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 (Text with EEA relevance)

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[(1)],

Acting in accordance with the ordinary legislative procedure[(2)],

Whereas:

(1) Article 114 of the Treaty on the Functioning of the European Union (TFEU) provides that, for measures having as their object the establishment and functioning of the internal market, and which concern, inter alia, health, safety and consumer protection, the Commission is to take as a base a high level of protection taking account in particular of any new development based on scientific facts.

(2) The free movement of safe and wholesome food is an essential aspect of the internal market and contributes significantly to the health and well-being of citizens, and to their social and economic interests.

(3) Union law applicable to food is intended, inter alia, to ensure that no food is placed on the market if it is unsafe. Therefore, any substances that are considered to be injurious to the health of the population groups concerned or unfit for human consumption should be excluded from the composition of the categories of food covered by this Regulation.

(4) Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses[3] lays down general rules on the composition and preparation of foods that are specially designed to meet the particular nutritional requirements of the persons for whom they are intended. The majority of the provisions laid down in that Directive date back to 1977 and need to be reviewed.

(5) Directive 2009/39/EC establishes a common definition for 'foodstuffs for particular nutritional uses', and general labelling requirements, including that such foods should bear an indication of their suitability for the nutritional purposes being claimed.

(6) The general compositional and labelling requirements laid down in Directive 2009/39/EC are complemented by a number of non-legislative Union acts, which are applicable to specific categories of food. In that respect, harmonised rules are laid down in Commission Directives 96/8/EC of 26 February 1996 on foods intended for use in energy-restricted diets for weight reduction[4] and 1999/21/EC of 25 March 1999 on dietary foods for special medical purposes[5]. Similarly, Commission Directive 2006/125/EC[6] lays down certain harmonised rules with respect to processed cereal-based foods and baby foods for infants and young children. Commission Directive 2006/141/EC[7] lays down harmonised rules with respect to infant formulae and follow-on formulae and Commission Regulation (EC) No 41/2009[8] lays down harmonised rules concerning the composition and labelling of foodstuffs suitable for people intolerant to gluten.

(7) In addition, harmonised rules are laid down in Council Directive 92/52/EEC of 18 June 1992 on infant formulae and follow-on formulae intended for export to third countries[9] and in Commission Regulation (EC) No 953/2009 of 13 October 2009 on substances that may be added for specific nutritional purposes in foods for particular nutritional uses[10].

(8) Directive 2009/39/EC requires a general notification procedure at national level for food presented by food business operators as coming within the definition of 'foodstuffs for particular nutritional uses' for which no specific provisions have been laid down in Union law, prior to its being placed on the Union market, in order to facilitate the efficient monitoring of such food by the Member States.

(9) A report from the Commission of 27 June 2008 to the European Parliament and to the Council on the implementation of that notification procedure showed that difficulties can arise from the definition of 'foodstuffs for particular nutritional uses' which appeared to be open to differing interpretations by the national authorities. It therefore concluded that a revision of Directive 2009/39/EC would be required to ensure a more effective and harmonised implementation of Union legal acts.

(10) A study report of 29 April 2009 by Agra CEAS Consulting, concerning the revision of Directive 2009/39/EC, confirmed the findings of the Commission report of 27 June 2008 on the implementation of the notification procedure and indicated that an increasing number of foodstuffs are currently marketed and labelled as foodstuffs suitable for particular nutritional uses, due to the broad definition laid down in that Directive. The study report also pointed out that food regulated under that Directive

differs significantly between Member States; similar food could at the same time be marketed in different Member States as food for particular nutritional uses and/or as food for normal consumption, including food supplements, addressed to the population in general or to certain subgroups thereof such as pregnant women, postmenopausal women, older adults, growing children, adolescents, variably active individuals and others. This state of affairs undermines the functioning of the internal market, creates legal uncertainty for competent authorities, food business operators, in particular small and medium-sized enterprises (SMEs), and consumers, while the risks of marketing abuse and distortion of competition cannot be ruled out. There is therefore a need to eliminate differences in interpretation by simplifying the regulatory environment.

