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Contents

[1] Text with EEA relevance

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

[1] Text with EEA relevance

II

(Non-legislative acts)

REGULATIONS

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(2) Directives 2009/39/EC and 2006/141/EC are repealed by Regulation (EU) No 609/2013.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

([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).

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 ([1]).

(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 ([2]).

(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 ([3]) and 4 June 1998 ([4]).

(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 ([5]). 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.

([1]) 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.

([2]) 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).

([3]) 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).

([4]) 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).

([5]) 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).

(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 ([1]). 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

([1]) 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).

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 ([1]) 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 ([2]) 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

([1]) OJ C 213, 8.7.2014, p. 1.
([2]) 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).

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:

Article 1

Placing on the market

1. Infant formula and follow-on formula may only be placed on the market if they comply with this Regulation.

2. No product other than infant formula may be marketed or otherwise represented as suitable for satisfying by itself the nutritional requirements of normal healthy infants during the first months of life until the introduction of appropriate complementary feeding.

Article 2

Compositional requirements

1. Infant formula shall comply with the compositional requirements set out in Annex I taking into account the values for the indispensable and conditionally indispensable amino acids set out in Annex III.

2. Follow-on formula shall comply with the compositional requirements set out in Annex II taking into account the values for the indispensable and conditionally indispensable amino acids set out in Annex III.

3. The values set out in Annexes I and II shall apply to the infant formula and follow-on formula ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions. For such preparation nothing more than the addition of water shall be required.

Article 3

Suitability of ingredients

1. Infant formula shall be manufactured from protein sources as set out in point 2 of Annex I and other food ingredients, as the case may be, whose suitability for infants from birth has been established by generally accepted scientific data.

2. Follow-on formula shall be manufactured from protein sources as set out in point 2 of Annex II and other food ingredients, as the case may be, whose suitability for infants aged over six months has been established by generally accepted scientific data.

3. The suitability referred to in paragraphs 1 and 2 shall be demonstrated by the food business operator through a systematic review of the available data relating to the expected benefits and to safety considerations as well as, where necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies.

Article 4

Requirements on pesticides

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. Infant formula and follow-on formula 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 IV, the maximum residue levels specified in that Annex shall apply.

4. Infant formula and follow-on formula shall only be produced from agricultural products for the production of which plant protection products containing the active substances listed in Annex V have not been used.

However, for the purpose of checks, plant protection products containing the active substances listed in Annex V 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 infant formula and follow-on formula ready for use, marketed as such or after preparation in accordance with the manufacturer's instructions.

Article 5

Name of the food

1. The name of infant formula and follow-on formula other than infant formula and follow-on formula manufactured entirely from cows' milk or goats' milk proteins shall be as set out in Part A of Annex VI.

2. The name of infant formula and follow-on formula manufactured entirely from cows' milk or goats' milk proteins shall be as set out in Part B of Annex VI.

Article 6

Specific requirements on food information

1. Unless otherwise provided in this Regulation, infant formula and follow-on formula 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 infant formula:

(a) a statement that the product is suitable for infants from birth when they are not breast fed;

(b) instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage;

(c) a statement concerning the superiority of breast feeding and a statement recommending that the product be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care. The particulars referred to in this point shall be preceded by the words 'important notice' or their equivalent and shall be given also in the presentation and advertising of infant formula.

3. 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 follow-on formula:

(a) a statement that the product is suitable only for infants over the age of six months, that it should form only part of a diversified diet, that it is not to be used as a substitute for breast milk during the first six months of life and that the decision to begin complementary feeding, including any exception to six months of age, should be made only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care, based on the individual infant's specific growth and development needs;

(b) instructions for appropriate preparation, storage and disposal of the product and a warning against the health hazards of inappropriate preparation and storage.

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

5. All mandatory particulars for infant formula and follow-on formula shall appear in a language easily understood by the consumers.

6. The labelling, presentation and advertising of infant formula and follow-on formula shall provide the necessary information about the appropriate use of the products, so as not to discourage breast feeding.

The labelling, presentation and advertising of infant formula and follow-on formula shall not use the terms 'humanised', 'maternalised', 'adapted', or terms similar to them.

The labelling, presentation and advertising of infant formula and follow-on formula shall be designed in such a way that it avoids any risk of confusion between infant formula and follow-on formula and enables consumers to make a clear distinction between them, in particular as to the text, images and colours used.

Article 7

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 infant formula and follow-on formula shall include the amount of each mineral substance and of each vitamin listed in Annex I or Annex II to this Regulation respectively and present in the product, with the exception of molybdenum.

The mandatory nutrition declaration for infant formula shall also include the amount of choline, inositol and carnitine.

By way of derogation from Article 30(1) of Regulation (EU) No 1169/2011, the mandatory nutrition declaration for infant formula and follow-on formula shall not include the amount of salt.

2. In addition to the information referred to in Article 30(2)(a) to (e) of Regulation (EU) No 1169/2011, the content of the mandatory nutrition declaration for infant formula and follow-on formula may be supplemented with one or more of the following:

(a) the amounts of components of protein, carbohydrate or fat;

(b) the whey protein/casein ratio;

(c) the amount of any of the substances listed in Annex I or Annex II to this Regulation or in the Annex to Regulation (EU) No 609/2013, where the indication of any of those substances is not covered by paragraph 1;

(d) the amount of any of the substances added to the product pursuant to Article 3.

3. By way of derogation from Article 30(3) of Regulation (EU) No 1169/2011, the information included in the mandatory nutrition declaration for infant formula and follow-on formula shall not be repeated on the labelling.

4. The nutrition declaration shall be mandatory for all infant formula and follow-on formula, irrespective of the size of the largest surface of the packaging or container.

5. Articles 31 to 35 of Regulation (EU) No 1169/2011 shall apply to all the nutrients included in the nutrition declaration for infant formula and follow-on formula.

6. By way of derogation from Articles 31(3), 32(2) and 33(1) of Regulation (EU) No 1169/2011, the energy value and the amounts of nutrients of infant formula and follow-on formula shall be expressed per 100 ml of the food ready for use after preparation in accordance with the manufacturer's instructions. Where appropriate, the information may in addition refer to 100 g of the food as sold.

7. 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 infant formula and follow-on formula shall not be expressed as a percentage of the reference intakes set out in Annex XIII to that Regulation.

In addition to the form of expression referred to in paragraph 6, in the case of follow-on formula, the declaration on vitamins and minerals in respect of the vitamins and minerals listed in Annex VII to this Regulation may be expressed as a percentage of the reference intakes set out in that Annex in relation to per 100 ml of the food ready for use after preparation in accordance with the manufacturer's instructions.

8. The particulars included in the nutrition declaration for infant formula and follow-on formula 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.

Article 8

Nutrition and health claims for infant formula

Nutrition and health claims shall not be made on infant formula.

Article 9

Statements related to lactose and docosahexaenoic acid (DHA)

1. The statement 'lactose only' may be used for infant formula and follow-on formula provided that lactose is the only carbohydrate present in the product.

2. The statement 'lactose free' may be used for infant formula and follow-on formula provided that the lactose content in the product is not greater than 2,5 mg/100 kJ (10 mg/100 kcal).

When the statement 'lactose free' is used for infant formula and follow-on formula manufactured from protein sources other than soya protein isolates, it shall be accompanied by the statement 'not suitable for infants with galactosaemia', which shall be indicated with the same font size and prominence as the statement 'lactose free' and in close proximity to it.

3. The statement 'contains Docosahexaenoic acid (as required by the legislation for all infant formula)' or 'contains DHA (as required by the legislation for all infant formula)' may only be used for infant formula placed on the market before 22 February 2025.

Article 10

Requirements for promotional and commercial practices for infant formula

1. Advertising of infant formula 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. Such information shall not imply or create a belief that bottle-feeding is equivalent or superior to breast feeding.

2. There shall be no point-of-sale advertising, giving of samples or any other promotional device to induce sales of infant formula directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales.

3. Manufacturers and distributors of infant formula shall not 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, either directly or indirectly via the health care system or health workers.

4. Donations or low-price sales of supplies of infant formula to institutions or organisations, whether for use in the institutions or for distribution outside them, shall only be used by or distributed for infants who have to be fed on infant formula and only for as long as required by such infants.

Article 11

Requirements on information relating to infant and young child feeding

1. Member States shall take measures ensuring that objective and consistent information is provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition, and covering the planning, provision, design and dissemination of information and their control.

2. Informational and educational materials, whether written or audiovisual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, shall include clear information on all the following points:

(a) the benefits and superiority of breast feeding;

(b) maternal nutrition and the preparation for and maintenance of breast feeding;

(c) the possible negative effect on breast feeding of introducing partial bottle feeding;

(d) the difficulty of reversing the decision not to breast feed;

(e) where needed, the proper use of infant formula.

Where such materials contain information about the use of infant formula, they shall include the social and financial implications of its use, the health hazards of inappropriate foods or feeding methods, and, in particular, the health hazards of improper use of infant formula. Such material shall not use any pictures which may idealise the use of infant formula.

3. Donations of informational or educational equipment or materials by manufacturers or distributors shall be made only on request and with the written approval of the appropriate national authority or within guidelines given by that authority for this purpose. Such equipment or materials may bear the donating company's name or logo, but shall not refer to a proprietary brand of infant formula and shall be distributed only through the health care system.

Article 12

Notification

1. When infant formula 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.

2. When follow-on formula manufactured from protein hydrolysates or follow-on formula containing other substances than those listed in Annex II are 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 13

Directive 2006/141/EC

In accordance with Article 20(4) of Regulation (EU) No 609/2013, Directive 2006/141/EC is repealed with effect from 22 February 2020. However, Directive 2006/141/EC shall continue to apply until 21 February 2021 to infant formula and follow-on formula manufactured from protein hydrolysates.

References to Directive 2006/141/EC in other acts shall be construed as references to this Regulation in accordance with the scheme set out in the first paragraph.

Article 14

Entry into force and application

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 22 February 2020, except in respect of infant formula and follow-on formula manufactured from protein hydrolysates, to which it shall apply from 22 February 2021.

For the purposes of the second subparagraph of Article 21(1) of Regulation (EU) No 609/2013, in respect of infant formula and follow-on formula manufactured from protein hydrolysates 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, 25 September 2015.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX I

COMPOSITIONAL REQUIREMENTS REFERRED TO IN ARTICLE 2(1)

1. ENERGY

Minimum	Maximum
250 kJ/100 ml	293 kJ/100 ml
(60 kcal/100 ml)	(70 kcal/100 ml)

2. PROTEINS

(Protein content = nitrogen content × 6,25)

2.1. Infant formula manufactured from cows' milk or goats' milk proteins

Minimum	Maximum
0,43 g/100 kJ	0,6 g/100 kJ
(1,8 g/100 kcal)	(2,5 g/100 kcal)

For an equal energy value, infant formula manufactured from cows' milk or goats' milk proteins must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine may be added together if the methionine:cysteine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2. The ratio of methionine:cysteine and of tyrosine:phenylalanine may be greater than 2, provided that the suitability of the product concerned for infants is demonstrated in accordance with Article 3(3).

