COMMISSION DELEGATED REGULATION (EU) …/…

of XXX

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)
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 empowers the European Commission to adopt delegated acts in order to update the delegated acts adopted pursuant to Article 11(1) of that Regulation, namely, amongst others, 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 formulae and follow-on formulae and as regards requirements on information relating to infant and young child feeding.

This delegated Regulation aims to amend Delegated Regulation (EU) 2016/127 by amending the requirements set out by that Regulation 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 (‘Authority’) on the matter. The Authority’s Scientific Opinion on the 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. constitutes the scientific basis for the requirements in this delegated Regulation.

Member States’ experts were consulted in writing in the context of the Expert Group on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control between 29 March 2021 and 16 April 2021.

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 proposed 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.

1 OJ L 181, 29.6.2013, p. 35.
4 Reference E02893 in the Register of Commission Expert Groups and other similar entities.
COMMISSION DELEGATED REGULATION (EU) .../

of XXX

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
Commission Regulations (EC) No 41/2009 and (EC) No 953/2009\(^5\), and in particular
Article 11(2) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) 2016/127\(^6\) 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\(^7\), 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.

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\(^5\) OJ L 181, 29.6.2013, p. 35.

\(^6\) 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).

\(^7\) EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2014. Scientific Opinion
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.

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. 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.

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.

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.

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 should 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.

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Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN