)/... amending Delegated Regulation (EU) 2016/127 as regards the protein-related requirements for infant and follow-on formula manufactured from protein hydrolysates

Delegations will find attached document C(2025) 6725 annex.

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ANNEX

ANNEX

to the

COMMISSION DELEGATED REGULATION (EU)

**amending Delegated Regulation (EU) 2016/127 as regards the protein-related
requirements for infant and follow-on formula manufactured from protein hydrolysates**

ANNEX

Annexes I, II and III are amended as follows:

- (1) in Annex I, point 2.3. is replaced by the following:

‘2.3. Infant formula manufactured from protein hydrolysates

Infant formula manufactured from protein hydrolysates shall comply with the protein-related requirements provided under point 2.3.1., point 2.3.2., point 2.3.3., point 2.3.4. or point 2.3.5.

2.3.1. Protein-related requirements group A

2.3.1.1. Protein content

Minimum	Maximum
0,44 g/100 kJ	0,67 g/100 kJ
(1,86 g/100 kcal)	(2,8 g/100 kcal)

2.3.1.2. Protein source

Demineralised sweet whey protein derived from cows' milk after enzymatic precipitation of caseins using chymosin, consisting of:

- (a) 63% caseino-glycomacropeptide free whey protein isolate with a minimum protein content of 95% of dry matter and protein denaturation of less than 70% and a maximum ash content of 3 %; and
- (b) 37% sweet whey protein concentrate with a minimum protein content of 87% of dry matter and protein denaturation of less than 70% and a maximum ash content of 3,5%.

2.3.1.3. Protein processing

Two-stage hydrolysis process using a trypsin preparation with a heat-treatment step (from 3 to 10 minutes at 80 to 100 °C) between the two hydrolysis steps.

2.3.1.4. Indispensable and conditionally indispensable amino acids and L-carnitine

For an equal energy value, infant formula manufactured from protein hydrolysates must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section B of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine may be added together if the methionine: cysteine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine: phenylalanine ratio is not greater

than 2. The ratio of methionine: cysteine and of tyrosine: phenylalanine may be greater than 2, provided that the suitability of the product concerned for infants is demonstrated in accordance with Article 3(3).

The L-carnitine content shall be at least equal to 0,3 mg/100 kJ (1,2 mg/100 kcal).

2.3.2. Protein-related requirements group B

2.3.2.1. Protein content

Minimum	Maximum
0,55 g/100 kJ	0,67 g/100 kJ
(2,3 g/100 kcal)	(2,8 g/100 kcal)

2.3.2.2. Protein source

Whey protein derived from cows' milk, consisting of:

- (a) 77% acid whey, coming from whey protein concentrate with a protein content of 35 to 80%;
- (b) 23% sweet whey, coming from demineralised sweet whey with a minimum protein content of 12,5%.

2.3.2.3. Protein processing

The source material is hydrated and heated. Following the heat-treatment step, the hydrolysis is carried out at a pH of 7,5 to 8,5 and a temperature of 55 to 70°C with the use of an enzyme mixture of a serine endopeptidase and a protease/peptidase complex. The food enzymes are inactivated in a heat treatment step (from 2 to 10 seconds at 120 to 150°C) during the production process.

2.3.2.4. Indispensable and conditionally indispensable amino acids and L-carnitine

For an equal energy value, infant formula manufactured from protein hydrolysates must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine may be added together if the methionine: cysteine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine: phenylalanine ratio is not greater than 2. The ratio of methionine: cysteine and of tyrosine: phenylalanine may be greater than 2, provided that the suitability of the product concerned for infants is demonstrated in accordance with Article 3(3).

The L-carnitine content shall be at least equal to 0,3 mg/100 kJ (1,2 mg/100 kcal).

2.3.3. Protein-related requirements group C

2.3.3.1. Protein content

Minimum	Maximum
0,45 g/100 kJ	0,67 g/100 kJ
(1,9 g/100 kcal)	(2,8 g/100 kcal)

2.3.3.2. Protein source

Whey protein derived from cows' milk, consisting of 100% sweet whey protein concentrate with a minimum protein content of 80%.

2.3.3.3. Protein processing

The source material is hydrated and heated. Prior to the hydrolysis, the pH is adjusted to 6,5 - 7,5 at a temperature of 50 – 65 °C. The hydrolysis is carried out with the use of an enzyme mixture of a serine endopeptidase and a metalloprotease. The food enzymes are inactivated in a heat treatment step (from 2 to 10 seconds at 110 to 140 °C) during the production process.

