

Directive 2009/48/EC of the European Parliament and of the Council  
of 18 June 2009 on the safety of toys (Text with EEA relevance)

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PARLIAMENT AND OF THE COUNCIL

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on the safety of toys

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THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee<sup>(1)</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty<sup>(2)</sup>,

Whereas:

- (1) Council Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys<sup>(3)</sup> was adopted in the context of establishing the internal market in order to harmonise the safety levels of toys throughout the Member States and to remove obstacles to trade in toys between Member States.
- (2) Directive 88/378/EEC is based on the New Approach principles, as set out in the Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards<sup>(4)</sup>. Thus, it sets out only the essential safety requirements with regard to toys, including the particular safety requirements regarding physical and mechanical properties, flammability, chemical properties, electrical properties, hygiene and radioactivity. Technical details are adopted by the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) in accordance with Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services<sup>(5)</sup>. Conformity with harmonised standards so set, the reference number of which is published in the *Official Journal of the European Union*, provides a presumption of conformity with the requirements of Directive 88/378/EEC. Experience has shown that these basic principles have worked well in the toys sector and should be maintained.
- (3) Technological developments in the toys market have, however, raised new issues with respect to the safety of toys and have given rise to increased consumer concerns. In order to take account of those developments and to provide clarification in relation to the framework within which toys may be marketed, certain aspects of Directive 88/378/

EEC should be revised and enhanced and, in the interests of clarity, that Directive should be replaced by this Directive.

- (4) Toys are also subject to Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety<sup>(6)</sup>, which applies in a complementary manner to specific sectoral legislation.
- (5) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products<sup>(7)</sup> lays down horizontal provisions on the accreditation of conformity assessment bodies, on the CE marking and on the Community market surveillance framework for, and controls of, products entering the Community market which also apply to the toys sector.
- (6) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products<sup>(8)</sup> provides common principles and reference provisions for the purposes of legislation based on the New Approach principles. In order to ensure consistency with other sectoral product legislation, it is appropriate to align certain provisions of this Directive to that Decision, in so far as sectoral specificities do not require a different solution. Therefore, certain definitions, the general obligations of economic operators, the presumption of conformity, formal objections against harmonised standards, rules for the CE marking, requirements for conformity assessment bodies and notification procedures and the provisions concerning procedures dealing with products presenting a risk should be aligned to that Decision.
- (7) In order to facilitate the application of this Directive by manufacturers and national authorities, the scope of this Directive should be clarified by completing the list of products which are not within its scope, in particular as regards certain new products, such as videogames and peripherals.
- (8) It is appropriate to provide for certain new definitions specific to the toys sector in order to facilitate the understanding and uniform application of this Directive.
- (9) Toys that are placed on the Community market should comply with the relevant Community legislation, and economic operators should be responsible for the compliance of toys, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety, and the protection of consumers and of the environment, and to guarantee fair competition on the Community market.
- (10) All economic operators are expected to act responsibly and in full accordance with the legal requirements applicable when placing or making toys available on the market.
- (11) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that under normal and reasonably foreseeable conditions of use, the toys they place on market do not jeopardise the safety and health of children and that they make available on the market only toys which comply with the relevant Community legislation. This Directive provides a clear and proportionate distribution of

obligations which correspond to the role of each operator in the supply and distribution process.

