Commission Delegated Regulation (EU) 2016/128 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 food for special medical purposes (Text with EEA relevance)

COMMISSION DELEGATED REGULATION (EU) 2016/128

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 food for special medical purposes

(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 1999/21/EC[(2)] lays down harmonised rules on dietary foods for special medical purposes in the framework of Directive 2009/39/EC of the European Parliament and of the Council[(3)].

(2) Directives 2009/39/EC and 1999/21/EC are repealed by Regulation (EU) No 609/2013. That Regulation lays down general compositional and information requirements for different categories of food, including food for special medical purposes. The Commission has to adopt specific compositional and information requirements for food for special medical purposes, taking into account the provisions of Directive 1999/21/EC.

(3) Food for special medical purposes is developed in close cooperation with health care professionals to feed patients affected by or malnourished because of a specific diagnosed disease, disorder or medical condition that makes it impossible or very difficult for those patients to satisfy their nutritional needs through the consumption of other foods. For that reason, food for special medical purposes must be used under medical supervision, which may be applied with the assistance of other competent health professionals.

(4) The composition of food for special medical purposes may differ substantially depending, among others, on the specific disease, disorder or medical condition for the

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dietary management of which the product is intended, on the age of the patients and the place in which they receive health care support, and the product's intended use. In particular, food for special medical purposes can be classified in different categories depending on whether its composition is standard or specifically nutrient-adapted for a disease, disorder or medical condition and on whether or not it constitutes the sole source of nourishment for the persons for whom it is intended.

(5) Because of the wide diversity of food for special medical purposes, the rapidly evolving scientific knowledge on which it is based, and the need to ensure adequate flexibility to develop innovative products, it is not appropriate to lay down detailed compositional rules for such food products. It is however important to set principles and requirements specific to them in order to ensure that they are safe, beneficial and effective for the persons for whom they are intended on the basis of generally accepted scientific data.

(6) In particular, the nutritional composition of food for special medical purposes developed to satisfy the nutritional requirements of infants should be based on that of infant formula and follow-on formula, in order to take into account the specificities of the nutritional requirements of infants. However, taking into account that infant formula and follow-on formula are intended for healthy infants, derogations should be provided for food for special medical purposes developed to satisfy the nutritional requirements of infants when this is necessary for the intended use of the product.

(7) It is important to set basic rules concerning the content of vitamin and mineral substances in food for special medical purposes in order to ensure the free circulation of products which are different in composition and the protection of consumers. Such rules should be based on those of Directive 1999/21/EC, given that they have ensured an adequate framework for food for special medical purposes so far. Rules should include minimum and maximum amounts, in the case of products considered to be nutritionally complete for covering the nutritional requirements of the patient, and maximum amounts only, in the case of products considered to be nutritionally incomplete, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

(8) 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 food for special medical purposes developed to satisfy the nutritional requirements of infants and young children. 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 European Food Safety Authority on a number of aspects, including the appropriateness of the toxicological reference values for infants and young children.

(9) Directive 1999/21/EC does not lay down such provisions. Commission Directives 2006/125/EC[(4)] and 2006/141/EC[(5)], however, do currently lay down specific requirements in this respect for foods for healthy infants and young children, based on two opinions given by the Scientific Committee for Food (SCF) on 19 September 1997[(6)] and 4 June 1998[(7)].

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(10) 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 Directives 2006/125/EC and 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[8].

(11) 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.

(12) A prohibition of the use of certain pesticides would not necessarily guarantee that food for special medical purposes developed to satisfy the nutritional requirements of infants and young children is 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.

(13) Food for special medical purposes has to comply with Regulation (EU) No 1169/2011 of the European Parliament and of the Council[9]. In order to take account of the specific nature of food for special medical purposes, this Regulation should lay down additions and exceptions to those general rules, where appropriate.

(14) Providing all information that is necessary to ensure the appropriate use of food for special medical purposes should be mandatory for this type of food. That information should include information on the properties and characteristics in relation to, among others, the special processing and formulation, nutritional composition and rationale of use of the product that make it useful for its specific intended purpose. Such information should not be considered as nutrition and health claims within the meaning of Regulation (EC) No 1924/2006 of the European Parliament and of the Council[10].