2.3.3.4. Indispensable and conditionally indispensable amino acids and L-carnitine

For an equal energy value, infant formula manufactured from protein hydrolysates must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine may be added together if the methionine: cysteine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine: phenylalanine ratio is not greater than 2. The ratio of methionine: cysteine and of tyrosine: phenylalanine may be greater than 2, provided that the suitability of the product concerned for infants is demonstrated in accordance with Article 3(3).

The L-carnitine content shall be at least equal to 0,3 mg/100 kJ (1,2 mg/100 kcal).

2.3.4. Protein-related requirements group D

2.3.4.1. Protein content

Minimum	Maximum
0,57 g/100 kJ	0,67 g/100 kJ
(2,4 g/100 kcal)	(2,8 g/100 kcal)

2.3.4.2. Protein source

Whey protein derived from cow's milk, consisting of 100% sweet whey protein concentrate with a minimum protein content of 70%.

2.3.4.3. Protein processing

The source material is hydrated and heated. Following the heat-treatment step, the hydrolysis is carried out at a pH of 7,0 to 8,0 and a temperature of 50 to 60°C, using a two-stage hydrolysis process with the use of a serine endopeptidase and a metalloprotease. The food enzymes are inactivated by heat treatment (at 100 to 120°C for at least 30 seconds) during the production process.

2.3.4.4. Indispensable and conditionally indispensable amino acids and L-carnitine

For an equal energy value, infant formula manufactured from protein hydrolysates must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine may be added together if the methionine: cysteine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine: phenylalanine ratio is not greater than 2. The ratio of methionine: cysteine and of tyrosine: phenylalanine may be greater than 2, provided that the suitability of the product concerned for infants is demonstrated in accordance with Article 3(3).

The L-carnitine content shall be at least equal to 0,3 mg/100 kJ (1,2 mg/100 kcal).

2.3.5. Protein-related requirements group E

2.3.5.1. Protein content

Minimum	Maximum
0,48 g/100 kJ	0,67 g/100 kJ
(2,0 g/100 kcal)	(2,8 g/100 kcal)

2.3.5.2. Protein source

Whey protein derived from cow's milk, consisting of 100% whey protein concentrate with a minimum protein content of 80%.

2.3.5.3. Protein processing

The source material is hydrated and heated. Following the heat-treatment step, the pH is adjusted to 7 to 8, at a temperature of 50 to 70 °C, using a two-stage hydrolysis process with the use of serine endopeptidases. The food enzymes are inactivated by heat

treatment (at 80 to 90 °C for 25 to 35 minutes) during the production process.

2.3.5.4. Indispensable and conditionally indispensable amino acids and L-carnitine

For an equal energy value, infant formula manufactured from protein hydrolysates must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine may be added together if the methionine:cysteine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine: phenylalanine ratio is not greater than 2. The ratio of methionine: cysteine and of tyrosine: phenylalanine may be greater than 2, provided that the suitability of the product concerned for infants is demonstrated in accordance with Article 3(3).

The L-carnitine content shall be at least equal to 0,3 mg/100 kJ (1,2 mg/100 kcal).’;

(2) in Annex II, point 2.3. is replaced by the following:

‘2.3. Follow-on formula manufactured from protein hydrolysates

Follow-on formula manufactured from protein hydrolysates shall comply with the protein-related requirements provided under point 2.3.1., point 2.3.2., point 2.3.3., point 2.3.4 or point 2.3.5.

2.3.1. Protein-related requirements group A

2.3.1.1. Protein content

Minimum	Maximum
0,44 g/100 kJ	0,67 g/100 kJ
(1,86 g/100 kcal)	(2,8 g/100 kcal)

2.3.1.2. Protein source

Demineralised sweet whey protein derived from cows' milk after enzymatic precipitation of caseins using chymosin, consisting of:

- (a) 63% caseino-glycomacropeptide free whey protein isolate with a minimum protein content of 95% of dry matter and protein denaturation of less than 70% and a maximum ash content of 3 %; and
- (b) 37% sweet whey protein concentrate with a minimum protein content of 87% of dry matter and protein

denaturation of less than 70% and a maximum ash content of 3,5%.

2.3.1.3. Protein processing

Two-stage hydrolysis process using a trypsin preparation with a heat-treatment step (from 3 to 10 minutes at 80 to 100 °C) between the two hydrolysis steps.