(11) It appears that other, recently adopted, Union legal acts are more adapted to an evolving and innovative food market than Directive 2009/39/EC. Of particular relevance and importance in that respect are: Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements[(11)], 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[(12)] and Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods[(13)]. Furthermore, the provisions of those Union legal acts would adequately regulate a number of the categories of food covered by Directive 2009/39/EC with less of an administrative burden and more clarity as to scope and objectives.

(12) Moreover, experience shows that certain rules included in, or adopted under, Directive 2009/39/EC are no longer effective in ensuring the functioning of the internal market.

(13) Therefore, the concept of 'foodstuffs for particular nutritional uses' should be abolished and Directive 2009/39/EC should be replaced by this act. To simplify the application of this act and to ensure consistency of application throughout the Member States, this act should take the form of a Regulation.

(14) 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[(14)] establishes common principles and definitions for Union food law. Certain definitions laid down in that Regulation should also apply in the context of this Regulation.

(15) A limited number of categories of food constitute a partial or the sole source of nourishment for certain population groups. Such categories of food are vital for the management of certain conditions and/or are essential to satisfy the nutritional requirements of certain clearly identified vulnerable population groups. Those categories of food include infant formula and follow-on formula, processed cereal-based food and baby food, and food for special medical purposes. Experience has shown that the provisions laid down in Directives 1999/21/EC, 2006/125/EC and 2006/141/EC ensure the free movement of those categories of food in a satisfactory manner, while ensuring a high level of protection of public health. It is therefore appropriate that

this Regulation focuses on the general compositional and information requirements for those categories of food, taking into account Directives 1999/21/EC, 2006/125/EC and 2006/141/EC.

(16) In addition, in view of the growing rates of people with problems related to being overweight or obese, an increasing number of foods are placed on the market as total diet replacement for weight control. Currently, for such foods present in the market a distinction can be made between products intended for low calorie diets, which contain between 3 360 kJ (800 kcal) and 5 040 kJ (1 200 kcal), and products intended for very low calorie diets, which normally contain fewer than 3 360 kJ (800 kcal). Given the nature of the foods in question it is appropriate to lay down certain specific provisions for them. Experience has shown that the relevant provisions laid down in Directive 96/8/EC ensure the free movement of foods presented as total diet replacement for weight control in a satisfactory manner while ensuring a high level of protection of public health. It is therefore appropriate that this Regulation focuses on the general compositional and information requirements for foods intended to replace the whole of the daily diet including foods of which the energy content is very low, taking into account the relevant provisions of Directive 96/8/EC.

(17) This Regulation should establish, inter alia, definitions of infant formula and follow-on formula, processed cereal-based food and baby food, food for special medical purposes, and total diet replacement for weight control, taking into account relevant provisions in Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC.

(18) Regulation (EC) No 178/2002 establishes the principles of risk analysis in relation to food and establishes the structures and mechanisms for the scientific and technical evaluations which are undertaken by the European Food Safety Authority ('the Authority'). For the purpose of this Regulation, the Authority should be consulted on all matters likely to affect public health.

(19) It is important that ingredients used in the manufacture of food covered by this Regulation are appropriate for satisfying the nutritional requirements of, and are suitable for, the persons for whom such food is intended and that their nutritional adequacy has been established by generally accepted scientific data. Such adequacy should be demonstrated through a systematic review of the available scientific data.

(20) Maximum residue levels of pesticides set out in relevant Union law, in particular 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[(15)], should apply without prejudice to specific provisions set out in this Regulation and delegated acts adopted pursuant to this Regulation.

(21) The use of pesticides can lead to pesticide residues in food that is covered by this Regulation. Such use should, therefore, be restricted as much as possible, taking into account the requirements of 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[(16)]. However, a restriction on, or a prohibition of, use would not necessarily guarantee that food covered by this Regulation, including food for infants and young children, is free from pesticides, since some pesticides contaminate the

environment and their residues can be found in such food. Therefore, the maximum residue levels in such food should be set at the lowest achievable level to protect vulnerable population groups, taking into account good agricultural practices as well as other sources of exposure, such as environmental contamination.

