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

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(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.

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(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

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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

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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

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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