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 formula and follow-on formula and as regards requirements on information relating to infant and young child feeding (Text with EEA relevance)

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 formula and follow-on formula and as regards requirements on information relating to infant and young child feeding

(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(1) thereof,

Whereas:

(1) Commission Directive 2006/141/EC[(2)] lays down harmonised rules on infant formula and follow-on formula in the framework of Directive 2009/39/EC of the European Parliament and of the Council[(3)].

(2) Directives 2009/39/EC and 2006/141/EC are repealed by Regulation (EU) No 609/2013. That Regulation lays down general compositional and information requirements for different categories of food, including infant formula and follow-on formula. The Commission has to adopt specific compositional and information requirements for infant formula and follow-on formula, taking into account the provisions of Directive 2006/141/EC.

(3) Infant formula is the only processed foodstuff which wholly satisfies the nutritional requirements of infants during the first months of life until the introduction of appropriate complementary feeding. In order to safeguard the health of those infants, it is necessary to ensure that infant formula is the only product marketed as suitable for such use during that period.

(4) The essential composition of infant formula and follow-on formula must satisfy the nutritional requirements of infants in good health as established by generally accepted scientific data.

(5) Infant formula and follow-on formula are sophisticated products that are specially formulated for a vulnerable group of consumers. In order to ensure the safety and suitability of such products, detailed requirements should be laid down on the composition of infant formula and follow-on formula, including requirements on energy value, macronutrient and micronutrient content. These requirements should be based on the latest scientific advice of the European Food Safety Authority ('the Authority') in its opinion on the essential composition of infant and follow-on formulae[(4)].

(6) In order to ensure innovation and product development, the voluntary addition to infant formula and follow-on formula of ingredients not covered by specific requirements of this Regulation should be possible. All ingredients used in the manufacture of infant formula and follow-on formula should be suitable for infants and their suitability should have been demonstrated, when necessary, by appropriate studies. It is the responsibility of food business operators to demonstrate such suitability and of national competent authorities to consider, on a case-by-case basis, whether this is the case. Guidance on the design and conduct of appropriate studies has been published by expert scientific groups such as the Scientific Committee on Food, the UK Committee on the Medical Aspects of Food and Nutrition Policy, and the European Society for Paediatric Gastroenterology, Hepatology and Nutrition. Such guidance should be taken into consideration in the manufacturing of infant formula or follow-on formula.

(7) Pursuant to Regulation (EU) No 609/2013, the Commission has to adopt provisions restricting or prohibiting the use of pesticides and on pesticide residues in infant formula and follow-on formula, taking account of those currently established in the Annexes to Directive 2006/141/EC. Adopting provisions that are in line with the current scientific knowledge requires a significant amount of time, given that a comprehensive evaluation has to be carried out by the Authority on a number of aspects, including the appropriateness of the toxicological reference values for infants and young children. Taking into account the date of 20 July 2015 set by Regulation (EU) No 609/2013 for the adoption of this Delegated Regulation, the relevant existing requirements of Directive 2006/141/EC should, at this stage, be taken over. However, it is appropriate to use the terminology of Regulation (EC) No 1107/2009 of the European Parliament and of the Council[(5)].

(8) Directive 2006/141/EC lays down specific requirements on the use of pesticides in products intended for the production of infant formula and follow-on formula and on pesticide residues in such food, based on two opinions given by the Scientific Committee for Food (SCF) on 19 September 1997[(6)] and 4 June 1998[(7)].

(9) A very low residue limit of 0,01 mg/kg for all pesticides is set on the basis of the precautionary principle. In addition, more severe limitations are set for a small number of pesticides or metabolites of pesticides for which even a maximum residue level (MRL) of 0,01 mg/kg might, under worst-case intake conditions, lead to an exposure exceeding the acceptable daily intake (ADI) for infants and young children.

(10) A prohibition of the use of certain pesticides would not necessarily guarantee that infant formula and follow-on formula are free from those pesticides, since some pesticides are persistent in the environment and their residues can be found in the food. For that

reason, those pesticides are considered not to have been used if residues are below a certain level.

(11) Infant formula and follow-on formula have to comply with Regulation (EU) No 1169/2011 of the European Parliament and of the Council[8]. In order to take account of the specific nature of infant formula and follow-on formula and in order to promote and protect breast feeding, this Regulation should lay down additions and exceptions to those general rules, where appropriate.