(22) Restrictions on and prohibitions of certain pesticides equivalent to those currently established in the Annexes to Directives 2006/125/EC and 2006/141/EC should be taken into account in delegated acts adopted pursuant to this Regulation. Those restrictions and prohibitions should be updated regularly, with particular attention to be paid to pesticides containing active substances, safeners or synergists classified in accordance with 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[(17)] as mutagen category 1A or 1B, carcinogen category 1A or 1B, toxic for reproduction category 1A or 1B, or considered to have endocrine-disrupting properties that can cause adverse effects in humans.

(23) Substances falling within the scope of Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients[(18)] should not be added to food covered by this Regulation unless such substances fulfil the conditions for being placed on the market under Regulation (EC) No 258/97 in addition to the conditions set out in this Regulation and delegated acts adopted pursuant to this Regulation. When there is a significant change in the production method of a substance that has been used in accordance with this Regulation or a change in particle size of such a substance, for example through nanotechnology, that substance should be considered different from the one that has been used in accordance with this Regulation and should be re-evaluated under Regulation (EC) No 258/97 and subsequently under this Regulation.

(24) 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[(19)] lays down general labelling requirements. Those labelling requirements should, as a general rule, apply to the categories of food covered by this Regulation. However, this Regulation should also provide for additional requirements to, or derogations from, Regulation (EU) No 1169/2011, where necessary, in order to meet the specific objectives of this Regulation.

(25) The labelling, presentation or advertising of food covered by this Regulation should not attribute to such food the property of preventing, treating or curing a human disease nor should they imply such properties. Food for special medical purposes, however, is intended for the dietary management of patients with a limited, impaired or disturbed capacity, for example, to take ordinary food because of a specific disease, disorder or medical condition. Reference to the dietary management of diseases, disorders or medical conditions for which the food is intended should not be considered as attribution of the property of preventing, treating or curing a human disease.

(26) In the interest of protecting vulnerable consumers, labelling requirements should ensure accurate product identification for consumers. In the case of infant formula and follow-on formula, all written and pictorial information should enable a clear distinction to be made between different formulae. Difficulty in identifying the precise

age of an infant pictured on labelling could confuse consumers and impede product identification. That risk should be avoided by appropriate restrictions on labelling. Furthermore, taking into account that infant formula constitutes food that satisfies by itself the nutritional requirements of infants from birth until introduction of appropriate complementary feeding, proper product identification is crucial for the protection of consumers. Appropriate restrictions should, therefore, be introduced concerning the presentation and advertising of infant formula.

(27) This Regulation should provide the criteria for the establishment of the specific compositional and information requirements for infant formula, follow-on formula, processed cereal-based food and baby food, food for special medical purposes, and total diet replacement for weight control, taking into account Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC.

(28) Regulation (EC) No 1924/2006 establishes the rules and conditions for the use of nutrition and health claims on food. Those rules should apply as a general rule to the categories of food covered by this Regulation, unless otherwise specified in this Regulation or delegated acts adopted pursuant to this Regulation.

(29) According to the recommendations of the World Health Organisation (WHO), low birth weight infants should be fed mother's milk. Nonetheless, low birth weight infants and pre-term infants may have special nutritional requirements which cannot be met by mother's milk or standard infant formula. In fact, the nutritional requirements of a low birth weight infant and a pre-term infant can depend on the medical condition of that infant, in particular on that infant's weight in comparison with that of an infant in good health, and on the number of weeks the infant is premature. It is to be decided on a case-by-case basis whether the infant's condition requires the consumption, under medical supervision, of a food for special medical purposes developed to satisfy the nutritional requirements of infants (formula) and adapted for the dietary management of that infant's specific condition.

(30) Directive 1999/21/EC requires that certain compositional requirements for infant formula and for follow-on formula as set out in Directive 2006/141/EC apply to food for special medical purposes intended for infants, depending on their age. However, certain provisions, including those relating to labelling, presentation, advertising, and promotional and commercial practices, set out in Directive 2006/141/EC currently do not apply to such food. Developments in the market accompanied by a significant increase of such food make it necessary to review requirements for formulae intended for infants such as requirements on the use of pesticides in products intended for production of such formulae, pesticide residues, labelling, presentation, advertising, and promotional and commercial practices that should also apply, as appropriate, to food for special medical purposes developed to satisfy the nutritional requirements of infants.