The L-carnitine content shall be at least equal to 0,3 mg/100 kJ (1,2 mg/100 kcal).

2.2. Infant formula manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins

Minimum	Maximum
0,54 g/100 kJ	0,67 g/100 kJ
(2,25 g/100 kcal)	(2,8 g/100 kcal)

Only protein isolates from soya shall be used in manufacturing this infant formula.

For an equal energy value, infant formula manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins, must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine may be added together if the methionine:cysteine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2. The ratio of methionine: cysteine and of tyrosine:phenylalanine may be greater than 2, provided that the suitability of the product concerned for infants is demonstrated in accordance with Article 3(3).

The L-carnitine content shall be at least equal to 0,3 mg/100 kJ (1,2 mg/100 kcal).

2.3. Infant formula manufactured from protein hydrolysates

Minimum	Maximum
0,44 g/100 kJ	0,67 g/100 kJ
(1,86 g/100 kcal)	(2,8 g/100 kcal)

2.3.1. Protein source

Demineralised sweet whey protein derived from cows' milk after enzymatic precipitation of caseins using chymosin, consisting of:

(a) 63 % caseino-glycomacropeptide free whey protein isolate with a minimum protein content of 95 % of dry matter and protein denaturation of less than 70 % and a maximum ash content of 3 %; and

(b) 37 % sweet whey protein concentrate with a minimum protein content of 87 % of dry matter and protein denaturation of less than 70 % and a maximum ash content of 3,5 %.

2.3.2. Protein processing

Two-stage hydrolysis process using a trypsin preparation with a heat-treatment step (from 3 to 10 minutes at 80 to 100 °C) between the two hydrolysis steps.

2.3.3. Indispensable and conditionally indispensable amino acids and L-carnitine

For an equal energy value, infant formula manufactured from protein hydrolysates must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section B of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine may be added together if the methionine:cysteine ratio is not greater than 2, and the concentration of phenylalanine and tyrosine may be added together if the tyrosine:phenylalanine ratio is not greater than 2. The ratio of methionine:cysteine and of tyrosine:phenylalanine may be greater than 2, provided that the suitability of the product concerned for infants is demonstrated in accordance with Article 3(3).

The L-carnitine content shall be at least equal to 0,3 mg/100 kJ (1,2 mg/100 kcal).

2.4. In all cases, amino acids may be added to infant formula solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.

3. TAURINE

If added to infant formula, the amount of taurine shall not be greater than 2,9 mg/100 kJ (12 mg/100 kcal).

4. CHOLINE

Minimum	Maximum
6,0 mg/100 kJ	12 mg/100 kJ
(25 mg/100 kcal)	(50 mg/100 kcal)

5. LIPIDS

Minimum	Maximum
1,1 g/100 kJ	1,4 g/100 kJ
(4,4 g/100 kcal)	(6,0 g/100 kcal)

5.1. The use of the following substances shall be prohibited:

— sesame seed oil,

— cotton seed oil.

5.2. The *trans* fatty acid content shall not exceed 3 % of the total fat content.

5.3. The erucic acid content shall not exceed 1 % of the total fat content.

5.4. Linoleic acid

Minimum	Maximum
120 mg/100 kJ	300 mg/100 kJ
(500 mg/100 kcal)	(1 200 mg/100 kcal)

5.5. Alpha-linolenic acid

Minimum	Maximum
12 mg/100 kJ	24 mg/100 kJ
(50 mg/100 kcal)	(100 mg/100 kcal)

5.6. Docosahexaenoic acid

Minimum	Maximum
4,8 mg/100 kJ	12 mg/100 kJ
(20 mg/100 kcal)	(50 mg/100 kcal)

5.7. Other long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids may be added. In that case the content of long-chain polyunsaturated fatty acids shall not exceed 2 % of the total fat content for n-6 long-chain polyunsaturated fatty acids (1 % of the total fat content for arachidonic acid (20:4 n-6)).

The eicosapentaenoic acid (20:5 n-3) content shall not exceed that of docosahexaenoic (22:6 n-3) acid content.

6. PHOSPHOLIPIDS

The amount of phospholipids in infant formula shall not be greater than 2 g/l.

7. INOSITOL

Minimum	Maximum
0,96 mg/100 kJ	9,6 mg/100 kJ
(4 mg/100 kcal)	(40 mg/100 kcal)

8. CARBOHYDRATES

Minimum	Maximum
2,2 g/100 kJ	3,3 g/100 kJ
(9 g/100 kcal)	(14 g/100 kcal)

8.1. Only the following carbohydrates may be used:

— lactose,

— maltose,

— sucrose,

— glucose,

— glucose syrup or dried glucose syrup,

— malto-dextrins,

— pre-cooked starch (naturally free of gluten),

— gelatinised starch (naturally free of gluten).

8.2. Lactose

Minimum	Maximum
1,1 g/100 kJ	—
(4,5 g/100 kcal)	—

Those minimum levels shall not apply to infant formula:

— in which soya protein isolates represent more than 50 % of the total protein content, or

— bearing the statement 'lactose free' in accordance with Article 9(2).

8.3. Sucrose

Sucrose may only be added to infant formula manufactured from protein hydrolysates. If added, the sucrose content shall not exceed 20 % of the total carbohydrate content.

8.4. Glucose

Glucose may only be added to infant formula manufactured from protein hydrolysates. If added, the glucose content shall not exceed 0,5 g/100 kJ (2 g/100 kcal).

8.5. Glucose syrup or dried glucose syrup

Glucose syrup or dried glucose syrup may be added to infant formula manufactured from cows' milk or goats' milk proteins or infant formula manufactured from soya protein isolates (alone or in a mixture with cows' milk or goats' milk proteins) only if its dextrose equivalent does not exceed 32. If glucose syrup or dried glucose syrup is added to these products, the glucose content resulting from glucose syrup or dried glucose syrup shall not exceed 0,2 g/100 kJ (0,84 g/100 kcal).

The maximum glucose amounts laid down in point 8.4 shall apply if glucose syrup or dried glucose syrup is added to infant formula manufactured from protein hydrolysates.

8.6. Pre-cooked starch and/or gelatinised starch

Minimum	Maximum
—	2 g/100 ml, and 30 % of the total carbohydrate content

9. FRUCTO-OLIGOSACCHARIDES AND GALACTO-OLIGOSACCHARIDES

Fructo-oligosaccharides and galacto-oligosaccharides may be added to infant formula. In that case their content shall not exceed: 0,8 g/100 ml in a combination of 90 % oligogalactosyl-lactose and 10 % high molecular weight oligofructosyl-saccharose.

Other combinations and maximum levels of fructo-oligosaccharides and galacto-oligosaccharides may be used, provided that their suitability for infants is demonstrated in accordance with Article 3(3).

10. MINERAL SUBSTANCES

10.1. Infant formula manufactured from cows' milk or goats' milk proteins or protein hydrolysates

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Sodium (mg)	6	14,3	25	60
Potassium (mg)	19,1	38,2	80	160
Chloride (mg)	14,3	38,2	60	160
Calcium (mg)	12	33,5	50	140
Phosphorus (mg) [1]	6	21,5	25	90
Magnesium (mg)	1,2	3,6	5	15
Iron (mg)	0,07	0,31	0,3	1,3
Zinc (mg)	0,12	0,24	0,5	1
Copper (µg)	14,3	24	60	100
Iodine (µg)	3,6	6,9	15	29
Selenium (µg)	0,72	2	3	8,6
Manganese (µg)	0,24	24	1	100
Molybdenum (µg)	—	3,3	—	14
Fluoride (µg)	—	24	—	100

[1] Total phosphorus.

The calcium:available phosphorus molar ratio shall not be less than 1 nor greater than 2. The amount of available phosphorus shall be calculated as 80 % of total phosphorus for infant formula manufactured from cow's milk protein, goats' milk protein or protein hydrolysates.

10.2. Infant formula manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins

All requirements of point 10.1 shall apply, except for those concerning iron, phosphorus and zinc, which shall be as follows:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Iron (mg)	0,11	0,48	0,45	2
Phosphorus (mg) (1)	7,2	24	30	100
Zinc (mg)	0,18	0,3	0,75	1,25

(1) Total phosphorus.

The calcium:available phosphorus molar ratio shall not be less than 1 nor greater than 2. The amount of available phosphorus shall be calculated as 70 % of total phosphorus for infant formula manufactured from soya protein isolates.

11. VITAMINS

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A (µg-RE) (1)	16,7	27,2	70	114
Vitamin D (µg)	0,48	0,72	2	3
Thiamine (µg)	9,6	72	40	300
Riboflavin (µg)	14,3	95,6	60	400
Niacin (mg) (2)	0,1	0,36	0,4	1,5
Pantothenic acid (mg)	0,1	0,48	0,4	2
Vitamin B_6 (µg)	4,8	41,8	20	175
Biotin (µg)	0,24	1,8	1	7,5
Folate (µg-DFE) (3)	3,6	11,4	15	47,6
Vitamin B_{12} (µg)	0,02	0,12	0,1	0,5
Vitamin C (mg)	0,96	7,2	4	30
Vitamin K (µg)	0,24	6	1	25
Vitamin E (mg α-tocopherol) (4)	0,14	1,2	0,6	5

(1) Preformed vitamin A; RE = all *trans* retinol equivalent.
(2) Preformed niacin.
(3) Dietary folate equivalent: 1 µg DFE = 1 µg food folate = 0,6 µg folic acid from formula.
(4) Based on vitamin E activity of RRR-α-tocopherol.

12. NUCLEOTIDES

The following nucleotides may be added:

	Maximum [1]	
	(mg/100 kJ)	(mg/100 kcal)
cytidine 5′-monophosphate	0,60	2,50
uridine 5′-monophosphate	0,42	1,75
adenosine 5′-monophosphate	0,36	1,50
guanosine 5′-monophosphate	0,12	0,50
inosine 5′-monophosphate	0,24	1,00

[1] The total concentration of nucleotides shall not exceed 1,2 mg/100 kJ (5 mg/100 kcal).

ANNEX II

COMPOSITIONAL REQUIREMENTS REFERRED TO IN ARTICLE 2(2)

1. ENERGY

Minimum	Maximum
250 kJ/100 ml	293 kJ/100 ml
(60 kcal/100 ml)	(70 kcal/100 ml)

2. PROTEINS

(Protein content = nitrogen content × 6,25)

2.1. Follow-on formula manufactured from cows' milk or goats' milk proteins

Minimum	Maximum
0,43 g/100 kJ	0,6 g/100 kJ
(1,8 g/100 kcal)	(2,5 g/100 kcal)

For an equal energy value, follow-on formula manufactured from cows' milk or goats' milk proteins must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine and the concentration of phenylalanine and tyrosine may be added together.