- (12) As certain tasks can be executed only by the manufacturer, it is necessary to distinguish clearly between the manufacturer and operators further down the distribution chain. It is also necessary to distinguish clearly between the importer and the distributor, as the importer introduces toys from third countries to the Community market. The importer has thus to make sure that those toys comply with the applicable Community requirements.
- (13) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the complete conformity assessment procedure for toys. Conformity assessment should therefore remain the obligation of the manufacturer alone.
- (14) It is necessary to ensure that toys from third countries entering the Community market comply with all applicable Community requirements, and in particular that appropriate assessment procedures have been carried out by manufacturers with regard to those toys. Provision should therefore be made for importers to make sure that the toys they place on the market comply with the applicable requirements and that they do not place on the market toys which do not comply with such requirements or which present a risk. For the same reason, provision should also be made for importers to make sure that conformity assessment procedures have been carried out and that product marking and documentation drawn up by manufacturers are available for inspection by the supervisory authorities.
- (15) Where the distributor makes a toy available on the market after the toy has been placed on the market by the manufacturer or the importer, it should act with due care to ensure that its handling of the toy does not adversely affect the compliance of the toy. Both importers and distributors are expected to act with due care in relation to the requirements applicable when placing or making toys available on the market.
- (16) When placing a toy on the market, importers should indicate on the toy their name and the address at which they can be contacted. Exceptions should be provided for in cases where the size or nature of the toy does not allow for such an indication. This includes cases where importers would have to open the packaging to put their name and address on the product.
- (17) Any economic operator that either places a toy on the market under its own name or trademark or modifies a toy in such a way that compliance with applicable requirements may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.
- (18) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the toy concerned.
- (19) Ensuring traceability of a toy throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates

market surveillance authorities' task of tracing economic operators who made non-compliant toys available on the market.

- (20) Certain essential safety requirements which were laid down in Directive 88/378/EEC should be updated to take account of technical progress since the adoption of that Directive. In particular, in the field of electrical properties, technical progress has made it possible to allow the limit of 24 volts set in Directive 88/378/EEC to be exceeded, while guaranteeing the safe use of the toy concerned.
- (21) It is also necessary to adopt new essential safety requirements. In order to ensure a high level of protection of children against risks caused by chemical substances in toys, the use of dangerous substances, in particular substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR), and allergenic substances and certain metals, should be subject to careful attention. It is therefore in particular necessary to complete and update the provisions on chemical substances in toys to specify that toys should comply with general chemicals legislation, in particular Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency<sup>(9)</sup>. Those provisions should, however, also be adapted to the particular needs of children, who are a vulnerable group of consumers. Therefore, new restrictions on CMR substances, in accordance with applicable Community legislation on the classification, labelling and packaging of substances and mixtures, and on fragrances in toys should be provided for on account of the special risks that these substances may entail for human health. Nickel in stainless steel has proven to be safe, and consequently it is appropriate that it can be used in toys.
- (22) The specific limit values laid down in Directive 88/378/EEC for certain substances should also be updated to take account of the development of scientific knowledge. Limit values for arsenic, cadmium, chromium VI, lead, mercury and organic tin, which are particularly toxic, and which should therefore not be intentionally used in those parts of toys that are accessible to children, should be set at levels that are half of those considered safe according to the criteria of the relevant Scientific Committee, in order to ensure that only traces that are compatible with good manufacturing practice will be present.
- (23) Toys or their parts and their packaging that can reasonably be expected to be brought into contact with food should comply with 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<sup>(10)</sup>.
- (24) In order to ensure adequate protection in the case of toys involving a high degree of exposure, it should be possible to adopt implementing measures establishing specific limit values for chemicals used in toys intended for use by children under 36 months and in other toys intended to be put in the mouth, taking into account the requirements of Regulation (EC) No 1935/2004 and the differences between toys and materials which come into contact with food.
- (25) The general and specific chemical requirements laid down by this Directive should aim at protecting the health of children from certain substances in toys, while the

environmental concerns presented by toys are addressed by horizontal environmental legislation applying to electrical and electronic toys, namely Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment<sup>(11)</sup> and Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment<sup>(12)</sup>. In addition, environmental issues on waste are regulated by Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006<sup>(13)</sup>, those on packaging and packaging waste by Directive 94/62/EC of the European Parliament and of the Council of 20 December 1994<sup>(14)</sup> and those on batteries and accumulators and waste batteries and accumulators by Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006<sup>(15)</sup>.

