II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2023/589

of 10 January 2023

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

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009 ([1]), and in particular Article 11(2) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) 2016/127 ([2]) lays down, amongst other things, specific compositional requirements for infant formula and follow-on formula manufactured from protein hydrolysates. It provides that infant formula and follow-on formula manufactured from protein hydrolysates are to comply with the requirements for protein content, protein source, protein processing as well as with the requirements for indispensable and conditionally indispensable amino acids and L-carnitine as set out in point 2.3 of Annex I and point 2.3 of Annex II to that Regulation.

(2) As stated in Delegated Regulation (EU) 2016/127, in its opinion of 24 July 2014 on the essential composition of infant and follow-on formulae ([3]), the European Food Safety Authority ('the Authority') noted that the safety and suitability of each specific formula containing protein hydrolysates has to be established by clinical evaluation in the target population. So far, the Authority has evaluated positively two protein hydrolysates used in infant and follow-on formulae. The composition of those two protein hydrolysates is reflected in the requirements currently set out in Delegated Regulation (EU) 2016/127. However, those requirements may be updated in order to allow the placing on the market of a formula manufactured from protein hydrolysates with a composition different from those already positively assessed, following a case-by-case evaluation by the Authority of their safety and suitability.

([1]) OJ L 181, 29.6.2013, p. 35.

([2]) Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 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 L 25, 2.2.2016, p. 1).

([3]) EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion on the essential composition of infant and follow-on formulae. *EFSA Journal* 2014;12(7):3760.

(3) On 6 February 2019, the Commission received a request from meyer.science GmbH, on behalf of HIPP-Werk Georg Hipp OHG and Arla Foods Ingredients, for the evaluation by the Authority of the safety and suitability of an infant and follow-on formula manufactured from a protein hydrolysate, the composition of which does not comply with the requirements laid down in point 2.3 of Annex I and point 2.3 of Annex II to Delegated Regulation (EU) 2016/127.

(4) Upon request from the Commission, the Authority issued a scientific opinion on 9 March 2022 on the nutritional safety and suitability of that infant and follow-on formula ([4]). In that opinion, the Authority concluded that the protein hydrolysate in question is a nutritionally safe and suitable protein source for use in an infant and follow-on formula, as long as the formula in which it is used contains a minimum of 0,45 g/100 kJ (1,9 g/100 kcal) protein and complies with the other compositional criteria set out in Delegated Regulation (EU) 2016/127 and with the amino acid pattern contained in Section A of Annex III to that Regulation.

(5) Taking into account the Authority's conclusions, it is appropriate to allow the placing on the market of infant and follow-on formula manufactured from the protein hydrolysate in question. Therefore, the requirements for protein hydrolysates set out in Delegated Regulation (EU) 2016/127 should be updated and adapted to include also the requirements for that protein hydrolysate.

(6) Annexes I, II and III to Delegated Regulation (EU) 2016/127 should therefore be amended accordingly.

(7) Delegated Regulation (EU) 2016/127 applies to infant and follow-on formula manufactured from protein hydrolysates as of 22 February 2022. In order to allow the placing on the market of infant and follow-on formula manufactured from hydrolysed protein in accordance with the requirements set out in this Regulation without unnecessary delay, this Regulation should enter into force as a matter of urgency,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I, II and III to Delegated Regulation (EU) 2016/127 are amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 10 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

([4]) EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), 2022. Nutritional safety and suitability of a specific protein hydrolysate derived from whey protein concentrate and used in an infant and follow-on formula manufactured from hydrolysed protein by HIPP-Werk Georg Hipp OHG (dossier submitted by meyer.science GmbH) EFSA Journal 2022;20(3):7141.

ANNEX

Annexes I, II and III to Delegated Regulation (EU) 2016/127 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, or point 2.3.3.

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) 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, or point 2.3.3.

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.';

(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 and 2.3.3 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:'.