2.2. Follow-on formula manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins

Minimum	Maximum
0,54 g/100 kJ	0,67 g/100 kJ
(2,25 g/100 kcal)	(2,8 g/100 kcal)

Only protein isolates from soya shall be used in manufacturing this follow-on formula.

For an equal energy value, follow-on formula manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins, must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section A of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine and the concentration of phenylalanine and tyrosine may be added together.

2.3. Follow-on formula manufactured from protein hydrolysates

Minimum	Maximum
0,44 g/100 kJ	0,67 g/100 kJ
(1,86 g/100 kcal)	(2,8 g/100 kcal)

2.3.1. Protein source

Demineralised sweet whey protein derived from cows' milk after enzymatic precipitation of caseins using chymosin, consisting of:

(a) 63 % caseino-glycomacropeptide free whey protein isolate with a minimum protein content of 95 % of dry matter and protein denaturation of less than 70 % and a maximum ash content of 3 %; and

(b) 37 % sweet whey protein concentrate with a minimum protein content of 87 % of dry matter and protein denaturation of less than 70 % and a maximum ash content of 3,5 %.

2.3.2. Protein processing

Two-stage hydrolysis process using a trypsin preparation with a heat-treatment step (from 3 to 10 minutes at 80 to 100 °C) between the two hydrolysis steps.

2.3.3. Indispensable and conditionally indispensable amino acids

For an equal energy value, follow-on formula manufactured from protein hydrolysates must contain an available quantity of each indispensable and conditionally indispensable amino acid at least equal to that contained in the reference protein as set out in Section B of Annex III. Nevertheless, for calculation purposes, the concentration of methionine and cysteine and the concentration of phenylalanine and tyrosine may be added together.

2.4. In all cases, amino acids may be added to follow-on formula solely for the purpose of improving the nutritional value of the proteins, and only in the proportions necessary for that purpose.

3. TAURINE

If added to follow-on formula, the amount of taurine shall not be greater than 2,9 mg/100 kJ (12 mg/100 kcal).

4. LIPIDS

Minimum	Maximum
1,1 g/100 kJ	1,4 g/100 kJ
(4,4 g/100 kcal)	(6,0 g/100 kcal)

4.1. The use of the following substances shall be prohibited:

— sesame seed oil,

— cotton seed oil.

4.2. The *trans* fatty acid content shall not exceed 3 % of the total fat content.

4.3. The erucic acid content shall not exceed 1 % of the total fat content.

4.4. Linoleic acid

Minimum	Maximum
120 mg/100 kJ	300 mg/100 kJ
(500 mg/100 kcal)	(1 200 mg/100 kcal)

4.5. Alpha-linolenic acid

Minimum	Maximum
12 mg/100 kJ	24 mg/100 kJ
(50 mg/100 kcal)	(100 mg/100 kcal)

4.6. Docosahexaenoic acid

Minimum	Maximum
4,8 mg/100 kJ	12 mg/100 kJ
(20 mg/100 kcal)	(50 mg/100 kcal)

4.7. Other long-chain (20 and 22 carbon atoms) polyunsaturated fatty acids may be added. In that case the content of long-chain polyunsaturated fatty acids shall not exceed 2 % of the total fat content for n-6 long-chain polyunsaturated fatty acids (1 % of the total fat content for arachidonic acid (20:4 n-6).

The eicosapentaenoic acid (20:5 n-3) content shall not exceed that of docosahexaenoic (22:6 n-3) acid content.

5. PHOSPHOLIPIDS

The amount of phospholipids in follow-on formula shall not be greater than 2 g/l.

6. CARBOHYDRATES

Minimum	Maximum
2,2 g/100 kJ	3,3 g/100 kJ
(9 g/100 kcal)	(14 g/100 kcal)

6.1. The use of ingredients containing gluten shall be prohibited.

6.2. Lactose

Minimum	Maximum
1,1 g/100 kJ	—
(4,5 g/100 kcal)	—

Those minimum levels shall not apply to follow-on formula:

— in which soya protein isolates represent more than 50 % of the total protein content, or

— bearing the statement 'lactose free' in accordance with Article 9(2).

6.3. Sucrose, fructose, honey

Minimum	Maximum
—	separately or as a whole: 20 % of the total carbohydrate content

Honey shall be treated to destroy spores of *Clostridium botulinum*.

6.4. Glucose

Glucose may only be added to follow-on formula manufactured from protein hydrolysates. If added, the glucose content shall not exceed 0,5 g/100 kJ (2 g/100 kcal).

6.5. Glucose syrup or dried glucose syrup

Glucose syrup or dried glucose syrup may be added to follow-on formula manufactured from cows' milk or goats' milk proteins or follow-on formula manufactured from soya protein isolates (alone or in a mixture with cows' milk or goats' milk proteins) only if its dextrose equivalent does not exceed 32. If glucose syrup or dried glucose syrup is added to these products, the glucose content resulting from glucose syrup or dried glucose syrup shall not exceed 0,2 g/100 kJ (0,84 g/100 kcal).

The maximum glucose amounts laid down in point 6.4 shall apply if glucose syrup or dried glucose syrup is added to follow-on formula manufactured from protein hydrolysates.

7. FRUCTO-OLIGOSACCHARIDES AND GALACTO-OLIGOSACCHARIDES

Fructo-oligosaccharides and galacto-oligosaccharides may be added to follow-on formula. In that case their content shall not exceed: 0,8 g/100 ml in a combination of 90 % oligogalactosyl-lactose and 10 % high molecular weight oligofructosyl-saccharose.

Other combinations and maximum levels of fructo-oligosaccharides and galacto-oligosaccharides may be used, provided that their suitability for infants is demonstrated in accordance with Article 3(3).

8. MINERAL SUBSTANCES

8.1. Follow-on formula manufactured from cows' milk or goats' milk proteins or protein hydrolysates

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Sodium (mg)	6	14,3	25	60
Potassium (mg)	19,1	38,2	80	160
Chloride (mg)	14,3	38,2	60	160
Calcium (mg)	12	33,5	50	140
Phosphorus (mg) [1]	6	21,5	25	90
Magnesium (mg)	1,2	3,6	5	15
Iron (mg)	0,14	0,48	0,6	2

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Zinc (mg)	0,12	0,24	0,5	1
Copper (μg)	14,3	24	60	100
Iodine (μg)	3,6	6,9	15	29
Selenium (μg)	0,72	2	3	8,6
Manganese (μg)	0,24	24	1	100
Molybdenum (μg)	—	3,3	—	14
Fluoride (μg)	—	24	—	100

(1) Total phosphorus.

The calcium:available phosphorus molar ratio shall not be less than 1 nor greater than 2. The amount of available phosphorus shall be calculated as 80 % of total phosphorus for follow-on formula manufactured from cow's milk protein, goats' milk protein or protein hydrolysates.

8.2. Follow-on formula manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins

All requirements of point 8.1 shall apply, except for those concerning iron, phosphorus and zinc, which shall be as follows:

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Iron (mg)	0,22	0,6	0,9	2,5
Phosphorus (mg) (1)	7,2	24	30	100
Zinc (mg)	0,18	0,3	0,75	1,25

(1) Total phosphorus.

The calcium:available phosphorus molar ratio shall not be less than 1 nor greater than 2. The amount of available phosphorus shall be calculated as 70 % of total phosphorus for follow-on formula manufactured from soya protein isolates.

9. VITAMINS

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin A (μg-RE) (1)	16,7	27,2	70	114
Vitamin D (μg)	0,48	0,72	2	3
Thiamine (μg)	9,6	72	40	300

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Riboflavin (µg)	14,3	95,6	60	400
Niacin (mg) (2)	0,1	0,36	0,4	1,5
Pantothenic acid (mg)	0,1	0,48	0,4	2
Vitamin B_6 (µg)	4,8	41,8	20	175
Biotin (µg)	0,24	1,8	1	7,5
Folate (µg-DFE) (3)	3,6	11,4	15	47,6
Vitamin B_{12} (µg)	0,02	0,12	0,1	0,5
Vitamin C (mg)	0,96	7,2	4	30
Vitamin K (µg)	0,24	6	1	25
Vitamin E (mg α-tocopherol) (4)	0,14	1,2	0,6	5

(1) Preformed vitamin A; RE = all *trans* retinol equivalent.
(2) Preformed niacin.
(3) Dietary folate equivalent: 1 µg DFE = 1 µg food folate = 0,6 µg folic acid from formula.
(4) Based on vitamin E activity of RRR-α-tocopherol.

10. NUCLEOTIDES

The following nucleotides may be added:

	Maximum (1)	
	(mg/100 kJ)	(mg/100 kcal)
cytidine 5′-monophosphate	0,60	2,50
uridine 5′-monophosphate	0,42	1,75
adenosine 5′-monophosphate	0,36	1,50
guanosine 5′-monophosphate	0,12	0,50
inosine 5′-monophosphate	0,24	1,00

(1) The total concentration of nucleotides shall not exceed 1,2 mg/100 kJ (5 mg/100 kcal).

ANNEX III

INDISPENSABLE AND CONDITIONALLY INDISPENSABLE AMINO ACIDS IN BREAST MILK

For the purposes of point 2 of Annexes I and II, breast milk shall be used as reference protein as set out in Sections A and B of this Annex, respectively.

A. Infant formula and follow-on formula manufactured from cows' milk or goats' milk proteins and infant formula and follow-on formula manufactured from soya protein isolates, alone or in a mixture with cows' milk or goats' milk proteins

For the purposes of points 2.1 and 2.2 of Annexes I and II, the indispensable and conditionally indispensable amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal, are the following:

	Per 100 kJ [1]	Per 100 kcal
Cysteine	9	38
Histidine	10	40
Isoleucine	22	90
Leucine	40	166
Lysine	27	113
Methionine	5	23
Phenylalanine	20	83
Threonine	18	77
Tryptophan	8	32
Tyrosine	18	76
Valine	21	88

[1] 1 kJ = 0,239 kcal.

B. Infant formula and follow-on formula manufactured from protein hydrolysates

For the purposes of point 2.3 of Annexes I and II, the indispensable and conditionally indispensable amino acids in breast milk, expressed in mg per 100 kJ and 100 kcal, are the following:

	Per 100 kJ [1]	Per 100 kcal
Arginine	16	69
Cysteine	6	24
Histidine	11	45
Isoleucine	17	72

	Per 100 kJ [1]	Per 100 kcal
Leucine	37	156
Lysine	29	122
Methionine	7	29
Phenylalanine	15	62
Threonine	19	80
Tryptophan	7	30
Tyrosine	14	59
Valine	19	80

[1] 1 kJ = 0,239 kcal.

ANNEX IV

ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 4(3)

Chemical name of the substance	Maximum residue level (mg/kg)
Cadusafos	0,006
Demeton-S-methyl/demeton-S-methyl sulfone/oxydemeton-methyl (individually or combined, expressed as demeton-S-methyl)	0,006
Ethoprophos	0,008
Fipronil (sum of fipronil and fipronil-desulfinyl, expressed as fipronil)	0,004
Propineb/propylenethiourea (sum of propineb and propylenethiourea)	0,006

ANNEX V

ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 4(4)

Chemical name of the substance (residue definition)
Aldrin and dieldrin, expressed as dieldrin
Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone expressed as disulfoton)
Endrin
Fensulfothion (sum of fensulfothion, its oxygen analogue and their sulfones, expressed as fensulfothion)
Fentin, expressed as triphenyltin cation
Haloxyfop (sum of haloxyfop, its salts and esters including conjugates, expressed as haloxyfop)
Heptachlor and *trans*-heptachlor epoxide, expressed as heptachlor
Hexachlorobenzene
Nitrofen
Omethoate
Terbufos (sum of terbufos, its sulfoxide and sulfone, expressed as terbufos)

ANNEX VI

NAMES REFERRED TO IN ARTICLE 5

PART A

Name referred to in Article 5(1)

The name of infant formula and follow-on formula other than infant formula and follow-on formula manufactured entirely from cows' milk or goats' milk proteins shall be respectively:

— in Bulgarian: 'Храни за кърмачета' and 'Преходни храни',

— in Spanish: 'Preparado para lactantes' and 'Preparado de continuación',

— in Czech: 'Počáteční kojenecká výživa' and 'Pokračovací kojenecká výživa',

— in Danish: 'Modermælkserstatning' and 'Tilskudsblanding',

— in German: 'Säuglingsanfangsnahrung' and 'Folgenahrung',

— in Estonian: 'Imiku piimasegu' and 'Jätkupiimasegu',

— in Greek: 'Παρασκεύασμα για βρέφη' and 'Παρασκεύασμα δεύτερης βρεφικής ηλικίας',

— in English: 'Infant formula' and 'Follow-on formula',

— in French: 'Préparation pour nourrissons' and 'Préparation de suite',

— in Croatian: 'Početna hrana za dojenčad' and 'Prijelazna hrana za dojenčad',

— in Italian: 'Formula per lattanti' and 'Formula di proseguimento',

— in Latvian: 'Maisījums zīdaiņiem' and 'Papildu ēdināšanas maisījums zīdaiņiem',

— in Lithuanian: 'Pradinio maitinimo kūdikių mišiniai' and 'Tolesnio maitinimo kūdikių mišiniai',

— in Hungarian: 'Anyatej-helyettesítő tápszer' and 'Anyatej-kiegészítő tápszer',

— in Maltese: 'Formula tat-trabi' and 'Formula tal-prosegwiment',

— in Dutch: 'Volledige zuigelingenvoeding' and 'Opvolgzuigelingenvoeding',

— in Polish: 'Preparat do początkowego żywienia niemowląt' and 'Preparat do dalszego żywienia niemowląt',

— in Portuguese: 'Fórmula para lactentes' and 'Fórmula de transição',

— in Romanian: 'Formulă de început' and 'Formulă de continuare',

— in Slovak: 'Počiatočná dojčenská výživa' and 'Následná dojčenská výživa'.

— in Slovenian: 'Začetna formula za dojenčke' and 'Nadaljevalna formula',

— in Finnish: 'Äidinmaidonkorvike' and 'Vieroitusvalmiste',

— in Swedish: 'Modersmjölksersättning' and 'Tillskottsnäring'.

PART B

Name referred to in Article 5(2)

The name of infant formula and follow-on formula manufactured entirely from cows' milk or goats' milk proteins shall be respectively:

— in Bulgarian: 'Млека за кърмачета' and 'Преходни млека',

— in Spanish: 'Leche para lactantes' and 'Leche de continuación',

— in Czech: 'Počáteční mléčná kojenecká výživa' and 'Pokračovací mléčná kojenecká výživa',

— in Danish: 'Modermælkserstatning udelukkende baseret på mælk' and 'Tilskudsblanding udelukkende baseret på mælk',

— in German: 'Säuglingsmilchnahrung' and 'Folgemilch',

— in Estonian: 'Piimal põhinev imiku piimasegu' and 'Piimal põhinev jätkupiimasegu',

— in Greek: 'Τάλα για βρέφη' and 'Τάλα δεύτερης βρεφικής ηλικίας',

— in English: 'Infant milk' and 'Follow-on milk',

— in French: 'Lait pour nourrissons' and 'Lait de suite',

— in Croatian: 'Početna mliječna hrana za dojenčad' and 'Prijelazna mliječna hrana za dojenčad',

— in Italian: 'Latte per lattanti' and 'Latte di proseguimento',

— in Latvian: 'Piena maisījums zīdaiņiem' and 'Papildu ēdināšanas piena maisījums zīdaiņiem',

— in Lithuanian: 'Pradinio maitinimo kūdikių pieno mišiniai' and 'Tolesnio maitinimo kūdikių pieno mišiniai',

— in Hungarian: 'Tejalapú anyatej-helyettesítő tápszer' and 'Tejalapú anyatej-kiegészítő tápszer',

— in Maltese: 'Ħalib tat-trabi' and 'Ħalib tal-prosegwiment',

— in Dutch: 'Volledige zuigelingenvoeding op basis van melk' or 'Zuigelingenmelk' and 'Opvolgmelk',

— in Polish: 'Mleko początkowe' and 'Mleko następne',

— in Portuguese: 'Leite para lactentes' and 'Leite de transição',

— in Romanian: 'Lapte de început' and 'Lapte de continuare',

— in Slovak: 'Počiatočná dojčenská mliečna výživa' and 'Následná dojčenská mliečna výživa',

— in Slovenian: 'Začetno mleko za dojenčke' and 'Nadaljevalno mleko',

— in Finnish: 'Maitopohjainen äidinmaidonkorvike' and 'Maitopohjainen vieroitusvalmiste',

— in Swedish: 'Modersmjölksersättning uteslutande baserad på mjölk' and 'Tillskottsnäring uteslutande baserad på mjölk'.

ANNEX VII

REFERENCE INTAKES REFERRED TO IN ARTICLE 7(7)

Nutrient	Reference intake
Vitamin A	(µg) 400
Vitamin D	(µg) 7
Vitamin E	(mg TE) 5
Vitamin K	(µg) 12
Vitamin C	(mg) 45
Thiamine	(mg) 0,5
Riboflavin	(mg) 0,7
Niacin	(mg) 7
Vitamin B_6	(mg) 0,7
Folate	(µg) 125
Vitamin B_{12}	(µg) 0,8
Pantothenic acid	(mg) 3
Biotin	(µg) 10
Calcium	(mg) 550
Phosphorus	(mg) 550
Potassium	(mg) 1 000
Sodium	(mg) 400
Chloride	(mg) 500
Iron	(mg) 8
Zinc	(mg) 5
Iodine	(µg) 80
Selenium	(µg) 20
Copper	(mg) 0,5
Magnesium	(mg) 80
Manganese	(mg) 1,2

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 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.

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[1] OJ L 181, 29.6.2013, p. 35.
[2] Commission Directive 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes (OJ L 91, 7.4.1999, p. 29).
[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).

(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 ([1]) and 2006/141/EC ([2]), 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 ([3]) and 4 June 1998 ([4]).

(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 ([5]).

(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 ([6]). 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

([1]) Commission Directive 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children (OJ L 339, 6.12.2006, p. 16).

([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]) 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).

([4]) 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).

([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]) 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).

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 ([1]).

(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.

(19) Article 17(2) of Regulation (EC) No 178/2002 of the European Parliament and of the Council ([2]) 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,

([1]) 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).

([2]) 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).

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.

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 contra-indications;

(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 22 February 2019. However, Directive 1999/21/EC shall continue to apply until 21 February 2020 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 twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 22 February 2019, except in respect of food for special medical purposes developed to satisfy the nutritional requirements of infants, to which it shall apply from 22 February 2020.

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, 25 September 2015.

For the Commission

The President

Jean-Claude JUNCKER

ANNEX I

COMPOSITIONAL REQUIREMENTS REFERRED TO IN ARTICLE 2(3)

PART A

Food for special medical purposes developed to satisfy the nutritional requirements of infants

1. Products referred to in Article 2(1)(a) developed to satisfy the nutritional requirements of infants shall contain the vitamins and mineral substances as specified in Table 1.

2. Products referred to in Article 2(1)(b) developed to satisfy the nutritional requirements of infants shall contain the vitamins and mineral substances as specified in Table 1, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

3. Maximum levels of vitamins and mineral substances present in products referred to in Article 2(1)(c) developed to satisfy the nutritional requirements of infants shall not exceed those specified in Table 1, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

4. Where this is not contrary to the requirements dictated by the intended use, food for special medical purposes developed to satisfy the nutritional requirements of infants shall comply with the provisions relating to other nutrients applicable to infant formula and follow-on formula, as the case may be, laid down in Commission Delegated Regulation (EU) 2016/127 [1].

Table 1

Values for vitamins and minerals in food for special medical purposes developed to satisfy the nutritional requirements of infants

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamins				
Vitamin A (µg-RE) [1]	16,7	43	70	180
Vitamin D (µg)	0,48	0,72	2	3
Vitamin K (µg)	0,24	6	1	25
Vitamin C (mg)	0,96	7,2	4	30
Thiamin (µg)	9,6	72	40	300
Riboflavin (µg)	14,3	107	60	450
Vitamin B_6 (µg)	4,8	72	20	300
Niacin (mg) [2]	0,1	0,72	0,4	3
Folate (µg-DFE) [3]	3,6	11,4	15	47,6

[1] 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 (see page 1 of this Official Journal).