- (26) The system established by this Directive should also encourage, and in certain cases ensure, that dangerous substances and materials used in toys are replaced by less dangerous substances or technologies, where suitable economically and technically viable alternatives are available.
- (27) In order to protect children from the risk of impairment of hearing caused by sound-emitting toys, more stringent and comprehensive standards to limit the maximum values for both impulse noise and continuous noise emitted by toys should be established. It is therefore necessary to lay down a new essential safety requirement concerning the sound from such toys.
- (28) In line with the precautionary principle, it is appropriate to lay down specific safety requirements to cover the potential specific hazard presented by toys in food, since the association of a toy and food could be the cause of a risk of choking that is distinct from the risks presented by the toy alone and which is, therefore, not covered by any specific measure at Community level.
- (29) Since it is possible that toys which present hazards which are not covered by a particular safety requirement laid down in this Directive might exist or be developed, it is necessary to set a general requirement of safety as the legal basis for taking action in respect of such toys. In this respect, the safety of toys should be determined by reference to the intended use, while taking into account the foreseeable use, and bearing in mind the behaviour of children, who do not generally show the same degree of care as the average adult user. Where a hazard cannot be sufficiently minimised by design or safeguards, the residual risk could be addressed by product-related information directed at the supervisors, taking into account their capacity to cope with the residual risk. According to acknowledged methods of risk assessment, it is not appropriate for information to supervisors or a lack of history of accidents to be used as a substitute for design improvements.
- (30) In order to further promote safe conditions of use of toys, it is necessary to supplement the provisions on warnings which should accompany the toy. In order to prevent the misuse of warnings to circumvent the applicable safety requirements, which has occurred in particular in case of the warning stating that the toy is not suitable for children under 36 months, it is necessary to provide explicitly that the warnings

provided for certain categories of toy may not be used if they conflict with the intended use of the toy.

- (31) The CE marking, indicating the conformity of a toy, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking should be laid down in this Directive.
- (32) It is crucial to make clear to both manufacturers and users that by affixing the CE marking to the toy, the manufacturer declares that the toy is in conformity with all applicable requirements and that the manufacturer takes full responsibility therefor.
- (33) The CE marking should be the only marking of conformity indicating that the toy is in conformity with Community harmonisation legislation. However, other markings may be used as long as they contribute to the improvement of consumer protection and are not covered by Community harmonisation legislation.
- (34) It is appropriate to lay down rules on the affixing of CE marking which ensure sufficient visibility of the marking in order to facilitate market surveillance of toys.
- (35) In order to ensure compliance with the essential safety requirements, it is necessary to lay down appropriate conformity assessment procedures to be followed by the manufacturer. To complete the legal obligations of the manufacturer which aim at ensuring the safety of toys, an explicit obligation to carry out an analysis of the various hazards that the toy may present and an assessment of the potential exposure to them, which for chemicals includes an assessment of the likelihood of the presence in the toy of prohibited or restricted substances, should be included in this Directive, and manufacturers should be obliged to keep this safety assessment in the technical documentation to allow market surveillance authorities to perform their tasks efficiently. Internal production control based on the manufacturer's own responsibility for the conformity assessment has proven adequate in cases where it has followed the harmonised standards, the reference number of which has been published in the *Official Journal of the European Union*, covering all the safety requirements for the toy. In cases where such harmonised standards do not exist, the toy should be submitted to third party verification, in this case EC-type examination. The same should apply if one or more such standards has been published with a restriction in the *Official Journal of the European Union*, or if the manufacturer has not followed such standards completely, or only in part. The manufacturer should submit the toy to EC-type examination in cases where it considers that the nature, design, construction or purpose of the toy necessitates third party verification.
- (36) Since it is necessary to ensure a uniformly high level of performance of bodies performing conformity assessment of toys throughout the Community, and since all such bodies should perform their functions to the same level and under conditions of fair competition, obligatory requirements should be set for conformity assessment bodies wishing to be notified in order to provide conformity assessment services under this Directive.

