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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	20 January 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2021) 155 final
Subject:	COMMISSION DELEGATED REGULATION (EU) …/... of 20.1.2021 amending Commission Delegated Regulation (EU) No 2016/127 as regards the date of application of certain of its provisions

Delegations will find attached document C(2021) 155 final.

Encl.: C(2021) 155 final

EUROPEAN
COMMISSION

Brussels, 20.1.2021
C(2021) 155 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 20.1.2021

amending Commission Delegated Regulation (EU) No 2016/127 as regards the date of application of certain of its provisions

(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 order to update the delegated acts adopted pursuant to Article 11(1) of that Regulation, namely, amongst others, Commission Delegated Regulation (EU) No 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[2].

This delegated Regulation aims to amend Delegated Regulation (EU) No 2016/127 by deferring the date of application of its provisions on infant formula and follow-on formula manufactured from protein hydrolysates, due to the unexpected delays in the scientific assessments of such formulae by the European Food Safety Authority ('Authority') caused by the COVID-19 pandemic.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Member States' experts were consulted 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[3] , which met on the subject on 15 October 2020.

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) No 2016/127, subject to the general requirements set out in Articles 6 and 9 of the same Regulation, to the additional requirements of Article 10, and taking into account relevant technical and scientific progress.

The proposed changes to Delegated Regulation (EU) No 2016/127 result from the fact that the COVID-19 pandemic and the associated public health crisis caused unexpected delays in the scientific assessments of infant and follow-on formulae manufactured from protein hydrolysate, which are currently under evaluation by the Authority. In order to avoid potential market disruptions, it is necessary to defer the application of the requirements for infant formula and follow-on formula manufactured from protein hydrolysates by one year.

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1 OJ L 181, 29.6.2013, p. 35.

2 OJ L 25, 2.2.2016, p. 1.

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

COMMISSION DELEGATED REGULATION (EU) …/...

of 20.1.2021

amending Commission Delegated Regulation (EU) No 2016/127 as regards the date of application of certain of its provisions

(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[4], and in particular Article 11(2) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) 2016/127[5] lays down, amongst others, specific compositional requirements for infant and follow-on formula manufactured from protein hydrolysate. Delegated Regulation (EU) 2016/127 provides that its provisions on infant and follow-on formula manufactured from protein hydrolysates apply from 22 February 2021.

(2) The use of protein hydrolysates as a source of protein in infant formula and follow-on formula has been allowed under Directive 2006/141/EC[6]. However, in its opinion on the essential composition of infant and follow-on formulae[7], the European Food Safety Authority ('Authority') noted that the safety and suitability of each specific formula containing protein hydrolysates has to be established by clinical evaluation.

(3) Only one of the formulae currently on the market has received a positive assessment by the Authority so far. Its composition corresponds to the requirements provided in Delegated Regulation (EU) 2016/127.

(4) The Authority is currently assessing the safety and suitability of a number of other compositions, corresponding to formulae currently lawfully placed on the market in accordance with Commission Directive 2006/141/EC.

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4 OJ L 181, 29.6.2013, p. 35.

5 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 (OJ L 25, 2.2.2016, p. 1).

6 Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC (OJ L 401, 30.12.2006, p. 1).

7 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.

(5) The requirements provided in Delegated Regulation (EU) 2016/127 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

(6) However, the COVID-19 pandemic and the associated public health crisis caused unexpected delays in the scientific assessments of the formulae currently under evaluation by the Authority.

(7) In order to avoid potential market disruptions, it is necessary to defer the application of the requirements for infant formula and follow-on formula manufactured from protein hydrolysates by a period of time considered appropriate to compensate the effects of the COVID-19 pandemic on the evaluation carried out by the Authority.

(8) In light of the need to avoid market disruptions, this Regulation should enter into force as a matter of urgency on the day of its publication in the *Official Journal of the European Union*.

(9) Commission Delegated Regulation (EU) 2016/127 should therefore be amended accordingly.

HAS ADOPTED THIS REGULATION:

Article 1

Delegated Regulation (EU) 2016/127 is amended as follows:

(1) In Article 13, the first paragraph is replaced by the following:

`In accordance with Article 20(4) of Regulation (EU) No 609/2013, Directive 2006/141/EC is repealed with effect from 22 February 2020. However, Directive 2006/141/EC shall continue to apply until 21 February 2022 to infant formula and follow-on formula manufactured from protein hydrolysates`

(2) In Article 14, the second paragraph is replaced by the following:

`It shall apply from 22 February 2020, except in respect of infant formula and follow-on formula manufactured from protein hydrolysates, to which it shall apply from 22 February 2022.`

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, 20.1.2021

For the Commission
The President
Ursula VON DER LEYEN