Commission Delegated Regulation (EU) 2019/828 of 14 March 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)

COMMISSION DELEGATED REGULATION (EU) 2019/828

of 14 March 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[(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 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[(3)], 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 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[(4)]. 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 March 2019.

For the Commission

The President

Jean-Claude JUNCKER