(31) There is an increasing number of milk-based drinks and similar products on the Union market which are promoted as being particularly suitable for young children. Such products, which can be derived from protein of animal or vegetable origin such as cows' milk, goats' milk, soy or rice, are often marketed as 'growing up milks' or 'toddlers' milks' or with similar terminology. While these products are currently

regulated by different legal acts of the Union, such as Regulations (EC) No 178/2002, (EC) No 1924/2006 and (EC) No 1925/2006, and Directive 2009/39/EC, they are not covered by the existing specific measures applying to food intended for infants and young children. Different views exist as to whether such products satisfy the specific nutritional requirements of the population group they target. The Commission should therefore, after consulting the Authority, present to the European Parliament and to the Council a report on the necessity, if any, of special provisions regarding the composition, labelling and other types of requirements, if appropriate, of those products. This report should consider, inter alia, the nutritional requirements of young children and the role of those products in their diet, taking into account the pattern of consumption, the nutritional intake and the levels of exposure of young children to contaminants and pesticides. The report should also consider the composition of such products and whether they have any nutritional benefits when compared to a normal diet for a child who is being weaned. The Commission could accompany this report with a legislative proposal.

(32) Directive 2009/39/EC provides that specific provisions can be adopted regarding the following two specific categories of food falling within the definition of foodstuffs for particular nutritional uses: ‘food intended to meet the expenditure of intense muscular effort, especially for sportsmen’ and ‘food for persons suffering from carbohydrate metabolism disorders (diabetes)’. As regards special provisions for food for persons suffering from carbohydrate metabolism disorders (diabetes), a Commission report to the European Parliament and to the Council of 26 June 2008 on foods for persons suffering from carbohydrate metabolism disorders (diabetes) concluded that the scientific basis for setting specific compositional requirements is lacking. With regard to food intended to meet the expenditure of intense muscular effort, especially for sportsmen, no successful conclusion could be reached as regards the development of specific provisions due to widely diverging views among the Member States and stakeholders concerning the scope of specific legislation, the number of subcategories of food to be included, the criteria for establishing compositional requirements and the potential impact on innovation in product development. Therefore, specific provisions should not be developed at this stage. Meanwhile, on the basis of requests submitted by food business operators, relevant claims have been considered for authorisation in accordance with Regulation (EC) No 1924/2006.

(33) However, different views exist as to whether additional rules are needed to ensure an adequate protection of consumers of food intended for sportsmen, also called food intended to meet the expenditure of intense muscular effort. The Commission should, therefore, be invited, after consulting the Authority, to submit to the European Parliament and to the Council a report on the necessity, if any, of provisions concerning food intended for sportsmen. The consultation of the Authority should take into account the report of 28 February 2001 of the Scientific Committee on Food on composition and specification of food intended to meet the expenditure of intense muscular effort, especially for sportsmen. In its report, the Commission should, in particular, evaluate whether provisions are necessary to ensure the protection of consumers.

(34) The Commission should be able to adopt technical guidelines aimed at facilitating compliance by food business operators, in particular SMEs, with this Regulation.

(35) Taking into account the existing situation on the market and Directives 2006/125/EC and 2006/141/EC, and Regulation (EC) No 953/2009, it is appropriate to establish and include in the Annex to this Regulation a Union list of substances belonging to the following categories of substances: vitamins, minerals, amino acids, carnitine and taurine, nucleotides, choline and inositol. Among the substances belonging to those categories, it should only be permissible for those included in the Union list to be added to the categories of food covered by this Regulation. When substances are included in the Union list, it should be specified to which category of food covered by this Regulation such substances may be added.

