Commission Delegated Regulation (EU) 2018/561 of 29 January 2018 amending Delegated Regulation (EU) 2016/127 with regard to protein requirements for follow-on formula (Text with EEA relevance)

COMMISSION DELEGATED REGULATION (EU) 2018/561

of 29 January 2018

amending Delegated Regulation (EU) 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 953/2009[(1)], and in particular Article 11(2) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) 2016/127[(2)] 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/100 kJ).

(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 Commission Directive 2006/141/EC[(3)] 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 kcal[(4)]. 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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Delegated Regulation (EU) 2018/561. (See end of Document for details)*

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

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Delegated Regulation (EU) 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 January 2018.

For the Commission

The President

Jean-Claude JUNCKER