(12) Given the particular role of infant formula and follow-on formula in the diet of infants, it is important to ensure that products exported to third countries provide food information in a language easily understood by parents and caregivers, in the absence of specific relevant provisions established by or agreed with the importing country.

(13) Given the different role of infant formula and follow-on formula in the diet of infants, it is appropriate to lay down provisions requiring that a clear distinction can be made between them, so as to avoid any risk of confusion.

(14) The nutrition declaration for infant formula and follow-on formula is essential in order to guarantee their appropriate use, both for parents and caregivers and for health care professionals who recommend their consumption. For that reason and in order to provide more complete information, the nutrition declaration should include more particulars than those required by Regulation (EU) No 1169/2011. In addition, the exemption provided for in point 18 of Annex V to Regulation (EU) No 1169/2011 should not apply and the nutrition declaration should be mandatory for all infant formula and follow-on formula, irrespective of the package or container size.

(15) Article 30(2) of Regulation (EU) No 1169/2011 contains a limited list of nutrients that may be included on a voluntary basis in the nutrition declaration for food. That Article does not cover all the substances that may be added to infant formula and follow-on formula. In order to ensure legal clarity, it should be laid down explicitly that the nutrition declaration for infant formula and follow-on formula may include such substances. In addition, in certain cases, more detailed information on protein, carbohydrate and fat present in the product could provide additional useful information for parents, caregivers and healthcare professionals. Food business operators should therefore be allowed to provide such information on a voluntary basis.

(16) In order to facilitate product comparisons, the nutrition declaration for infant formula and follow-on formula should be expressed per 100 ml of the product ready for use after preparation in accordance with the manufacturer's instructions.

(17) Infant formula is a food intended for use by infants during the first months of life and satisfying by itself the nutritional requirements of such infants until the introduction of appropriate complementary feeding. The expression of nutrition information on the energy value and the amount of nutrients of infant formula as a percentage of daily reference intake values would mislead consumers and should therefore not be allowed. Follow-on formula is, on the contrary, a food intended for use by infants when appropriate complementary feeding is introduced and which constitutes the principal liquid element in a progressively diversified diet of such infants. For that reason, and

in order to ensure comparisons with other foods that can be included in the diet of such infants, the expression of nutrition information for follow-on formula as a percentage of daily reference intake values should be allowed. Given that healthy infants have different nutritional needs than adults, the use of daily reference intake values set out for the general adult population in Regulation (EU) No 1169/2011 would mislead consumers and should therefore not be allowed. For follow-on formula it should only be allowed to express nutrition information as a percentage of specific reference intakes that are appropriate for the age group.

(18) Nutrition and health claims are promotional tools that are used on a voluntary basis by food business operators in commercial communication, in line with the rules of Regulation (EC) No 1924/2006 of the European Parliament and of the Council[9]. Given the particular role of infant formula in the diet of infants, the use of nutrition and health claims should not be allowed for infant formula.

(19) Statements relating to the presence or absence of lactose in infant formula and follow-on formula can provide useful information to parents and caregivers. Therefore, it is appropriate to lay down rules on such statements, which might be reviewed taking account of future developments on the market.

(20) The mandatory addition of docosahexaenoic acid (DHA) to infant formula and follow-on formula is a new requirement introduced by this Regulation, as recently recommended by the Authority in its opinion on the essential composition of infant and follow-on formulae. Given that the addition of DHA was allowed on a voluntary basis under Directive 2006/141/EC, and parents and caregivers are familiar with the nutrition claim about the presence of DHA in infant formula, the use of which was permitted under that Directive, food business operators should be allowed to continue to refer to the presence of DHA in infant formula by a statement provided for in this Regulation for a limited period of time in order to avoid confusion. However, it is important that that statement provides full information to consumers about the mandatory presence of DHA in all infant formula products on the market.

