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COVER NOTE

From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	14 March 2019
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2019) 1883 final
Subject:	COMMISSION DELEGATED REGULATION (EU) …/... of 14.3.2019 amending Delegated Regulation (EU) 2016/127 with regard to vitamin D requirements for infant formula and erucic acid requirements for infant formula and follow-on formula

Delegations will find attached document C(2019) 1883 final.

Encl.: C(2019) 1883 final

EUROPEAN
COMMISSION

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C(2019) 1883 final

COMMISSION DELEGATED REGULATION (EU) …/...

of 14.3.2019

amending Delegated Regulation (EU) 2016/127 with regard to vitamin D requirements for infant formula and erucic acid requirements for infant formula and follow-on formula

(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, 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[2].

This delegated Regulation aims to amend Commission Delegated Regulation (EU) 2016/127 by lowering the maximum vitamin D content for infant formula and by lowering the maximum level of erucic acid for infant formula and follow-on formula.

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission consulted the European Food Safety Authority (EFSA) on the matter. EFSA's Scientific Opinions on the update of the tolerable upper intake level for vitamin D for infants[3] as well as on erucic acid in feed and food[4] constitute respectively the scientific basis for the requirements on vitamin D and erucic acid in the delegated Regulation.

Member States' experts were consulted in the context of the meeting of the Expert Group on food intended for infants and young children, food for special medical purposes and total diet replacement for weight control[5] of 11 June 2018. Additional written consultation of the Expert Group was carried out between 15 June 2018 and 2 September 2018.

Other stakeholders were consulted on the subject in writing in the context of the Advisory Group on the Food Chain and Animal and Plant Health[6] between 18 October 2018 and 30 October 2018. One comment was provided by an industry association indicating potential technical difficulties in manufacturing infant formulae in line with the proposed requirements for vitamin D. Concerns expressed with regard to the latter disregarded EFSA`s scientific opinion with respect to the safety aspects of the products concerned. Due to safety considerations as well as considering that non-compliance with the proposed requirements for Vitamin D remains a probability, such concerns could not be taken into account.

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1 OJ L 181, 29.6.2013, p. 35.
2 OJ L 25, 2.2.2016, p. 1.
3 EFSA Journal 2018;16(8):5365, 118 pp.
4 EFSA Journal 2016;14(11):4593, 173 pp.
5 Reference E02893 in the Register of Commission Expert Groups and other similar entities.
6 Reference E00860 in the Register of Commission Expert Groups and other similar entities.

The lowering of the maximum level for erucic acid has been discussed with the Member States in the Working Group Agricultural Contaminants and a targeted stakeholder consultation including all relevant stakeholder organisations representing industry and consumers on the lowering of the maximum level has taken place. No objections to the lowering of the maximum level were raised.

3. LEGAL ELEMENTS OF THE DELEGATED ACT

The legal basis of the delegated Regulation is Article 11(2) of Regulation (EU) No 609/2013. According to that provision, read in conjunction with Article 11(1) and 1(1) of Regulation (EU) No 609/2013, the Commission is empowered to adopt delegated acts in order to update the specific compositional requirements applicable to infant formula and follow-on formula which are laid down in Delegated Regulation (EU) 2016/127. The empowerment is subject to the general requirements set out in Article 6 and 9 thereof and taking into account relevant technical and scientific progress.

The proposed changes to Delegated Regulation (EU) 2016/127 relate to the reduction of the maximum vitamin D content permitted for infant formula and the lowering of the maximum content of erucic acid in infant formula and follow-on formula.

COMMISSION DELEGATED REGULATION (EU) …/...

of 14.3.2019

amending Delegated Regulation (EU) 2016/127 with regard to vitamin D requirements for infant formula and erucic acid requirements for infant formula and follow-on formula

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

Whereas:

(1) Commission Delegated Regulation (EU) 2016/127[8] lays down inter alia compositional and labelling rules for infant formula and follow-on formula.

(2) Delegated Regulation (EU) 2016/127 specifically provides for infant formula to contain vitamin D at amounts in the range 2–3 μg/100 kcal.

(3) Concerns have been raised that high consumption of formula containing 3 μg/100 kcal of vitamin D, combined with additional vitamin D intakes through supplementation, could lead some infants to consume vitamin D at amounts that could pose safety risks. In order to ensure the highest level of protection of infants, the Commission requested the European Food Safety Authority ('the Authority') to assess the safety of consumption by infants of formulae containing 3 μg/100 kcal of vitamin D.

(4) In its Scientific Opinion of 28 June 2018 on the update of the tolerable upper intake level for vitamin D for infants,[9] the Authority concluded that the use of infant formula containing vitamin D at 3 μg/100 kcal may lead some infants aged up to 4 months to

[7] OJ L 181, 29.6.2013, p. 35.

[8] 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.

[9] EFSA Journal 2018; 16(8):5365,118 pp.

consume amounts of vitamin D above the tolerable upper intake level from the formula alone.

(5) That opinion also concluded that the use of a maximum vitamin D content of 2.5 µg/100 kcal in infant formula does not result in intakes of vitamin D above the tolerable upper intake level from the formula alone. On the basis of that opinion, the maximum vitamin D content permitted under Delegated Regulation (EU) 2016/127 for infant formula should be lowered to 2.5 µg/100 kcal, in accordance with Article 6 and paragraphs (1) to (4) of Article 9 of Regulation (EU) No 609/2013.

(6) Maximum levels for erucic acid in infant formulae and follow-on formulae have been established by Delegated Regulation (EU) 2016/127.

(7) The Authority has adopted a scientific opinion on the presence of erucic acid in feed and food.[10] That opinion concluded that the 95th percentile dietary exposure level was highest in infants and other children which may indicate a risk for young individuals with high erucic acid exposure.

(8) Taking into account the conclusions of the opinion, it is appropriate to lower the maximum levels of erucic acid in infant formula and follow-on formula.

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

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I and II 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, 14.3.2019

For the Commission
The President
Jean-Claude JUNCKER

[10] EFSA Journal 2016;14(11):4593, 173 pp.