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[...] (2015) **XXX** draft

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

**of XXX**

**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)

## EXPLANATORY MEMORANDUM

### 1. CONTEXT OF THE DELEGATED ACT

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<sup>1</sup> repeals Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses<sup>2</sup> from 20 July 2016. Article 11 of the Regulation empowers the European Commission to adopt delegated acts laying down specific compositional and information requirements for the foods under its scope. These delegated acts shall be adopted by 20 July 2015. The relevant foods are:

- Infant formula and follow-on formula;
- Processed cereal-based food and baby food;
- Food for special medical purposes;
- Total diet replacement for weight control.

Recital 27 of the Regulation requires the Commission to take into account, when adopting such rules, Commission Directives 1996/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction<sup>3</sup>, 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes<sup>4</sup>, 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children<sup>5</sup> and 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae<sup>6</sup>, which lay down rules for the abovementioned foods today.

Article 20(4) of the Regulation foresees that the existing Commission Directives are repealed from the date of application of the delegated acts adopted by the Commission.

This delegated Regulation transfers the existing rules of Commission Directive 1999/21/EC on food for special medical purposes under the new framework of Regulation (EU) No 609/2013 and updates them where relevant on the basis of the consultations described in point 2.

### 2. CONSULTATIONS PRIOR TO THE ADOPTION OF THE ACT

Member States' experts were consulted 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 control<sup>7</sup>, which met on the subject on 15 May, 13 September and 15 November 2013, 7 February 2014 and 18 February 2015.

NGOs and other stakeholders were consulted in the context of the Advisory Group on the Food Chain and Animal and Plant Health<sup>8</sup>, which held a Working Group on the subject on 17 February 2015. The possibility to provide written comments was

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<sup>1</sup> OJ L 181, 29.6.2013, p. 35.

<sup>2</sup> OJ L 124, 20.5.2009, p. 21.

<sup>3</sup> OJ L 55, 6.3.1996, p. 22.

<sup>4</sup> OJ L 91, 7.4.1999, p. 29.

<sup>5</sup> OJ L 339, 6.12.2006, p. 16.

<sup>6</sup> OJ L 401, 30.12.2006, p. 1.

<sup>7</sup> Reference E02893 in the Register of Commission Expert Groups and other similar entities.

<sup>8</sup> Reference E00860 in the Register of Commission Expert Groups and other similar entities.

granted to all interested parties and comments were taken into account where relevant. Bilateral meetings were also held with all interested parties, as appropriate.

### **3. LEGAL ELEMENTS OF THE DELEGATED ACT**

Minor adjustments to the compositional requirements of food for special medical purposes for infants are introduced to increase consistency with the rules applicable to infant formula and follow-on formula, in line with the advice of the European Food Safety Authority<sup>9</sup>.

With respect to labelling, changes compared to Directive 1999/21/EC are aimed at ensuring consistency with horizontal rules of 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<sup>10</sup>, taking into account the specificities of the products. Rules are also adjusted to increase legal certainty on the intended use of the products.

Given that food for special medical purposes is to be used under medical supervision and should not be promoted directly to consumers, it is proposed to forbid the possibility to make nutrition and health claims on this type of food.

Upon request of the European Parliament and the Council in Regulation (EU) No 609/2013, it is proposed to extend to food for special medical purposes for infants all rules on labelling, presentation, advertising and marketing applicable to formulae for healthy infants that would not be contrary to the product's intended use. Also upon request of the Parliament and the Council, it is proposed to extend to food for special medical purposes for infants and young children the same rules on pesticides that apply to infant formula, follow-on formula, processed cereal-based food and baby food.

The application of the Delegated Regulation is deferred to allow food business operators to adapt to the technical changes.

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<sup>9</sup> 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.

<sup>10</sup> OJ L 304, 22.11.2011, p. 18.

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**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<sup>11</sup>, and in particular Article 11(1) thereof,

Whereas:

- (1) Commission Directive 1999/21/EC<sup>12</sup> 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<sup>13</sup>.
- (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 dietary management of which the product is intended, on the age of the patients and

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<sup>11</sup> OJ L 181, 29.6.2013, p. 35.

<sup>12</sup> Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes (OJ L 91, 7.4.1999, p. 29).

<sup>13</sup> 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).