- (37) In order to ensure a consistent level of quality in the performance of conformity assessment of toys, it is necessary not only to consolidate the requirements that conformity assessment bodies wishing to be notified must fulfil, but also, in parallel, to set requirements that notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies must fulfil.
- (38) Where the available scientific evidence is insufficient to allow an accurate risk assessment, Member States, when taking measures under this Directive, should apply the precautionary principle, which is a principle of Community law outlined, *inter alia*, in the Communication from the Commission of 2 February 2000, while taking due consideration of the other rules and principles contained in this Directive, such as the free movement of goods and the presumption of conformity.
- (39) Regulation (EC) No 765/2008 complements and strengthens the existing framework for the market surveillance of products covered by Community harmonisation legislation, including toys. Member States should therefore organise and carry out market surveillance of toys in accordance with that Regulation. In accordance with that Regulation, its application does not prevent the market surveillance authorities from taking more specific market surveillance measures as are available under Directive 2001/95/EC. Furthermore, specific measures concerning the possibility for a market surveillance authority to request information from a notified body and to give instructions to it should be included in this Directive in order to strengthen the possibilities for action by market surveillance authorities in the case of toys covered by an EC-type examination certificate.
- (40) Directive 88/378/EEC already provides for a safeguard procedure allowing the Commission to examine the justification for a measure taken by a Member State against toys it considers to be non-compliant. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with the aim of making it more efficient and of drawing on expertise available in the Member States.
- (41) The existing system should be complemented by a procedure allowing interested parties to be informed of measures taken with regard to toys presenting a risk to the health and safety of persons or other issues of public interest protection. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such toys.
- (42) Where Member States and the Commission agree as to the justification for a measure taken by a Member State, no further involvement of the Commission should be required.
- (43) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission<sup>(16)</sup>.
- (44) In particular, the Commission should be empowered to adapt requirements concerning chemical properties in certain well-defined cases and to grant exemptions from the prohibition of CMR substances in certain cases, as well as to adapt the wording of the specific warnings for certain categories of toy. Since those measures are of general

scope and are designed to amend non-essential elements of this Directive, *inter alia*, by supplementing it with new non-essential elements, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

- (45) Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products<sup>(17)</sup> applies, *inter alia*, to toys which are not in conformity with Community harmonisation legislation. Manufacturers and importers who have placed non-compliant toys on the Community market are liable for damages under that Directive.
- (46) Member States should provide for penalties applicable to infringements of this Directive. Those penalties should be effective, proportionate and dissuasive.
- (47) In order to allow toy manufacturers and other economic operators sufficient time to adapt to the requirements laid down by this Directive, it is necessary to provide for a transitional period of two years after the entry into force of this Directive during which toys which comply with Directive 88/378/EEC may be placed on the market. In the case of chemical requirements, this period should be set at four years so as to allow the development of the harmonised standards which are necessary for compliance with those requirements.
- (48) Since the objective of this Directive, namely to ensure a high level of safety of toys with a view to ensuring the health and safety of children whilst guaranteeing the functioning of the internal market by setting harmonised safety requirements for toys and minimum requirements for market surveillance, cannot be sufficiently achieved by the Member States and can therefore, by reason of its scale and effects, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective,

HAVE ADOPTED THIS DIRECTIVE:



- (1) OJ C 77, 31.3.2009, p. 8.
- (2) Opinion of the European Parliament of 18 December 2008 (not yet published in the Official Journal) and Council Decision of 11 May 2009.
- (3) OJ L 187, 16.7.1988, p. 1.
- (4) OJ C 136, 4.6.1985, p. 1.
- (5) OJ L 204, 21.7.1998, p. 37.
- (6) OJ L 11, 15.1.2002, p. 4.
- (7) OJ L 218, 13.8.2008, p. 30.
- (8) OJ L 218, 13.8.2008, p. 82.
- (9) OJ L 396, 30.12.2006, p. 1.
- (10) OJ L 338, 13.11.2004, p. 4.
- (11) OJ L 37, 13.2.2003, p. 19.
- (12) OJ L 37, 13.2.2003, p. 24.
- (13) OJ L 114, 27.4.2006, p. 9.
- (14) OJ L 365, 31.12.1994, p. 10.
- (15) OJ L 266, 26.9.2006, p. 1.
- (16) OJ L 184, 17.7.1999, p. 23.
- (17) OJ L 210, 7.8.1985, p. 29.