(15) The nutrition declaration for food for special medical purposes is essential in order to guarantee its appropriate use, both for patients consuming that food and for health care professionals who recommend its consumption. For that reason and in order to provide more complete information to patients and healthcare professionals, 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 food for special medical purposes, irrespective of the package or container size.

(16) Consumers of food for special medical purposes have different nutritional needs than the normal population. The expression of nutrition information on the energy value and the amount of nutrients of food for special medical purposes as a percentage of daily reference intake values set out in Regulation (EU) No 1169/2011 would mislead consumers and should therefore not be allowed.

(17) The use of nutrition and health claims authorised under Regulation (EC) No 1924/2006 to promote food for special medical purposes would not be appropriate, since consumers

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of such products are patients suffering from a disease, disorder or condition and are, therefore, not part of the general healthy population. In addition, food for special medical purposes is to be used under medical supervision and its consumption should not be promoted through the use of nutrition and health claims directly targeting consumers. For those reasons, the use of nutrition and health claims should not be allowed for food for special medical purposes.

(18) In the past years, an increasing number of products have been placed on the market as food for special medical purposes developed to satisfy the nutritional requirements of infants. These products are sometimes promoted with means directly targeting consumers that are not subject to the restrictions under Union legislation applicable to infant formula and follow-on formula. In order to avoid possible abuses linked to the misclassification of products, reduce confusion for consumers on the nature of the different products being offered to them and guarantee conditions of fair competition, it seems appropriate to introduce additional restrictions on the labelling, presentation, advertising, and promotional and commercial practices of food for special medical purposes developed to satisfy the nutritional requirements of infants. Those restrictions should be similar to those applicable to infant formula and follow-on formula for healthy infants, with adjustments taking into account the intended use of the product and without prejudice to the need to provide food information to patients and health care professionals to ensure the product's appropriate use. Given that food for special medical purposes is to be used under medical supervision, those restrictions should not make it more difficult for food business operators to communicate with health care professionals and should allow health care professionals to assess the suitability of different products for their intended use.

(19) 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 food for special medical purposes, food business operators placing food for special medical purposes 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, unless Member States have a different efficient monitoring system.

(20) In order to enable food business operators to adapt to the new requirements, this Regulation should apply from a date that is 3 years after its entry into force. Taking into account the number and importance of the new requirements applicable to food for special medical purposes developed to satisfy the nutritional requirements of infants, in respect of such products this Regulation should apply from a date that is 4 years after its entry into force,

HAS ADOPTED THIS REGULATION:

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Article 1

Placing on the market

Food for special medical purposes may only be placed on the market if it complies with this Regulation.

Article 2

Compositional requirements

1 Food for special medical purposes is classified in the following three categories:

a nutritionally complete food with a standard nutrient formulation which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom it is intended;

b nutritionally complete food with a nutrient-adapted formulation specific for a disease, disorder or medical condition which, used in accordance with the manufacturer's instructions, may constitute the sole source of nourishment for the persons for whom it is intended;

c nutritionally incomplete food with a standard formulation or a nutrient-adapted formulation specific for a disease, disorder or medical condition which is not suitable to be used as the sole source of nourishment.

The food referred to in points (a) and (b) of the first subparagraph may also be used as a partial replacement or as a supplement to the patient's diet.

2 The formulation of food for special medical purposes shall be based on sound medical and nutritional principles. Its use, in accordance with the manufacturer's instructions, shall be safe, beneficial and effective in meeting the specific nutritional requirements of the persons for whom it is intended, as demonstrated by generally accepted scientific data.

3 Food for special medical purposes developed to satisfy the nutritional requirements of infants shall comply with the compositional requirements set out in Part A of Annex I.

Food for special medical purposes other than that developed to satisfy the nutritional requirements of infants shall comply with the compositional requirements set out in Part B of Annex I.

4 The compositional requirements set out in Annex I shall apply to the food for special medical purposes ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions.

Article 3

Requirements on pesticides in food for special medical purposes developed to satisfy the nutritional requirements of infants and young children

1 For the purposes of this Article, ‘residue’ means the residue of an active substance as referred to in Article 2(2) of Regulation (EC) No 1107/2009 used in a plant protection product as referred to in Article 2(1) of that Regulation, including metabolites and products resulting from the degradation or reaction of that active substance.