COMMISSION DELEGATED REGULATION (EU) 2022/519

of 14 January 2022

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 others, specific compositional requirements for infant formula and follow-on formula manufactured from protein hydrolysates. It provides that infant 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 the recitals of 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. The Authority further stated that only one formula containing partially hydrolysed whey protein had been positively evaluated by the Authority so far. The composition of the formula evaluated by the Authority corresponds to 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 formula manufactured from protein hydrolysates with a composition different from the one already positively assessed, following a case-by-case evaluation of their safety and suitability by the Authority.

(3) On 20 September 2019, the Commission received a request from Danone Trading ELN B.V. 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.

([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.

(4) Upon request from the Commission, the Authority issued a scientific opinion on 28 November 2020 on the nutritional safety and suitability of the specific protein hydrolysate derived from whey protein concentrate and used in an infant and follow-on formula manufactured from hydrolysed protein by Danone Trading ELN B.V ([4]). The Authority concluded that the protein hydrolysate in question is a nutritionally safe and suitable protein source for use in infant and follow-on formula, as long as the formula in which it is used contains a minimum of 0,55 g/100 kJ (2,3 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 conclusions of the Authority's opinion of 2020, 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 Regulation (EU) 2016/127 should be updated and adapted to include also the requirements concerning this protein hydrolysate.

(6) Delegated Regulation (EU) 2016/127 provides that its provisions on infant and follow-on formula manufactured from protein hydrolysates are to apply from 22 February 2022. In order to allow infant and follow-on formula manufactured from hydrolysed protein in accordance with the requirements set out in this Regulation to remain in the market from that date, this Regulation should enter into force as a matter of urgency.

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

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, 14 January 2022.

For the Commission
The President
Ursula VON DER LEYEN

([4]) EFSA NDA Panel (EFSA Panel on Nutrition, Novel Foods and Food Allergens), 2020. 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 Danone Trading ELN B.V. EFSA Journal 2020;18(11):6304.

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 either with the protein related requirements provided under point 2.3.1, or with the protein related requirements provided under point 2.3.2.

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) 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 either with the protein related requirements provided under point 2.3.1, or with the protein related requirements provided under point 2.3.2.

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, 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.';

(3) Annex III is amended as follows:

(a) Section A is amended as follows:

(i) the title is replaced by the following:

'Infant formula and follow-on formula manufactured from cows' milk or goats' milk proteins and infant formula and follow-on formula manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins and infant formula and follow-on formula manufactured from protein hydrolysates';

(ii) the introductory sentence is replaced by the following:

'For the purposes of points 2.1, 2.2 and 2.3.2 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:';

(b) in Section B, the introductory sentence is replaced by the following:

'For the purposes of point 2.3.1 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:'.