

## I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

## DIRECTIVES

## 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)

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.

<sup>(1)</sup> OJ C 77, 31.3.2009, p. 8.

<sup>(2)</sup> Opinion of the European Parliament of 18 December 2008 (not yet published in the Official Journal) and Council Decision of 11 May 2009.

<sup>(3)</sup> OJ L 187, 16.7.1988, p. 1.

<sup>(4)</sup> OJ C 136, 4.6.1985, p. 1.

<sup>(5)</sup> OJ L 204, 21.7.1998, p. 37.

<sup>(6)</sup> OJ L 11, 15.1.2002, p. 4.

<sup>(7)</sup> OJ L 218, 13.8.2008, p. 30.

- (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>(1)</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.

<sup>(1)</sup> OJ L 218, 13.8.2008, p. 82.

- (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>(1)</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>(2)</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>(3)</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>(4)</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>(5)</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>(6)</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>(7)</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.

<sup>(1)</sup> OJ L 396, 30.12.2006, p. 1.

<sup>(2)</sup> OJ L 338, 13.11.2004, p. 4.

<sup>(3)</sup> OJ L 37, 13.2.2003, p. 19.

<sup>(4)</sup> OJ L 37, 13.2.2003, p. 24.

<sup>(5)</sup> OJ L 114, 27.4.2006, p. 9.

<sup>(6)</sup> OJ L 365, 31.12.1994, p. 10.

<sup>(7)</sup> OJ L 266, 26.9.2006, p. 1.

- (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>(1)</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>(2)</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.

<sup>(1)</sup> OJ L 184, 17.7.1999, p. 23.

<sup>(2)</sup> OJ L 210, 7.8.1985, p. 29.

(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:

#### CHAPTER I

#### GENERAL PROVISIONS

##### Article 1

##### Subject-matter

This Directive lays down rules on the safety of toys and on their free movement in the Community.

##### Article 2

##### Scope

1. This Directive shall apply to products designed or intended, whether or not exclusively, for use in play by children under 14 years of age (hereinafter referred to as toys).

The products listed in Annex I shall not be considered as toys within the meaning of this Directive.

2. This Directive shall not apply to the following toys:

- (a) playground equipment intended for public use;
- (b) automatic playing machines, whether coin operated or not, intended for public use;
- (c) toy vehicles equipped with combustion engines;
- (d) toy steam engines; and
- (e) slings and catapults.

##### Article 3

##### Definitions

For the purposes of this Directive the following definitions shall apply:

1. 'making available on the market' means any supply of a toy for distribution, consumption or use on the Community

market in the course of a commercial activity, whether in return for payment or free of charge;

- 2. 'placing on the market' means the first making available of a toy on the Community market;
- 3. 'manufacturer' means any natural or legal person who manufactures a toy or has a toy designed or manufactured, and markets that toy under his name or trademark;
- 4. 'authorised representative' means any natural or legal person established within the Community who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;
- 5. 'importer' means any natural or legal person established within the Community who places a toy from a third country on the Community market;
- 6. 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a toy available on the market;
- 7. 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;
- 8. 'harmonised standard' means a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC on the basis of a request made by the Commission in accordance with Article 6 of that Directive;
- 9. 'Community harmonisation legislation' means any Community legislation harmonising the conditions for the marketing of products;
- 10. 'accreditation' shall have the meaning assigned to it by Regulation (EC) No 765/2008;
- 11. 'conformity assessment' means the process demonstrating whether specified requirements relating to a toy have been fulfilled;
- 12. 'conformity assessment body' means a body that performs conformity assessment activities, including calibration, testing, certification and inspection;
- 13. 'recall' means any measure aimed at achieving the return of a toy that has already been made available to the end user;
- 14. 'withdrawal' means any measure aimed at preventing a toy in the supply chain from being made available on the market;
- 15. 'market surveillance' means the activities carried out and measures taken by public authorities to ensure that toys comply with the applicable requirements set out in Community harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;

16. 'CE marking' means a marking by which the manufacturer indicates that the toy is in conformity with the applicable requirements set out in Community harmonisation legislation providing for its affixing;
17. 'functional product' means a product which performs and is used in the same way as a product, appliance or installation intended for use by adults, and which may be a scale model of such product, appliance or installation;
18. 'functional toy' means a toy which performs and is used in the same way as a product, appliance or installation intended for use by adults, and which may be a scale model of such product, appliance or installation;
19. 'aquatic toy' means a toy intended for use in shallow water which is capable of carrying or supporting a child on the water;
20. 'design speed' means representative potential operating speed that is determined by the design of the toy;
21. 'activity toy' means a toy for domestic use in which the support structure remains stationary while the activity is taking place and which is intended for the performance by a child of any of the following activities: climbing, jumping, swinging, sliding, rocking, spinning, crawling and creeping, or any combination thereof;
22. 'chemical toy' means a toy intended for the direct handling of chemical substances and mixtures and which is used in a manner appropriate to a given age-group and under the supervision of an adult;
23. 'olfactory board game' means a toy the purpose of which is to assist a child to learn to recognise different odours or flavours;
24. 'cosmetic kit' means a toy the purpose of which is to assist a child to learn to make products such as fragrances, soaps, creams, shampoos, bath foams, glosses, lipsticks, other make-up, tooth-paste and conditioners;
25. 'gustative game' means a toy the purpose of which is to allow children to make sweets or dishes which involve the use of food ingredients such as sweets, liquids, powders and aromas;
26. 'harm' means physical injury or any other damage to health, including long-term health effects;
27. 'hazard' means a potential source of harm;
28. 'risk' means the probable rate of occurrence of a hazard causing harm and the degree of severity of the harm;
29. 'intended for use by' means that a parent or supervisor shall reasonably be able to assume by virtue of the functions,

dimensions and characteristics of a toy that it is intended for use by children of the stated age group.