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamin B_{12} (µg)	0,02	0,12	0,1	0,5
Panthotenic Acid (mg)	0,1	0,48	0,4	2
Biotin (µg)	0,24	4,8	1	20
Vitamin E (mg α-tocopherol) (4)	0,14	1,2	0,6	5
Minerals				
Sodium (mg)	6	14,3	25	60
Chloride (mg)	14,3	38,2	60	160
Potassium (mg)	19,1	38,2	80	160
Calcium (mg) (5)	12	60	50	250
Phosphorus (mg) (6)	6	24	25	100
Magnesium (mg)	1,2	3,6	5	15
Iron (mg)	0,07	0,6	0,3	2,5
Zinc (mg)	0,12	0,6	0,5	2,4
Copper (µg)	14,3	29	60	120
Iodine (µg)	3,6	8,4	15	35
Selenium (µg)	0,72	2	3	8,6
Manganese (µg)	0,24	24	1	100
Chromium (µg)	—	2,4	—	10
Molybdenum (µg)	—	3,3	—	14
Fluoride (µg)	—	47,8	—	200

(1) Preformed vitamin A; RE = all *trans* retinol equivalent.
(2) Preformed niacin.
(3) Dietary folate equivalent: 1 µg DFE = 1 µg food folate = 0,6 µg folic acid from food for special medical purposes.
(4) Based on vitamin E activity of RRR-α-tocopherol.
(5) The calcium:available phosphorus molar ratio shall not be less than 1 nor greater than 2.
(6) Total phosphorus.

PART B

Food for special medical purposes other than that developed to satisfy the nutritional requirements of infants

1. Products referred to in Article 2(1)(a) other than those developed to satisfy the nutritional requirements of infants shall contain the vitamins and mineral substances as specified in Table 2.

2. Products referred to in Article 2(1)(b) other than those developed to satisfy the nutritional requirements of infants shall contain the vitamins and mineral substances as specified in Table 2, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

3. Maximum levels of vitamins and mineral substances present in products referred to in Article 2(1)(c) other than those developed to satisfy the nutritional requirements of infants shall not exceed those specified in Table 2, without prejudice to modifications for one or more of these nutrients rendered necessary by the intended use of the product.

Table 2

Values for vitamins and minerals in food for special medical purposes other than that developed to satisfy the nutritional requirements of infants

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Vitamins				
Vitamin A (µg-RE)	8,4	43	35	180
Vitamin D (µg)	0,12	0,65/0,75 [1]	0,5	2,5/3 [1]
Vitamin K (µg)	0,85	5	3,5	20
Vitamin C (mg)	0,54	5,25	2,25	22
Thiamin (mg)	0,015	0,12	0,06	0,5
Riboflavin (mg)	0,02	0,12	0,08	0,5
Vitamin B_6 (mg)	0,02	0,12	0,08	0,5
Niacin (mg NE)	0,22	0,75	0,9	3
Folic Acid (µg)	2,5	12,5	10	50
Vitamin B_{12} (µg)	0,017	0,17	0,07	0,7
Panthotenic Acid (mg)	0,035	0,35	0,15	1,5
Biotin (µg)	0,18	1,8	0,75	7,5
Vitamin E (mg α-TE)	0,5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,1 mg per 100 available kJ	0,75	0,5/g of polyunsaturated fatty acids expressed as linoleic acid but in no case less than 0,5 mg per 100 available kcal	3

	Per 100 kJ		Per 100 kcal	
	Minimum	Maximum	Minimum	Maximum
Minerals				
Sodium (mg)	7,2	42	30	175
Chloride (mg)	7,2	42	30	175
Potassium (mg)	19	70	80	295
Calcium (mg)	8,4/12 (1)	42/60 (1)	35/50 (1)	175/250 (1)
Phosphorus (mg)	7,2	19	30	80
Magnesium (mg)	1,8	6	7,5	25
Iron (mg)	0,12	0,5	0,5	2
Zinc (mg)	0,12	0,36	0,5	1,5
Copper (µg)	15	125	60	500
Iodine (µg)	1,55	8,4	6,5	35
Selenium (µg)	0,6	2,5	2,5	10
Manganese (mg)	0,012	0,12	0,05	0,5
Chromium (µg)	0,3	3,6	1,25	15
Molybdenum (µg)	0,84	4,3	3,5	18
Fluoride (mg)	—	0,05	—	0,2

(1) For products intended for children of 1 to 10 years of age.

ANNEX II

ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 3(3)

Chemical name of the substance	Maximum residue level (mg/kg)
Cadusafos	0,006
Demeton-S-methyl/demeton-S-methyl sulfone/oxydemeton-methyl (individually or combined, expressed as demeton-S-methyl)	0,006
Ethoprophos	0,008
Fipronil (sum of fipronil and fipronil-desulfinyl, expressed as fipronil)	0,004
Propineb/propylenethiourea (sum of propineb and propylenethiourea)	0,006

ANNEX III

ACTIVE SUBSTANCES REFERRED TO IN ARTICLE 3(4)

Chemical name of the substance (residue definition)
Aldrin and dieldrin, expressed as dieldrin
Disulfoton (sum of disulfoton, disulfoton sulfoxide and disulfoton sulfone expressed as disulfoton)
Endrin
Fensulfothion (sum of fensulfothion, its oxygen analogue and their sulfones, expressed as fensulfothion)
Fentin, expressed as triphenyltin cation
Haloxyfop (sum of haloxyfop, its salts and esters including conjugates, expressed as haloxyfop)
Heptachlor and trans-heptachlor epoxide, expressed as heptachlor
Hexachlorobenzene
Nitrofen
Omethoate
Terbufos (sum of terbufos, its sulfoxide and sulfone, expressed as terbufos)

ANNEX IV

NAME REFERRED TO IN ARTICLE 4

The name of food for special medical purposes shall be respectively:

— in Bulgarian: 'Храни за специални медицински цели',

— in Spanish: 'Alimento para usos médicos especiales',

— in Czech: 'Potravina pro zvláštní lékařské účely',

— in Danish: 'Fødevare til særlige medicinske formål',

— in German: 'Lebensmittel für besondere medizinische Zwecke (bilanzierte Diät)',

— in Estonian: 'Meditsiinilisel näidustusel kasutamiseks ettenähtud toit',

— in Greek: 'Τρόφιμα για ειδικούς ιατρικούς σκοπούς',

— in English: 'Food for special medical purposes',

— in French: 'Denrée alimentaire destinée à des fins médicales spéciales',

— in Croatian: 'Hrana za posebne medicinske potrebe',

— in Italian: 'Alimento a fini medici speciali',

— in Latvian: 'Īpašiem medicīniskiem nolūkiem paredzēta pārtika',

— in Lithuanian: 'Specialios medicininės paskirties maisto produktai',

— in Hungarian: 'Speciális gyógyászati célra szánt élelmiszer',

— in Maltese: 'Ikel għal skopijiet mediċi speċjali',

— in Dutch: 'Voeding voor medisch gebruik',

— in Polish: 'Żywność specjalnego przeznaczenia medycznego',

— in Portuguese: 'Alimento para fins medicinais específicos',

— in Romanian: 'Alimente destinate unor scopuri medicale speciale',

— in Slovak: 'Potraviny na osobitné lekárske účely',

— in Slovenian: 'Živila za posebne zdravstvene namene',

— in Finnish: 'Erityisiin lääkinnällisiin tarkoituksiin tarkoitettu elintarvike (kliininen ravintovalmiste)',

— in Swedish: 'Livsmedel för speciella medicinska ändamål'.

COMMISSION IMPLEMENTING REGULATION (EU) 2016/129

of 1 February 2016

amending Regulation (EU) No 37/2010 as regards the substance 'Purified semi-solid extract from *Humulus lupulus* L. containing approximately 48 % of beta acids (as potassium salts)'

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and the Council ([1]), and in particular Article 14 in conjunction with Article 17 thereof,

Having regard to the opinion of the European Medicines Agency formulated by the Committee for Medicinal Products for Veterinary Use,

Whereas:

(1) Article 17 of Regulation (EC) No 470/2009 requires that the maximum residue limit (hereinafter 'MRL') for pharmacologically active substances intended for use in the Union in veterinary medicinal products for food-producing animals or in biocidal products used in animal husbandry is established in a Regulation.

(2) Table 1 of the Annex to Commission Regulation (EU) No 37/2010 ([2]) sets out the pharmacologically active substances and their classification regarding MRLs in foodstuffs of animal origin.

(3) Purified semi-solid extract from *Humulus lupulus* L. containing approximately 48 % of beta acids (as potassium salts) is not yet included in that table.

(4) An application for the establishment of MRLs for purified semi-solid extract from *Humulus lupulus* L. containing approximately 48 % of beta acids (as potassium salts) in honey has been submitted to the European Medicines Agency (hereinafter 'EMA').

(5) The EMA, based on the opinion of the Committee for Medicinal Products for Veterinary Use, has recommended that the establishment of an MRL for purified semi-solid extract from *Humulus lupulus* L. containing approximately 48 % of beta acids (as potassium salts) in honey, is not necessary for the protection of human health.

(6) According to Article 5 of Regulation (EC) No 470/2009, the EMA is to consider using MRLs established for a pharmacologically active substance in a particular foodstuff for another foodstuff derived from the same species, or MRLs established for a pharmacologically active substance in one or more species for other species.

(7) Given that residues in honey are not subject to the metabolic processes to which they may be subjected in other food commodities of animal origin, the EMA concluded that an extrapolation of the recommendation on MRL for purified semi-solid extract from *Humulus lupulus* L. containing approximately 48 % of beta acids (as potassium salts) is not appropriate.

(8) Regulation (EU) No 37/2010 should therefore be amended accordingly.

(9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Veterinary Medicinal Products,

([1]) OJ L 152, 16.6.2009, p. 11.
([2]) Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin (OJ L 15, 20.1.2010, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EU) No 37/2010 is amended as set out in 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, 1 February 2016.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

In Table 1 of the Annex to Regulation (EU) No 37/2010, an entry for the following substance is inserted in alphabetical order:

Pharmacologically active substance	Marker residue	Animal species	MRL	Target tissues	Other provisions (according to Article 14(7) of Regulation (EC) No 470/2009)	Therapeutic Classification
'Purified semi-solid extract from *Humulus lupulus L.* containing approximately 48 % of beta acids (as potassium salts)	NOT APPLICABLE	Bees	No MRL required	Honey	NO ENTRY	Antiparasitic agents/ Agents against ectoparasites'

COMMISSION REGULATION (EU) 2016/130

of 1 February 2016

adapting to technical progress Council Regulation (EEC) No 3821/85 on recording equipment in road transport

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EEC) No 3821/85 of 20 December 1985 on recording equipment in road transport ([1]), and in particular Article 17 thereof,

Whereas:

(1) Annex IB to Regulation (EEC) No 3821/85 sets out the technical specifications for the construction, testing, installation and inspection of digital tachographs.

(2) Commission Regulation (EC) No 68/2009 ([2]) introduced an adaptor as a temporary solution, until 31 December 2013, to make it possible to install tachographs in conformity with Annex IB to Regulation (EEC) No 3821/85 in M1 and N1 type vehicles.

(3) Commission Regulation (EU) No 1161/2014 ([3]) amended Regulation (EEC) No 3821/85 in order to extend the period of validity of the adaptor until 31 December 2015.