(36) The inclusion of substances in the Union list should not mean that their addition to one or more categories of food covered by this Regulation is necessary or desirable. The Union list is intended only to reflect which substances belonging to certain categories of substances are authorised to be added to one or more categories of food covered by this Regulation, whereas the specific compositional requirements are intended to establish the composition of each category of food covered by this Regulation.

(37) A number of the substances that may be added to food covered by this Regulation could be added for technological purposes as food additives, colourings or flavourings, or for other such purposes, including authorised oenological practices and processes, provided for by relevant Union legal acts applicable to food. In this context specifications are adopted for those substances at Union level. It is appropriate that those specifications should be applicable to the substances whatever the purpose of their use in food unless otherwise provided for by this Regulation.

(38) For the substances included in the Union list for which purity criteria have not yet been adopted at Union level, and in order to ensure a high level of protection of public health, generally acceptable purity criteria recommended by international organisations or agencies including but not limited to the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and European Pharmacopoeia should apply. Member States should be permitted to maintain national rules setting stricter purity criteria, without prejudice to the rules set out in the TFEU.

(39) In order to specify requirements for the categories of food covered by this Regulation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the laying down of specific compositional and information requirements with regard to the categories of food covered by this Regulation, including additional labelling requirements to, or derogations from, Regulation (EU) No 1169/2011 and with regard to the authorisation of nutrition and health claims. Furthermore, in order to enable consumers to benefit rapidly from technical and scientific progress, especially in relation to innovative products, and thus to stimulate innovation the power to adopt acts in accordance with Article 290 TFEU should also be delegated to the Commission in respect of the regular updating of those specific requirements, taking into account all relevant data, including data provided by interested parties. In addition, in order to take into account technical progress,

scientific developments or consumers' health, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of the addition of categories of substances that have a nutritional or physiological effect to be covered by the Union list, or in respect of the removal of such categories from the categories of substances covered by the Union list. For the same purposes and subject to additional requirements laid down in this Regulation, the power to adopt delegated acts in accordance with Article 290 TFEU should also be delegated to the Commission in respect of amending the Union list by adding a new substance, removing a substance or adding, removing or amending the elements in the Union list related to a substance. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(40) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to decide whether a given food falls within the scope of this Regulation and to which category of food it belongs. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers[(20)].

(41) Currently, the rules on the use of the statements 'gluten-free' and 'very low gluten' are specified in Regulation (EC) No 41/2009. That Regulation harmonises the information that is provided to consumers on the absence or reduced presence of gluten in food and sets specific rules for food that is specially produced, prepared and/or processed in order to reduce the gluten content of one or more gluten-containing ingredients or to substitute such gluten-containing ingredients and other food that is made exclusively from ingredients that are naturally free of gluten. Regulation (EU) No 1169/2011 sets out rules on information to be provided for all food, including non-prepacked food, on the presence of ingredients, such as gluten-containing ingredients, with a scientifically proven allergenic or intolerance effect in order to enable consumers, particularly those suffering from a food allergy or intolerance such as gluten-intolerant people, to make informed choices which are safe for them. For the sake of clarity and consistency, the rules on the use of the statements 'gluten-free' and 'very low gluten' should also be regulated under Regulation (EU) No 1169/2011. The legal acts to be adopted pursuant to Regulation (EU) No 1169/2011, which are to transfer the rules on the use of the statements 'gluten-free' and 'very low gluten', as contained in Regulation (EC) No 41/2009, should ensure at least the same level of protection for people who are intolerant to gluten as currently provided for under Regulation (EC) No 41/2009. That transfer of rules should be completed before this Regulation applies. Furthermore, the Commission should consider how to ensure that people who are intolerant to gluten are adequately informed of the difference between a food that is specially produced, prepared and/or processed in order to reduce the gluten content of one or more gluten-containing ingredients and other food that is made exclusively from ingredients naturally free of gluten.

(42) Labelling and compositional rules indicating the absence or reduced presence of lactose in food are currently not harmonised at Union level. Those indications are, however, important for people who are intolerant to lactose. Regulation (EU) No 1169/2011 sets out rules on information to be provided concerning substances with a scientifically proven allergenic or intolerant effect, to enable consumers, such as lactose-intolerant people, to make informed choices which are safe for them. For the sake of clarity and consistency, the establishment of rules on the use of statements indicating the absence or reduced presence of lactose in food should be regulated under Regulation (EU) No 1169/2011, taking into account the Scientific Opinion of the Authority of 10 September 2010 on lactose thresholds in lactose intolerance and galactosaemia.