(21) 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 for many years and the use of protein hydrolysates in the manufacturing of formula is widespread in the market. This is due, in particular, to the possibility, recognised by that Directive, to make a health claim on infant formula manufactured from protein hydrolysates describing the role of such formula in reducing the risk of developing allergy to milk proteins, under certain conditions laid down in that Directive. In its opinion on the essential composition of infant and follow-on formulae, the Authority noted that the safety and suitability of each specific formula containing protein hydrolysates has to be established by clinical evaluation and that only one formula containing partially hydrolysed whey protein has been positively evaluated so far. The Authority also noted that clinical studies are necessary to demonstrate if and to what extent a particular formula reduces the risk of developing short and long-term clinical manifestations of allergy in at-risk-infants who are not breast-fed. Taking into account the Authority's opinion, infant formula and follow-on formula manufactured from protein hydrolysates should only be allowed to

be placed on the market if their composition corresponds to the requirements of this Regulation. Those requirements 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. In addition, after the assessment by the Authority, on the basis of studies, where it is demonstrated that a specific formula manufactured from protein hydrolysates reduces the risk of developing allergy to milk proteins, further consideration will be given to how to adequately inform parents and caregivers about that property of the product.

(22) Regulation (EU) No 609/2013 provides that the labelling, presentation and advertising of infant formula and follow-on formula is to be designed so as not to discourage breastfeeding. There is scientific consensus that breast milk is the preferred food for healthy infants and the Union and its Member States are continuously committed to supporting breastfeeding. The conclusions adopted by the Council on nutrition and physical activity[(10)] invited Member States to promote and support adequate breastfeeding and welcomed the Member States' agreement on an EU Action Plan on Childhood Obesity 2014-2020, which includes a series of actions aimed at increasing breastfeeding rates in the Union. In this context, the EU Action Plan recognised the continuous importance of the World Health Organisation (WHO) International Code of Marketing of Breast-milk Substitutes, on which Directive 2006/141/EC was based. The WHO Code, adopted by the 34th World Health Assembly, aims at contributing to the provision of safe and adequate nutrition for infants, by the protection and promotion of breast-feeding, and by ensuring the proper use of breast-milk substitutes. It includes a series of principles related to, among others, marketing, information and responsibilities of health authorities.

(23) In order to protect the health of infants, the rules laid down in this Regulation and in particular those on labelling, presentation and advertising, and promotional and commercial practices should continue being in conformity with the principles and the aims of the International Code of Marketing of Breast-milk Substitutes bearing in mind the particular legal and factual situation existing in the Union. In particular, evidence shows that advertising directly to the consumer and other marketing techniques influence parents and caregivers in their decisions on how to feed their infants. For this reason, and taking into account the particular role of infant formula in the diet of infants, specific restrictions should be laid down in this Regulation on advertising and other marketing techniques for this type of product. However, this Regulation should not concern the conditions of sale of publications specialising in baby care and of scientific publications.

(24) In addition, information given on infant and young child feeding influences pregnant women, parents and caregivers when choosing the type of nourishment for children. It is therefore necessary to lay down requirements in order that such information ensures an adequate use of the products in question and is not counter to the promotion of breast feeding, in line with the principles of the WHO code.

(25) Article 17(2) of Regulation (EC) No 178/2002 of the European Parliament and of the Council[11] requires Member States to enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food and feed business operators at all stages of production, processing and distribution. In this context, in order to facilitate the efficient official monitoring of infant formula and follow-on formula, food business operators placing infant formula on the market should provide the national competent authorities with a model of the label used and all relevant information considered necessary to demonstrate compliance with this Regulation. A similar obligation should apply in respect of certain types of follow-on formula, unless Member States have a different efficient monitoring system.

(26) In order to enable food business operators to adapt to the new requirements, this Regulation should apply from a date that is four years after its entry into force. Taking into account the number and importance of the new requirements applicable to infant formula and follow-on formula manufactured from protein hydrolysates, in respect of such products this Regulation should apply from a date that is five years after its entry into force,

HAS ADOPTED THIS REGULATION:

(**1**) OJ L 181, 29.6.2013, p. 35.

(**2**) 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).

(**3**) Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses (OJ L 124, 20.5.2009, p. 21).

(**4**) 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**) Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC (OJ L 309, 24.11.2009, p. 1).

(**6**) Opinion of the Scientific Committee for Food on a maximum residue limit (MRL) of 0,01 mg/kg for pesticides in foods intended for infants and young children (expressed on the 19 September 1997).

(**7**) Further advice on the opinion of the Scientific Committee for Food expressed on the 19 September 1997 on a Maximum Residue Limit (MRL) of 0,01 mg/kg for pesticides in foods intended for infants and young children (adopted by the SCF on 4 June 1998).

(**8**) Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

(**9**) Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9).

(**10**) OJ C 213, 8.7.2014, p. 1.

(**11**) Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).