(4) Regulation (EEC) No 3821/85 has been replaced by Regulation (EU) No 165/2014 of the European Parliament and of the Council ([4]). However, in accordance with Article 46 of Regulation (EU) No 165/2014 the provisions of Regulation (EEC) No 3821/85, including Annex IB thereto, continue to apply, on a transitional basis, until the date of application of the implementing acts referred to in Regulation (EU) No 165/2014.

(5) Recital 5 of Regulation (EU) No 165/2014 provides that the Commission will consider extending the period of validity of the adaptor for Ml and N1 vehicles until 2015 and give further consideration to a long-term solution for M1 and N1 vehicles before 2015.

(6) The Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions 'Digital tachograph: Roadmap for future activities' ([5]), which accompanied the proposal for Regulation (EU) No 165/2014, foresees a time-frame of 2 years for the preparation and adoption of annexes and appendices, following the adoption of Regulation (EU) No 165/2014.

(7) A permanent solution concerning the adaptor should be laid down in the technical specifications related to the implementation of Regulation (EU) No 165/2014. In application of the principle of legitimate expectation, the possibility to use adaptors in M1 and N1 type vehicles should therefore be extended at least until the adoption of those technical specifications by implementing acts.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 42 of Regulation (EU) No 165/2014,

([1]) OJ L 370, 31.12.1985, p. 8.
([2]) Commission Regulation (EC) No 68/2009 of 23 January 2009 adapting for the ninth time to technical progress Council Regulation (EEC) No 3821/85 on recording equipment in road transport (OJ L 21, 24.1.2009, p. 3).
([3]) Commission Regulation (EU) No 1161/2014 of 30 October 2014 adapting to technical progress Council Regulation (EEC) No 3821/85 on equipment in road transport (OJ L 311, 31.10.2014, p. 19).
([4]) Regulation (EU) No 165/2014 of the European Parliament and of the Council of 4 February 2014 on tachographs in road transport, repealing Council Regulation (EEC) No 3821/85 on recording equipment in road transport and amending Regulation (EC) No 561/2006 of the European Parliament and of the Council on the harmonisation of certain social legislation relating to road transport (OJ L 60, 28.2.2014, p. 1).
([5]) COM(2011) 454 final.

HAS ADOPTED THIS REGULATION:

Article 1

Annex IB to Regulation (EEC) No 3821/85 is amended as follows:

In part I, Definitions, point (rr), first indent, the date of '31 December 2015' is replaced by '31 December 2016'.

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, 1 February 2016.

For the Commission
The President
Jean-Claude JUNCKER

COMMISSION IMPLEMENTING REGULATION (EU) 2016/131

of 1 February 2016

approving C(M)IT/MIT (3:1) as an existing active substance for use in biocidal products for product-types 2, 4, 6, 11, 12 and 13

(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 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular the third subparagraph of Article 89(1) thereof,

Whereas:

(1) Commission Delegated Regulation (EU) No 1062/2014 ([2]) establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes C(M)IT/MIT (3:1).

(2) C(M)IT/MIT (3:1) has been evaluated in accordance with Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council ([3]) for use in product-type 2, private area and public health area disinfectants and other biocidal products, product-type 4, food and feed area disinfectants, product-type 6, in-can preservatives, product-type 11, preservatives for liquid-cooling and processing systems, product-type 12, slimicides, and product-type 13, metalworking-fluid preservatives, as defined in Annex V to that Directive, which correspond respectively to product-types 2, 4, 6, 11, 12 and 13 as defined in Annex V to Regulation (EU) No 528/2012.

(3) France was designated as evaluating competent authority and submitted the assessment reports, together with its recommendations, to the Commission on 19 October 2011, 27 November 2012 and 22 April 2013 in accordance with paragraphs 4 and 6 of Article 14 of Commission Regulation (EC) No 1451/2007 ([4]).

(4) In accordance with Article 7(1)(b) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency were formulated on 5 February 2015, 14 April 2015 and 17 June 2015 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.

(5) According to those opinions, biocidal products used for product-types 2, 4, 6, 11, 12 and 13 and containing C(M)IT/MIT (3:1) may be expected to satisfy the requirements of Article 5 of Directive 98/8/EC, provided that certain conditions concerning its use are complied with.

(6) It is therefore appropriate to approve C(M)IT/MIT (3:1) for use in biocidal products for product-types 2, 4, 6, 11, 12 and 13 subject to compliance with certain specifications and conditions.

(7) For the use in product-type 4, the evaluation did not address the incorporation of biocidal products containing C(M)IT/MIT (3:1) in materials and articles intended to come into contact directly or indirectly with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004 of the European Parliament and of the Council ([5]). Such materials may require the establishment of specific limits on the migration into food, as referred to in Article 5(1)(e) of that Regulation. The approval should therefore not cover such use unless the Commission has established such limits or it has been established pursuant to that Regulation that such limits are not necessary.

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).
([3]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).
([4]) Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3).
([5]) Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC (OJ L 338, 13.11.2004, p. 4).

(8) Since C(M)IT/MIT (3:1) meets the criteria for classification as skin sensitiser category 1 as defined in Annex I to Regulation (EC) No 1272/2008 of the European Parliament and of the Council [1], treated articles treated with or incorporating C(M)IT/MIT (3:1) should be appropriately labelled when placed on the market.

(9) A reasonable period should be allowed to elapse before an active substance is approved, in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

C(M)IT/MIT (3:1) is approved as an active substance for use in biocidal products for product-types 2, 4, 6, 11, 12 and 13, subject to the specifications and conditions set out in the Annex.

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, 1 February 2016.

For the Commission
The President
Jean-Claude JUNCKER

[1] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Date of approval	Expiry date of approval	Product type	Specific conditions
C(M)IT/MIT (3:1)	IUPAC Name: Reaction mass of 5-chloro-2-methyl-2h-isothiazol-3-one and 2-methyl-2h-isothiazol-3-one (3:1) EC No: n/a CAS No: 55965-84-9	579 g/kg (theoretical calculated dry weight). The active substance is manufactured as a technical concentrate (TK) with different solvents and stabilisers.	1 July 2017	30 June 2027	2	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. The authorisations of biocidal products are subject to the following condition: For professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means. The placing on the market of treated articles is subject to the following condition: The person responsible for the placing on the market of a treated article treated with or incorporating C(M)IT/MIT (3:1) shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.
					4	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. The authorisations of biocidal products are subject to the following conditions: (1) For professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means. (2) In view of the risks identified for professional users, biocidal products shall only be loaded by automated systems, unless it can be demonstrated that risks can be reduced to an acceptable level by other means.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Date of approval	Expiry date of approval	Product type	Specific conditions
						(3) For products that may lead to residues in food or feed, the need to set new or to amend existing maximum residue levels (MRLs) in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council (2) or Regulation (EC) No 396/2005 of the European Parliament and of the Council (3) shall be verified, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded. (4) Products shall not be incorporated in materials and articles intended to come into contact with food within the meaning of Article 1(1) of Regulation (EC) No 1935/2004, unless the Commission has established specific limits on the migration of C(M)IT/MIT (3:1) into food or it has been established pursuant to that Regulation that such limits are not necessary. The placing on the market of treated articles is subject to the following condition: The person responsible for the placing on the market of a treated article treated with or incorporating C(M)IT/MIT (3:1) shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.
					6	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. The authorisations of biocidal products are subject to the following conditions: (1) For industrial or professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means. (2) In view of the risks to the environment, biocidal products shall not be used to preserve pulp and paper processing fluids, unless it can be demonstrated that risks can be reduced to an acceptable level.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Date of approval	Expiry date of approval	Product type	Specific conditions
						The placing on the market of treated articles is subject to the following conditions: (1) In view of the risks identified for human health, mixtures treated with or incorporating C(M)IT/MIT (3:1) and placed on the market for use by the general public shall not contain C(M)IT/MIT (3:1) at a concentration triggering classification as skin sensitiser, unless exposure can be avoided by other means than the wearing of personal protective equipment. (2) In view of the risks identified for human health, liquid detergents treated with or incorporating C(M)IT/MIT (3:1) and placed on the market for use by professional users shall not contain C(M)IT/MIT (3:1) at a concentration triggering classification as skin sensitiser, unless exposure can be avoided by other means than the wearing of personal protective equipment. (3) In view of the risks identified for human health, mixtures treated with or incorporating C(M)IT/MIT (3:1), other than liquid detergents, and placed on the market for use by professional users shall not contain C(M)IT/MIT (3:1) at a concentration triggering classification as skin sensitiser, unless exposure can be avoided, including by the wearing of personal protective equipment. (4) The person responsible for the placing on the market of a treated article treated with or incorporating C(M)IT/MIT (3:1) shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.
					11	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. The authorisations of biocidal products are subject to the following conditions: (1) For professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Date of approval	Expiry date of approval	Product type	Specific conditions
						(2) In view of the risks identified for the environment, products shall not be authorised for the preservation of photographic processing liquid, preservation of wood treatment solution and for the use in large open recirculating cooling systems unless it can be demonstrated that risks can be reduced to an acceptable level. (3) In view of risks identified for the environment, and unless it can be demonstrated that risks can be reduced to an acceptable level, labels and, where provided, safety data sheet of products shall indicate that: (a) For uses in small open recirculating cooling systems, risk mitigation measures shall be in place to reduce the direct contamination of terrestrial compartment via air deposition. (b) For uses other than those specified under condition (2), release of waste water from the facilities shall be directed to a sewage treatment plant. The placing on the market of treated articles is subject to the following condition: The person responsible for the placing on the market of a treated article treated with or incorporating C(M)IT/MIT (3:1) shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.
					12	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. The authorisations of biocidal products are subject to the following conditions: (1) For professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Date of approval	Expiry date of approval	Product type	Specific conditions
						(2) In view of the risks identified for the environment, products shall not be authorised for use in off-shore installations, unless it can be demonstrated that risks can be reduced to an acceptable level. (3) In view of the risks identified for human health, labels or safety data sheets of products authorised for off-shore installations shall indicate that drilling mud shall not contain C(M)IT/MIT (3:1) at a concentration triggering classification as skin sensitiser, unless safe operational procedures and appropriate organisational measures can be established for workers. (4) In view of the risks identified for the environment, labels or safety data sheets of products authorised for use in paper mills shall indicate the need for an appropriate dilution of the industrial release from the facilities into the watercourse after mechanical/chemical treatment or after treatment in a sewage treatment plant, unless it can be demonstrated that risks can be reduced to an acceptable level by other means. The placing on the market of treated articles is subject to the following condition: The person responsible for the placing on the market of a treated article treated with or incorporating C(M)IT/MIT (3:1) shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.
					13	The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. The authorisations of biocidal products are subject to the following conditions: (1) For professional users, safe operational procedures and appropriate organisational measures shall be established. Products shall be used with appropriate personal protective equipment where exposure cannot be reduced to an acceptable level by other means. (2) In view of the risks identified for professional users, loading of the products into metalworking fluids shall be semi-automated or automated, unless it can be demonstrated that risks can be reduced to an acceptable level by other means.