2.3.1.4. Indispensable and conditionally indispensable amino acids

For an equal energy value, follow-on formula manufactured from protein hydrolysates must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section B of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine and the concentration of phenylalanine and tyrosine may be added together.

2.3.2. Protein related requirements group B

2.3.2.1 Protein content

Minimum	Maximum
0,55 g/100 kJ	0,67 g/100 kJ
(2,3 g/100 kcal)	(2,8 g/100 kcal)

2.3.2.2. Protein source

Whey protein derived from cows' milk, consisting of:

- (a) 77% acid whey, coming from whey protein concentrate with a protein content of 35 to 80%;
- (b) 23% sweet whey, coming from demineralised sweet whey with a minimum protein content of 12,5%.

2.3.2.3. Protein processing

The source material is hydrated and heated. Following the heat-treatment step, the hydrolysis is carried out at a pH of 7,5 to 8,5 and a temperature of 55 to 70°C with the use of an enzyme mixture of a serine endopeptidase and a protease/peptidase complex. The food enzymes are inactivated in a heat treatment step (from 2 to 10 seconds at 120 to 150°C) during the production process.

2.3.2.4. Indispensable and conditionally indispensable amino acids

For an equal energy value, follow-on formula manufactured from protein hydrolysates must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine and the

concentration of phenylalanine and tyrosine may be added together.

2.3.3. Protein related requirements group C

2.3.3.1. Protein content

Minimum	Maximum
0,45 g/100 kJ	0,67 g/100 kJ
(1,9 g/100 kcal)	(2,8 g/100 kcal)

2.3.3.2. Protein source

Whey protein derived from cows' milk, consisting of 100% sweet whey protein concentrate with a minimum protein content of 80%.

2.3.3.3. Protein processing

The source material is hydrated and heated. Prior to the hydrolysis, the pH is adjusted to 6,5 - 7,5 at a temperature of 50 - 65°C. The hydrolysis is carried out with the use of an enzyme mixture of a serine endopeptidase and a metalloprotease. The food enzymes are inactivated in a heat treatment step (from 2 to 10 seconds at 110 to 140°C) during the production process.

2.3.3.4. Indispensable and conditionally indispensable amino acids

For an equal energy value, follow-on formula manufactured from protein hydrolysates must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine and the concentration of phenylalanine and tyrosine may be added together.

2.3.4. Protein-related requirements group D

2.3.4.1. Protein content

Minimum	Maximum
0,57 g/100 kJ	0,67 g/100 kJ
(2,4 g/100 kcal)	(2,8 g/100 kcal)

2.3.4.2. Protein source

Whey protein derived from cow's milk, consisting of 100% sweet whey protein concentrate with a minimum protein content of 70%.

2.3.4.3. Protein processing

The source material is hydrated and heated. Following the heat-treatment step, the hydrolysis is carried out at a pH of 7.0 to 8.0 and a temperature of 50 to 60°C, using a two-stage hydrolysis process with the use of a serine endopeptidase and a metalloprotease. The food enzymes are inactivated by heat treatment (at 100 to 120°C for at least 30 seconds) during the production process.

2.3.4.4. Indispensable and conditionally indispensable amino acids

For an equal energy value, follow-on formula manufactured from protein hydrolysates must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine and the concentration of phenylalanine and tyrosine may be added together.

2.3.5. Protein-related requirements group E

2.3.5.1. Protein content

Minimum	Maximum
0,48 g/100 kJ	0,67 g/100 kJ
(2,0 g/100 kcal)	(2,8 g/100 kcal)

2.3.5.2. Protein source

Whey protein derived from cow's milk, consisting of 100% whey protein concentrate with a minimum protein content of 80%.

2.3.5.3. Protein processing

The source material is hydrated and heated. Following the heat-treatment step, the pH is adjusted to 7 to 8, at a temperature of 50 to 70 °C, using a two-stage hydrolysis process with the use of serine endopeptidases. The food enzymes are inactivated by heat treatment (at 80 to 90 °C for 25 to 35 minutes) during the production process.

2.3.5.4. Indispensable and conditionally indispensable amino acids

For an equal energy value, follow-on formula manufactured from protein hydrolysates must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine and the concentration of phenylalanine and tyrosine may be added together.';

- (3) in Annex III, the introductory sentence under Section A is replaced by the following:
- ‘For the purposes of points 2.1., 2.2., 2.3.2., 2.3.3., 2.3.4. and 2.3.5 of Annexes I and II, the indispensable and conditionally indispensable amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal, are the following:’.