(43) 'Meal replacement for weight control' intended to replace part of the daily diet is considered as food for particular nutritional uses and is currently governed by specific rules under Directive 96/8/EC. However, more and more foods intended for the general population have appeared on the market carrying similar statements which are presented as health claims for weight control. In order to eliminate any potential confusion within this group of foods marketed for weight control and in the interests of legal certainty and coherence of Union legal acts, such statements should be regulated solely under Regulation (EC) No 1924/2006 and comply with requirements set out in that Regulation. It is necessary that technical adaptations made pursuant to Regulation (EC) No 1924/2006, relating to health claims referring to control of body weight and made in respect of food presented as 'meal replacement for weight control', and to the conditions of use of such claims, as regulated by Directive 96/8/EC, be completed prior to the application of this Regulation.

(44) This Regulation does not affect the obligation to respect fundamental rights and fundamental legal principles, including the freedom of expression, as enshrined in Article 11, in conjunction with Article 52, of the Charter of Fundamental Rights of the European Union, and in other relevant provisions.

(45) Since the objectives of this Regulation, namely, the establishment of compositional and information requirements for certain categories of food, the establishment of a Union list of substances that may be added to certain categories of food and the establishment of the rules for the update of the Union list, cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale of the proposed action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(46) Directive 92/52/EEC provides that infant formulae and follow-on formulae exported or re-exported from the Union are to comply with Union law unless otherwise requested or stipulated by provisions established by the importing country. That principle has already been established for food in Regulation (EC) No 178/2002. For the sake of simplification and legal certainty, Directive 92/52/EEC should therefore be repealed.

(47) Directives 96/8/EC, 1999/21/EC, 2006/125/EC, 2006/141/EC, 2009/39/EC and Regulations (EC) No 41/2009 and (EC) No 953/2009 should also be repealed.

(48) Adequate transitional measures are necessary to enable food business operators to adapt to the requirements of this Regulation,

HAVE ADOPTED THIS REGULATION:

(**1**) OJ C 24, 28.1.2012, p. 119.

(**2**) Position of the European Parliament of 14 June 2012 (not yet published in the Official Journal) and position of the Council at first reading of 22 April 2013 (not yet published in the Official Journal). Position of the European Parliament of 11 June 2013 (not yet published in the Official Journal).

(**3**) OJ L 124, 20.5.2009, p. 21.

(**4**) OJ L 55, 6.3.1996, p. 22.

(**5**) OJ L 91, 7.4.1999, p. 29.

(**6**) OJ L 339, 6.12.2006, p. 16.

(**7**) OJ L 401, 30.12.2006, p. 1.

(**8**) OJ L 16, 21.1.2009, p. 3.

(**9**) OJ L 179, 1.7.1992, p. 129.

(**10**) OJ L 269, 14.10.2009, p. 9.

(**11**) OJ L 183, 12.7.2002, p. 51.

(**12**) OJ L 404, 30.12.2006, p. 9.

(**13**) OJ L 404, 30.12.2006, p. 26.

(**14**) OJ L 31, 1.2.2002, p. 1.

(**15**) OJ L 70, 16.3.2005, p. 1.

(**16**) OJ L 309, 24.11.2009, p. 1.

(**17**) OJ L 353, 31.12.2008, p. 1.

(**18**) OJ L 43, 14.2.1997, p. 1.

(**19**) OJ L 304, 22.11.2011, p. 18.

(**20**) OJ L 55, 28.2.2011, p. 13.

Changes to legislation:
There are outstanding changes not yet made to Regulation (EU) No 609/2013 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to the whole legislation item and associated provisions

– Art. 16E omitted in earlier amending provision S.I. 2019/651, reg. 19(15) by S.I. 2020/1476 reg. 5(4)(d)(ii)