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance (1)	Date of approval	Expiry date of approval	Product type	Specific conditions
						(3) In view of the risks identified for professional users, labels and, where provided, safety data sheets shall indicate that the products shall not be used in metal working fluids at a concentration triggering classification as skin sensitiser, unless it can be demonstrated that risks can be reduced to an acceptable level by other means. The placing on the market of treated articles is subject to the following condition: The person responsible for the placing on the market of a treated article treated with or incorporating C(M)IT/MIT (3:1) shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.

(1) The purity indicated in this column was the minimum degree of purity of the active substance used for the evaluation made in accordance with Article 16(2) of Directive 98/8/EC. The active substance in the product placed on the market can be of equal or different purity if it has been proven technically equivalent with the evaluated active substance.

(2) Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

(3) Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

COMMISSION IMPLEMENTING REGULATION (EU) 2016/132

of 1 February 2016

fixing the closing date for the submission of applications for private storage aid for pigmeat under Implementing Regulation (EU) 2015/2334

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 [1], and in particular point (b) of the first subparagraph and the second subparagraph of Article 18(2) thereof,

Whereas:

(1) Private storage aid granted pursuant to Commission Implementing Regulation (EU) 2015/2334 [2] has had a favourable effect on the pigmeat market. A further stabilisation of prices is expected.

(2) The granting of private storage aid for pigmeat should therefore be ended and a closing date for the submission of applications should be set.

(3) For the sake of legal certainty, Implementing Regulation (EU) 2015/2334 should be repealed.

(4) In order to avoid speculation, this Regulation should enter into force on the day following that of its publication in the *Official Journal of the European Union*.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

The closing date for the submission of applications for private storage aid for pigmeat under Implementing Regulation (EU) 2015/2334 shall be 3 February 2016.

Article 2

Implementing Regulation (EU) 2015/2334 is repealed with effect from 3 February 2016.

However, it shall continue to apply in respect of contracts concluded under that Regulation.

Article 3

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

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[1] OJ L 347, 20.12.2013, p. 671.

[2] Commission Implementing Regulation (EU) 2015/2334 of 14 December 2015 opening private storage for pigmeat and fixing in advance the amount of aid (OJ L 329, 15.12.2015, p. 10).

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

Done at Brussels, 1 February 2016.

For the Commission,
On behalf of the President,
Phil HOGAN
Member of the Commission

COMMISSION IMPLEMENTING REGULATION (EU) 2016/133

of 1 February 2016

establishing the standard import values for determining the entry price of certain fruit and vegetables

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 ([1]),

Having regard to Commission Implementing Regulation (EU) No 543/2011 of 7 June 2011 laying down detailed rules for the application of Council Regulation (EC) No 1234/2007 in respect of the fruit and vegetables and processed fruit and vegetables sectors ([2]), and in particular Article 136(1) thereof,

Whereas:

(1) Implementing Regulation (EU) No 543/2011 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the standard values for imports from third countries, in respect of the products and periods stipulated in Annex XVI, Part A thereto.

(2) The standard import value is calculated each working day, in accordance with Article 136(1) of Implementing Regulation (EU) No 543/2011, taking into account variable daily data. Therefore this Regulation should enter into force on the day of its publication in the *Official Journal of the European Union*,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 136 of Implementing Regulation (EU) No 543/2011 are fixed in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the day 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, 1 February 2016.

For the Commission,
On behalf of the President,
Jerzy PLEWA
Director-General for Agriculture and Rural Development

([1]) OJ L 347, 20.12.2013, p. 671.
([2]) OJ L 157, 15.6.2011, p. 1.

ANNEX

Standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	EG	162,9
	IL	236,2
	MA	83,1
	TN	85,0
	TR	93,7
	ZZ	132,2
0707 00 05	MA	86,8
	TR	165,2
	ZZ	126,0
0709 93 10	MA	46,9
	TR	141,3
	ZZ	94,1
0805 10 20	EG	47,7
	MA	61,0
	TN	46,0
	TR	61,0
	ZZ	53,9
0805 20 10	IL	143,7
	MA	80,4
	TR	102,3
	ZZ	108,8
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	IL	128,5
	JM	154,6
	MA	115,1
	TR	63,3
	ZZ	115,4
0805 50 10	TR	100,5
	ZZ	100,5
0808 10 80	CL	87,5
	US	161,8
	ZZ	124,7
0808 30 90	CL	224,0
	CN	57,3
	TR	200,0
	ZA	87,5
	ZZ	142,2

(1) Nomenclature of countries laid down by Commission Regulation (EU) No 1106/2012 of 27 November 2012 implementing Regulation (EC) No 471/2009 of the European Parliament and of the Council on Community statistics relating to external trade with non-member countries, as regards the update of the nomenclature of countries and territories (OJ L 328, 28.11.2012, p. 7). Code 'ZZ' stands for 'of other origin'.

DECISIONS

COUNCIL DECISION (EU) 2016/134

of 16 November 2015

on the position to be adopted on behalf of the European Union within the Stabilisation and Association Council established by the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and Bosnia and Herzegovina, of the other part, as regards the replacement of Protocol 2 to that Agreement, concerning the definition of the concept of 'originating products' and methods of administrative cooperation, by a new protocol which, as regards the rules of origin, refers to the Regional Convention on pan-Euro-Mediterranean preferential rules of origin

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular the first subparagraph of Article 207(4) in conjunction with Article 218(9) thereof,

Having regard to the proposal from the European Commission,

Whereas:

(1) Protocol 2 to the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and Bosnia and Herzegovina, of the other part [1] ('the Agreement'), concerns the definition of the concept of 'originating products' and methods of administrative cooperation.

(2) The Regional Convention on pan-Euro-Mediterranean preferential rules of origin [2] ('the Convention') lays down provisions on the origin of goods traded under relevant agreements concluded between the Contracting Parties. Bosnia and Herzegovina and other participants in the Stabilisation and Association Process from the Western Balkans were invited to join the system of pan-European diagonal cumulation of origin in the Thessaloniki agenda, endorsed by the European Council of June 2003. They were invited to join the Convention by a decision of the Euro-Mediterranean Ministerial Conference of October 2007.

(3) The Union and Bosnia and Herzegovina signed the Convention on 15 June 2011 and 24 September 2013 respectively.

(4) The Union and Bosnia and Herzegovina deposited their instruments of acceptance with the depositary of the Convention on 26 March 2012 and 26 September 2014 respectively. Consequently, pursuant to Article 10(3) of the Convention, the Convention entered into force in relation to the Union and Bosnia and Herzegovina on 1 May 2012 and on 1 November 2014 respectively.

(5) Article 6 of the Convention provides that each Contracting Party is to take appropriate measures to ensure that the Convention is effectively applied. To that effect, the Stabilisation and Association Council established by the Agreement should adopt a decision replacing Protocol 2 to the Agreement with a new protocol which, with regard to the rules of origin, refers to the Convention.

(6) The position of the Union within the Stabilisation and Association Council should therefore be based on the attached draft decision,

[1] OJ L 164, 30.6.2015, p. 2.
[2] OJ L 54, 26.2.2013, p. 4.

HAS ADOPTED THIS DECISION:

Article 1

The position to be adopted on behalf of the European Union within the Stabilisation and Association Council established by the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and Bosnia and Herzegovina, of the other part, as regards the replacement of Protocol 2 to that Agreement, concerning the definition of the concept of 'originating products' and methods of administrative cooperation, by a new protocol which, as regards the rules of origin, refers to the Regional Convention on pan-Euro-Mediterranean preferential rules of origin, shall be based on the draft decision of the Stabilisation and Association Council attached to this Decision.

Technical changes to the draft decision of the Stabilisation and Association Council may be agreed to by the representatives of the Union in the Stabilisation and Association Council without any further decision of the Council.

Article 2

The Decision of the Stabilisation and Association Council shall be published in the *Official Journal of the European Union*.

Article 3

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 16 November 2015.

For the Council
The President
F. MOGHERINI

DRAFT

DECISION No … OF THE EU-BOSNIA AND HERZEGOVINA STABILISATION AND ASSOCIATION COUNCIL

of

replacing Protocol 2 to the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and Bosnia and Herzegovina, of the other part, concerning the definition of the concept of 'originating products' and methods of administrative cooperation

THE EU-BOSNIA AND HERZEGOVINA STABILISATION AND ASSOCIATION COUNCIL,

Having regard to the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and Bosnia and Herzegovina, of the other part ([1]), and in particular Article 42 thereof,

Having regard to Protocol 2 to the Stabiliation and Association Agreement between the European Communities and their Member States, of the one part, and Bosnia and Herzegovina, of the other part, concerning the definition of the concept of 'originating products' and methods of administrative cooperation,

Whereas:

(1) Article 42 of the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and Bosnia and Herzegovina, of the other part ('the Agreement') refers to Protocol 2 to the Agreement ('Protocol 2'), which lays down the rules of origin and provides for cumulation of origin between the European Union, Bosnia and Herzegovina, Turkey and any country or territory participating in the European Union's Stabilisation and Association Process.

(2) Article 39 of Protocol 2 provides that the Stabilisation and Association Council established in Article 115 of the Agreement may decide to amend the provisions of the Protocol.

(3) The Regional Convention on pan-Euro-Mediterranean preferential rules of origin ([2]) ('the Convention') aims to replace the protocols on rules of origin currently in force among the countries of the pan-Euro-Mediterranean area with a single legal act. Bosnia and Herzegovina and other participants in the Stabilisation and Association Process from the Western Balkans were invited to join the system of pan-European diagonal cumulation of origin in the Thessaloniki agenda, endorsed by the European Council of June 2003. They were invited to join the Convention by a decision of the Euro-Mediterranean Ministerial Conference of October 2007.

(4) The European Union and Bosnia and Herzegovina signed the Convention on 15 June 2011 and 24 September 2013 respectively.

(5) The European Union and Bosnia and Herzegovina deposited their instruments of acceptance with the depositary of the Convention on 26 March 2012 and 26 September 2014 respectively. Consequently, pursuant to Article 10(3) of the Convention, the Convention entered into force in relation to the European Union and Bosnia and Herzegovina on 1 May 2012 and on 1 November 2014 respectively.

(6) Protocol 2 should therefore be replaced by a new protocol making reference to the Convention,

HAS ADOPTED THIS DECISION:

Article 1

Protocol 2 to the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and Bosnia and Herzegovina, of the other part, concerning the definition of the concept of 'originating products' and methods of administrative cooperation is replaced by the text set out in the Annex to this Decision.

([1]) OJ L 164, 30.6.2015, p. 2.
([2]) OJ L 54, 26.2.2013, p. 4.