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<sup>14</sup> and 2006/141/EC<sup>15</sup>, 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<sup>16</sup> and 4 June 1998<sup>17</sup>.
- (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<sup>18</sup>.
- (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<sup>19</sup>. 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

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<sup>14</sup> Commission Directive 2006/125/EC on processed cereal-based foods and baby foods for infants and young children (OJ L 339, 6.12.2006, p. 16).

<sup>15</sup> Commission Directive 2006/141/EC of 22 December 2006 on infant formula and follow-on formula and amending Directive 1999/21/EC (OJ L 401, 30.12.2006, p. 1).

<sup>16</sup> 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 19th September 1997).

<sup>17</sup> 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).

<sup>18</sup> 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).

<sup>19</sup> 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).

meaning of Regulation (EC) No 1924/2006 of the European Parliament and of the Council<sup>20</sup>.

- (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 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.

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<sup>20</sup> 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).

- (19) Article 17(2) of Regulation (EC) No 178/2002 of the European Parliament and of the Council<sup>21</sup> 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 three 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 four years after its entry into force,

HAS ADOPTED THIS REGULATION:

*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.

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<sup>21</sup> 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).

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.
2. Food for special medical purposes developed to satisfy the nutritional requirements of infants and young children shall not contain residues at levels exceeding 0,01 mg/kg per active substance.  
Those levels shall be determined by generally accepted standardised analytical methods.
3. By way of derogation from paragraph 2, for the active substances listed in Annex II, the maximum residue levels specified in that Annex shall apply.
4. Food for special medical purposes developed to satisfy the nutritional requirements of infants and young children shall only be produced from agricultural products for the production of which plant protection products containing the active substances listed in Annex III have not been used.  
However, for the purpose of checks, plant protection products containing the active substances listed in Annex III are considered not to have been used if their residues do not exceed a level of 0,003 mg/kg.
5. The levels referred to in paragraphs 2, 3 and 4 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 4*

##### *Name of the food*

The name of food for special medical purposes shall be as set out in Annex IV.

#### *Article 5*

##### *Specific requirements on food information*

1. Unless otherwise provided in this Regulation, food for special medical purposes shall comply with Regulation (EU) No 1169/2011.

2. In addition to the mandatory particulars listed in Article 9(1) of Regulation (EU) No 1169/2011, the following shall be additional mandatory particulars for food for special medical purposes:
- (a) a statement that the product must be used under medical supervision;
  - (b) a statement whether the product is suitable for use as the sole source of nourishment;
  - (c) a statement that the product is intended for a specific age group, as appropriate;
  - (d) where appropriate, a statement that the product poses a health hazard when consumed by persons who do not have the disease, disorder or medical condition for which the product is intended;
  - (e) the statement ‘For the dietary management of...’ where the blank shall be filled in with the disease, disorder or medical condition for which the product is intended;
  - (f) where appropriate, a statement concerning adequate precautions and contraindications;
  - (g) a description of the properties and/or characteristics that make the product useful in relation to the disease, disorder or medical condition for the dietary management of which the product is intended, in particular, as the case may be, relating to the special processing and formulation, the nutrients which have been increased, reduced, eliminated or otherwise modified and the rationale of the use of the product;
  - (h) where appropriate, a warning that the product is not for parenteral use;
  - (i) instructions for appropriate preparation, use and storage of the product after the opening of the container, as appropriate.

The particulars referred to in points (a) to (d) shall be preceded by the words ‘important notice’ or their equivalent.

3. Article 13(2) and (3) of Regulation (EU) No 1169/2011 shall also apply to the additional mandatory particulars referred to in paragraph 2 of this Article.

#### *Article 6*

##### *Specific requirements on the nutrition declaration*

1. In addition to the information referred to in Article 30(1) of Regulation (EU) No 1169/2011, the mandatory nutrition declaration for food for special medical purposes shall include the following:
- (a) the amount of each mineral substance and of each vitamin listed in Annex I to this Regulation and present in the product;
  - (b) the amount of components of protein, carbohydrate, fat and/or of other nutrients and their components, the declaration of which would be necessary for the appropriate intended use of the product;
  - (c) information on the osmolality or the osmolarity of the product where appropriate;
  - (d) information on the source and the nature of the protein and/or protein hydrolysates contained in the product.

