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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	30 March 2026
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2026) 2042 final
Subject:	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(2026) 2042 final.

Encl.: C(2026) 2042 final

EUROPEAN
COMMISSION

Brussels, 30.3.2026
C(2026) 2042 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 30.3.2026

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

(Text with EEA relevance)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE DELEGATED ACT

Article 11(2) of 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[1] empowers the European Commission to adopt delegated acts in accordance with Article 18 of that Regulation, in order to update the delegated acts adopted pursuant to Article 11(1) thereof, such as Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 as regards the specific compositional and information requirements for infant formulae and follow-on formulae and as regards requirements on information relating to infant and young child feeding[2].

This Delegated Regulation aims to amend Delegated Regulation (EU) 2016/127 by amending the requirements set out therein for the protein content, protein source, protein processing and protein quality for infant and follow-on formula manufactured from hydrolysates.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission consulted the European Food Safety Authority (the 'Authority') on the matter. The Authority`s scientific opinion on nutritional safety and suitability of a specific protein hydrolysate derived from sources of skimmed cow's milk and whey protein concentrates and used in infant and follow-on formula manufactured from hydrolysed protein by Healthcare Reckitt B.V.[3] constitutes the scientific basis for the requirements in this Delegated Regulation.

Member States' experts were consulted in writing within the Expert Group on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control[4] between 5 and 27 June 2025.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The legal basis of this Delegated Regulation is Article 11(2) of Regulation (EU) No 609/2013. According to that provision, the Commission is empowered to adopt delegated acts in order to update the delegated acts adopted pursuant to Article 11(1) of that Regulation, such as Delegated Regulation (EU) 2016/127 subject to the general requirements set out in Article 6 and 9 thereof, to the additional requirements of Article 10, and taking into account relevant technical and scientific progress.

The changes to Delegated Regulation (EU) 2016/127 relate to the update of the compositional requirements for infant and follow-on formula manufactured from protein hydrolysates laid down in Annexes I and II of that Regulation following the Authority's positive assessment of a protein hydrolysate.

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1 OJ L 181, 29.6.2013, p. 35.

2 OJ L 25, 2.2.2016, p. 1.

3 EFSA NDA Panel. Nutritional safety and suitability of a specific protein hydrolysate derived from sources of skimmed cow's milk and whey protein concentrates and used in infant and follow-on formula manufactured from hydrolysed protein by Healthcare Reckitt B.V., https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2025.9278.

4 Reference E02893 in the Register of Commission Expert Groups and other similar entities.

COMMISSION DELEGATED REGULATION (EU) …/...

of 30.3.2026

amending Delegated Regulation (EU) 2016/127 as regards the protein-related 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 specific compositional requirements for infant 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 in point 2.3 of Annex II to that Delegated Regulation.

(2) 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 positively evaluated five protein hydrolysates used in infant and follow-on formulae. The composition of those five protein hydrolysates is included in the requirements 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 different composition from those already positively assessed, following their evaluation by the Authority of their safety and suitability.

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1 OJ L 181, 29.6.2013, p. 35, ELI: http://data.europa.eu/eli/reg/2013/609/oj.

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, ELI: http://data.europa.eu/eli/reg_del/2016/127/oj).

3 EFSA NDA Panel (2014). Scientific Opinion on the essential composition of infant and follow-on formulae, https://doi.org/10.2903/j.efsa.2014.3760.

(3) On 15 February 2019, the Commission received a request from Healthcare Reckitt B.V. for the evaluation by the Authority of the safety and suitability of two products, an infant and follow-on formula, manufactured from a specific protein hydrolysate, the composition of which did not comply with the requirements laid down in point 2.3 of Annex I and in point 2.3 of Annex II to Delegated Regulation (EU) 2016/127.

(4) Upon request from the Commission, the Authority adopted a scientific opinion on 29 January 2025 on the nutritional safety and suitability of that specific protein hydrolysate in infant and follow-on formula[4]. In that opinion, the Authority concluded that the specific protein hydrolysate as described in the opinion is a nutritionally safe and a 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 remaining 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 Delegated 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 specific protein hydrolysate. Therefore, it is appropriate to add 'Protein-related requirements group F' to the compositional requirements for protein hydrolysates set out in Delegated Regulation (EU) 2016/127.

(6) 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 twentieth day following that 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, 30.3.2026

For the Commission
The President
Ursula VON DER LEYEN

[4] EFSA NDA Panel (2025). Nutritional safety and suitability of a specific protein hydrolysate derived from sources of skimmed cow's milk and whey protein concentrates and used in infant and follow-on formula manufactured from hydrolysed protein by Healthcare Reckitt B.V., https://doi.org/10.2903%2Fj.efsa.2025.9278.