Article 2

This Decision shall enter into force on the date of its adoption.

It shall apply from …

Done at …,

For the Stabilisation and Association Council
The Chairman

ANNEX

Protocol 2

concerning the definition of the concept of 'originating products' and methods of administrative cooperation

Article 1

Applicable rules of origin

1. For the purpose of implementing this Agreement, Appendix I and the relevant provisions of Appendix II to the Regional Convention on pan-Euro-Mediterranean preferential rules of origin [1] ('the Convention') shall apply.

2. All references to the 'relevant Agreement' in Appendix I and in the relevant provisions of Appendix II to the Convention shall be construed as references to this Agreement.

Article 2

Dispute settlement

1. Where disputes arise in relation to the verification procedures of Article 32 of Appendix I to the Convention that cannot be settled between the customs authorities requesting the verification and the customs authorities responsible for carrying out that verification, they shall be submitted to the Stabilisation and Association Council.

2. In all cases the settlement of disputes between the importer and the customs authorities of the importing country shall take place under the legislation of that country.

Article 3

Amendments to the Protocol

The Stabilisation and Association Council may decide to amend the provisions of this Protocol.

Article 4

Withdrawal from the Convention

1. Should either the European Union or Bosnia and Herzegovina give notice in writing to the depositary of the Convention of their intention to withdraw from the Convention according to Article 9 thereof, the European Union and Bosnia and Herzegovina shall immediately enter into negotiations on rules of origin for the purpose of implementing this Agreement.

2. Until the entry into force of such newly negotiated rules of origin, the rules of origin contained in Appendix I and, where appropriate, the relevant provisions of Appendix II to the Convention, applicable at the moment of withdrawal, shall continue to apply to this Agreement. However, as of the moment of withdrawal, the rules of origin contained in Appendix I and, where appropriate, the relevant provisions of Appendix II to the Convention shall be construed so as to allow bilateral cumulation between the European Union and Bosnia and Herzegovina only.

Article 5

Transitional provisions — cumulation

Notwithstanding Articles 16(5) and 21(3) of Appendix I to the Convention, where cumulation involves only EFTA States, the Faroe Islands, the European Union, Turkey and the participants in the Stabilisation and Association Process, the proof of origin may be a movement certificate EUR.1 or an origin declaration.

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[1] OJ L 54, 26.2.2013, p. 4.

COMMISSION IMPLEMENTING DECISION (EU) 2016/135

of 29 January 2016

postponing the expiry date of approval of flocoumafen, brodifacoum and warfarin for use in biocidal products for product-type 14

(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 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ([1]), and in particular Article 14(5) thereof,

Whereas:

(1) The active substances flocoumafen, brodifacoum and warfarin were included into Annex I to Directive 98/8/EC of the European Parliament and of the Council ([2]) for use in biocidal products for product-type 14, and pursuant to Article 86 of Regulation (EU) No 528/2012 are considered approved under that Regulation subject to the specifications and conditions set out in Annex I to that Directive.

(2) Their approval will expire on 30 September 2016 for flocoumafen and 31 January 2017 for brodifacoum and warfarin. In accordance with Article 13(1) of Regulation (EU) No 528/2012, applications have been submitted for the renewal of the approval of these active substances.

(3) Because of the risks identified when using the active substances flocoumafen, brodifacoum and warfarin, the renewal of their approval is subject to an assessment of an alternative active substance or substances. In addition, due to those risks, the approval of those active substances may be renewed only if it is shown that at least one of the conditions of the first subparagraph of Article 5(2) of Regulation (EU) No 528/2012 is fulfilled.

(4) The Commission has launched a study on the risk-mitigation measures that may be applied to anticoagulant rodenticides with a view to proposing the measures that are most suitable for mitigating the risks associated to the properties of those active substances.

(5) The possibility should be given to the applicants for the renewal of approval of those active substances to address the conclusions of the study in their application. Furthermore, the conclusions of that study should be taken into account when deciding on the renewal of the approval of all anticoagulant rodenticides.

(6) In order to facilitate the review and comparison of the risks and benefits of all anticoagulant rodenticides as well as of the risk-mitigation measures applied to them, the assessment of flocoumafen, brodifacoum and warfarin should be performed in parallel to the assessment of the other anticoagulant rodenticides.

(7) Consequently, for reasons beyond the control of the applicants, the approval of flocoumafen, brodifacoum and warfarin is likely to expire before a decision has been taken on a possible renewal of their approval. It is, therefore, appropriate to postpone the expiry date of approval of those active substances for a period of time sufficient to enable the examination of the applications.

(8) Except for the expiry date of the approval, those substances should remain approved subject to the specifications and conditions set out in Annex I to Directive 98/8/EC.

(9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

([1]) OJ L 167, 27.6.2012, p. 1.
([2]) Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

HAS ADOPTED THIS DECISION:

Article 1

The expiry date of approval of flocoumafen, brodifacoum and warfarin for use in biocidal products for product-type 14 is postponed to 30 June 2018.

Article 2

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

Done at Brussels, 29 January 2016.

For the Commission
The President
Jean-Claude JUNCKER

RECOMMENDATIONS

COMMISSION RECOMMENDATION (EU) 2016/136

of 28 January 2016

on the implementation of measures against tax treaty abuse

(notified under document C(2016) 271)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 292 thereof,

Whereas:

(1) Tax treaties play an important role in encouraging cross-border trade efficiency by improving certainty for tax payers as regards their international dealings. By entering into a tax treaty the Contracting States agree to attribute the taxing rights between themselves with a view to eliminating double taxation and thereby fostering economic activity and growth. Tax treaties should not create opportunities for non- or reduced taxation through treaty shopping or other abusive strategies which only frustrate the purpose of such conventions and undermine the tax revenues of the Contracting States. The European Commission lends its full support to the efforts to tackle tax treaty abuse.

(2) Following the release of the report 'Addressing Base Erosion and Profit Shifting' (BEPS) in February 2013, OECD and the G20 countries adopted a 15-point Action Plan to address BEPS in September 2013. As a result of the joint undertaking final reports on Actions 6 (preventing the granting of treaty benefits in inappropriate circumstances) and 7 (preventing the artificial avoidance of permanent establishment status) were published in October 2015. Both reports propose changes to the OECD Model Tax Convention and for the inclusion in the multilateral instrument implementing the results of the work on treaty issues by the end of 2016, as mandated by the OECD-G20 Project. Taken together, the changes proposed in the two reports are intended to enable countries to address their tax treaty related BEPS concerns.

(3) The final report on Action 6 identifies tax treaty abuse, and in particular treaty shopping, as an important source of BEPS concerns and, proposes an approach based on different types of safeguards against such abuse of treaty provisions and a certain degree of flexibility regarding how to use them. In addition to suggesting a clarification that tax treaties are not intended to create opportunities for double non-taxation, the report recommends, inter alia, the inclusion in the multilateral instrument of a general anti-abuse rule based on a 'principal purpose test' (PPT) of transactions or arrangements.

(4) The final report as regards Action 7 distinguishes in particular commissionaire arrangements and the exploitation of the specific exceptions to the definition of a permanent establishment (PE) as the most common strategies to artificially avoid taxable presence in the form of a PE. The commissionaire arrangements typically take advantage of the relatively formal approach of the current Article 5(5) of the OECD Model Tax Convention as regards conclusion of sales contracts. The specific exceptions to the definition of a PE applicable to activities of preparatory or auxiliary nature are, in addition to being vulnerable to abuse through strategies based on fragmented activities, ill-equipped to deal with business models of digital economy. The report therefore proposes changes to Article 5 of the OECD Model Tax Convention to make it more resilient against artificial structures to circumvent its application.

(5) It is essential for the good functioning of the internal market that the Member States are able to operate efficient tax systems and prevent their tax bases from being unduly eroded because of inadvertent non-taxation and abuse and, that the solutions to protect their tax bases create no undue mismatches and market distortions.

(6) It is equally vital that the measures the Member States make use of in order to implement the commitments they have taken under BEPS are in line with the agreed standards across the Union so as to provide legal certainty both for taxpayers as well as tax administrations.

(7) With a view to ensuring compliance with EU law, the general anti-abuse rule based on a principal purpose test as suggested in the final report on Action 6 needs to be aligned with the case law of the Court of Justice of the European Union as regards the abuse of law.

HAS ADOPTED THIS RECOMMENDATION:

1. SUBJECT MATTER AND SCOPE

This Recommendation addresses the implementation by the Member States of the European Union of measures against tax treaty abuse.

2. GENERAL ANTI-AVOIDANCE RULE BASED ON A PRINCIPAL PURPOSE TEST (PPT)

Where Member States, in tax treaties which they conclude among themselves or with third countries, include a principal purpose test based general anti-avoidance rule in application of the template provided for in the OECD Model Tax Convention, Member States are encouraged to insert in them the following modification:

'Notwithstanding the other provisions of this Convention, a benefit under this Convention shall not be granted in respect of an item of income or capital if it is reasonable to conclude, having regard to all relevant facts and circumstances, that obtaining that benefit was one of the principal purposes of any arrangement or transaction that resulted directly or indirectly in that benefit, unless it is established that ***it reflects a genuine economic activity or that*** granting that benefit in these circumstances would be in accordance with the object and purpose of the relevant provisions of this Convention.'

3. DEFINITION OF A PERMANENT ESTABLISHMENT (PE)

Member States are encouraged, in tax treaties which they conclude among themselves or with third countries, to implement and make use of the proposed new provisions to Article 5 of the OECD Model Tax Convention in order to address artificial avoidance of permanent establishment status as drawn up in the final report on Action 7 of the Action Plan to address Base Erosion and Profit Shifting (BEPS).

4. FOLLOW-UP

Member States should inform the Commission on the measures taken in order to comply with the present Recommendation, as well as on any changes made to such measures.

The Commission will publish a report on the application of this Recommendation within three years after its adoption.

5. ADDRESSEES

This recommendation is addressed to the Member States.

Done at Brussels, 28 January 2016.

For the Commission
Pierre MOSCOVICI
Member of the Commission

CORRIGENDA

Corrigendum to Commission Implementing Regulation (EU) 2016/12 of 6 January 2016 terminating the partial interim review of the anti-dumping and countervailing measures applicable to imports of crystalline silicon photovoltaic modules and key components (i.e. cells) originating in or consigned from the People's Republic of China

(Official Journal of the European Union L 4 of 7 January 2016)

On page 8, in recital 64:

for: 'This Regulation is in accordance with the opinion of the Committee established by Article 15(1) of Regulation (EC) No 1225/2009 and by Article 25(1) of Regulation (EC) No 597/2009,',

read: 'The Committee established by Article 15(1) of the basic anti-dumping Regulation and by Article 25(1) of the basic anti-subsidy Regulation did not deliver an opinion,'.

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