2. By way of derogation from Article 30(3) of Regulation (EU) No 1169/2011, the information included in the mandatory nutrition declaration for food for special medical purposes shall not be repeated on the labelling.
3. The nutrition declaration shall be mandatory for all food for special medical purposes, irrespective of the size of the largest surface of the packaging or container.
4. Articles 31 to 35 of Regulation (EU) No 1169/2011 shall apply to all the nutrients included in the nutrition declaration for food for special medical purposes.
5. By way of derogation from Article 31(3) of Regulation (EU) No 1169/2011, the energy value and the amounts of nutrients of food for special medical purposes shall be those of the food as sold and, where appropriate, those of the food ready for use after preparation in accordance with the manufacturer's instructions.
6. By way of derogation from Article 32(3) and (4) of Regulation (EU) No 1169/2011, the energy value and the amount of nutrients of food for special medical purposes shall not be expressed as a percentage of the reference intakes set out in Annex XIII to that Regulation.
7. The particulars included in the nutrition declaration for food for special medical purposes that are not listed in Annex XV to Regulation (EU) No 1169/2011 shall be presented after the most relevant entry of that Annex they belong to or are components of.

Particulars not listed in Annex XV to Regulation (EU) No 1169/2011 that do not belong to or are not components of any of the entries of that Annex shall be presented in the nutrition declaration after the last entry of that Annex.

The indication of the amount of sodium shall appear together with the other minerals and may be repeated next to the indication of the salt content as follows: "Salt: X g (of which sodium: Y mg)".

#### *Article 7*

#### *Nutrition and health claims*

Nutrition and health claims shall not be made on food for special medical purposes.

#### *Article 8*

#### *Specific requirements for food for special medical purposes developed to satisfy the nutritional requirements of infants*

1. All mandatory particulars for food for special medical purposes developed to satisfy the nutritional requirements of infants shall appear in a language easily understood by the consumers.
2. The labelling, presentation and advertising of food for special medical purposes developed to satisfy the nutritional requirements of infants shall not include pictures of infants, or other pictures or text which may idealise the use of the product.  
  
However, graphic representations for easy identification of the product and for illustrating methods of preparation shall be permitted.
3. The labelling, presentation and advertising of food for special medical purposes developed to satisfy the nutritional requirements of infants shall be designed in such a way that it enables consumers to make a clear distinction between such products

and infant formula and follow-on formula, in particular as to the text, images and colours used, so as to avoid any risk of confusion.

4. Advertising of food for special medical purposes developed to satisfy the nutritional requirements of infants shall be restricted to publications specialising in baby care and scientific publications.

Member States may further restrict or prohibit such advertising. Such advertising shall contain only information of a scientific and factual nature.

The first and second subparagraphs shall not prevent the dissemination of information exclusively intended for health care professionals.

5. There shall be no point-of-sale advertising, giving of samples or any other promotional device to induce sales of food for special medical purposes developed to satisfy the nutritional requirements of infants directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales.
6. Manufacturers and distributors of food for special medical purposes developed to satisfy the nutritional requirements of infants shall not directly provide, to the general public or to pregnant women, mothers or members of their families, free or low-priced products, samples or any other promotional gifts.

#### *Article 9* *Notification*

When food for special medical purposes is placed on the market, the food business operator shall notify the competent authority of each Member State where the product concerned is being marketed of the information appearing on the label, by sending to it a model of the label used for the product, and of any other information the competent authority may reasonably request to establish compliance with this Regulation, unless a Member State exempts the food business operator from that obligation under a national system that guarantees an efficient official monitoring of the product concerned.

#### *Article 10* *Directive 1999/21/EC*

In accordance with Article 20(4) of Regulation (EU) No 609/2013, Directive 1999/21/EC is repealed with effect from [3 years after entry into force, same date as the first date in the second paragraph of Article 11]. However, Directive 1999/21/EC shall continue to apply until [4 years after entry into force minus 1 day] to food for special medical purposes developed to satisfy the nutritional requirements of infants.

References to Directive 1999/21/EC in other acts shall be construed as references to this Regulation in accordance with the scheme set out in the first paragraph.

#### *Article 11* *Entry into force and application*

This Regulation shall enter into force on the [...] day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [*3 years after entry into force*], except in respect of food for special medical purposes developed to satisfy the nutritional requirements of infants, to which it shall apply from [*4 years after entry into force*].

For the purposes of the second subparagraph of Article 21(1) of Regulation (EU) No 609/2013, in respect of food for special medical purposes developed to satisfy the nutritional requirements of infants the later date referred to in the second paragraph of this Article shall be considered as the date of application.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission*  
*The President*  
*Jean-Claude JUNCKER*