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From:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	29 January 2018
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	C(2018) 438 final
Subject:	COMMISSION DELEGATED REGULATION (EU) .../... of 29.1.2018 amending Commission Delegated Regulation (EU) No 2016/127 with regard to protein requirements for follow-on formula

Delegations will find attached document C(2018) 438 final.

Encl.: C(2018) 438 final

Brussels, 29.1.2018
C(2018) 438 final

COMMISSION DELEGATED REGULATION (EU) .../...

of 29.1.2018

**amending Commission Delegated Regulation (EU) No 2016/127 with regard to protein
requirements for 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 control¹ empowers the European Commission to adopt delegated acts in order to update, 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 feeding².

This delegated Regulation aims to amend Commission Delegated Regulation (EU) No 2016/127 by lowering the minimum protein content required in that Regulation for follow-on formula based on cows' milk or goats' milk protein to 1.6 g/100 kcal (0,38 g/100 kJ).

2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

The Commission consulted the European Food Safety Authority (EFSA) on the matter. EFSA's Scientific Opinion on the safety and suitability for use by infants of follow-on formulae with a protein content of at least 1.6 g/100 kcal³ 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 control⁴. The written consultation of the Expert Group was carried out between 30 June 2017 and 6 September 2017.

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 Delegated Regulation (EU) No 2016/127 taking into account relevant technical and scientific progress.

The proposed changes to Delegated Regulation (EU) No 2016/127 relate to the minimum protein content required in that Regulation for follow-on formula based on cows' milk or goats' milk protein that are reduced on the basis of EFSA's advice.

¹ OJ L 181, 29.6.2013, p. 35.

² OJ L 25, 2.2.2016, p. 1.

³ EFSA NDA Panel (EFSA Panel on Dietetic Products, Nutrition and Allergies), 2017, Scientific Opinion on the safety and suitability for use by infants of follow-on formulae with a protein content of at least 1.6 g/100 kcal. EFSA Journal 2017;15(5):4781.

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

COMMISSION DELEGATED REGULATION (EU) .../...

of 29.1.2018

amending Commission Delegated Regulation (EU) No 2016/127 with regard to protein requirements for 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 953/2009⁵, and in particular Article 11(2) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) 2016/127⁶ lays down inter alia compositional and labelling rules for infant formula and follow-on formula.
- (2) Delegated Regulation (EU) 2016/127 specifically provides for follow-on formula manufactured from cow's milk or goat's milk proteins to contain at least 1.8 g protein/100 kcal (0.43 g/100kJ).
- (3) The Commission received a request from a food business operator for the placing on the market of a follow-on formula based on intact protein from cow's milk with a protein content of at least 1.61 g/100 kcal, which is below the permitted levels of Directive 2006/141/EC and Delegated Regulation (EU) 2016/127.
- (4) On request from the Commission, the European Food Safety Authority issued a scientific opinion on 5 April 2017 on the safety and suitability for use by infants of follow-on formulae with a protein content of at least 1.6 g/100 kcal⁷. The European Food Safety Authority concluded that the use of follow-on formula, based on intact protein from cow's milk or from goat's milk, with a protein content of 1.6 g/100 kcal (0.38 g/100 kJ) and otherwise complying with the requirements of the relevant Union rules, is safe and suitable for healthy infants living in Europe with an intake of complementary foods of a sufficient quality. On the basis of that opinion, and in order to foster the development of innovative products, the minimum protein content required under Delegated Regulation (EU) 2016/127 for follow-on formula based on cow's milk or goat's milk protein should be lowered to 1.6 g/100 kcal.

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 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.

⁷ EFSA Journal 2017;15(5):4781.

- (5) Annex II to Delegated Regulation (EU) 2016/127 should therefore be amended accordingly.

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Commission Delegated Regulation (EU) No 2016/127 is 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, 29.1.2018

For the Commission
The President
Jean-Claude JUNCKER