## CHAPTER II

### OBLIGATIONS OF ECONOMIC OPERATORS

#### Article 4

#### Obligations of manufacturers

1. When placing their toys on the market, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements set out in Article 10 and Annex II.

2. Manufacturers shall draw up the required technical documentation in accordance with Article 21 and carry out or have carried out the applicable conformity assessment procedure in accordance with Article 19.

Where compliance of a toy with the applicable requirements has been demonstrated by that procedure, manufacturers shall draw up an EC declaration of conformity, as referred to in Article 15, and affix the CE marking, as set out in Article 17(1).

3. Manufacturers shall keep the technical documentation and the EC declaration of conformity for a period of 10 years after the toy has been placed on the market.

4. Manufacturers shall ensure that procedures are in place for series production to remain in conformity. Changes in toy design or characteristics and changes in the harmonised standards by reference to which conformity of a toy is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by a toy, manufacturers shall, to protect the health and safety of consumers, carry out sample testing of marketed toys, investigate, and, if necessary, keep a register of complaints, of non-conforming toys and toy recalls, and shall keep distributors informed of any such monitoring.

5. Manufacturers shall ensure that their toys bear a type, batch, serial or model number or other element allowing their identification, or, where the size or nature of the toy does not allow it, that the required information is provided on the packaging or in a document accompanying the toy.

6. Manufacturers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the toy or, where that is not possible, on its packaging or in a document accompanying the toy. The address shall indicate a single point at which the manufacturer can be contacted.

7. Manufacturers shall ensure that the toy is accompanied by instructions and safety information in a language or languages easily understood by consumers, as determined by the Member State concerned.

8. Manufacturers who consider or have reason to believe that a toy which they have placed on the market is not in conformity with the relevant Community harmonisation legislation shall immediately take the corrective measures necessary to bring that toy into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the toy presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the toy available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

9. Manufacturers shall, further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the toy, in a language easily understood by that authority. They shall cooperate with that authority, at its request, as regards any action taken to eliminate the risks posed by toys which they have placed on the market.

#### Article 5

##### Authorised representatives

1. A manufacturer may, by a written mandate, appoint an authorised representative.

2. The obligations laid down in Article 4(1) and the drawing up of technical documentation shall not form part of the authorised representative's mandate.

3. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

- (a) keep the EC declaration of conformity and the technical documentation at the disposal of national surveillance authorities for a period of 10 years after the toy has been placed on the market;
- (b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of a toy;
- (c) cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by toys covered by the mandate.

#### Article 6

##### Obligations of importers

1. Importers shall place only compliant toys on the Community market.

2. Before placing a toy on the market, importers shall ensure that the appropriate conformity assessment procedure has been carried out by the manufacturer.

They shall ensure that the manufacturer has drawn up the technical documentation, that the toy bears the required conformity marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 4(5) and (6).

Where an importer considers or has reason to believe that a toy is not in conformity with the requirements set out in Article 10 and Annex II, it shall not place the toy on the market until the toy has been brought into conformity. Furthermore, where the toy presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3. Importers shall indicate their name, registered trade name or registered trade mark and the address at which they can be contacted on the toy or, where that is not possible, on its packaging or in a document accompanying the toy.

4. Importers shall ensure that the toy is accompanied by instructions and safety information in a language or languages easily understood by consumers, as determined by the Member State concerned.

5. Importers shall ensure that, while a toy is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in Article 10 and Annex II.

6. When deemed appropriate with regard to the risks presented by a toy, importers shall, to protect the health and safety of consumers, carry out sample testing of marketed toys, investigate, and, if necessary, keep a register of complaints, of non-conforming toys and toy recalls, and shall keep distributors informed of such monitoring.

7. Importers who consider or have reason to believe that a toy which they have placed on the market is not in conformity with the relevant Community harmonisation legislation shall immediately take the corrective measures necessary to bring that toy into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the toy presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the toy available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.



8. Importers shall, for a period of 10 years after the toy has been placed on the market, keep a copy of the EC declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

9. Importers shall, further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the toy in a language easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by toys which they have placed on the market.

#### Article 7

##### Obligations of distributors

1. When making a toy available on the market, distributors shall act with due care in relation to the applicable requirements.

2. Before making a toy available on the market, distributors shall verify that the toy bears the required conformity marking, that it is accompanied by the required documents and by instructions and safety information in a language or languages easily understood by consumers in the Member State in which the toy is to be made available on the market, and that the manufacturer and the importer have complied with the requirements set out in Article 4(5) and (6) and Article 6(3).

Where a distributor considers or has reason to believe that a toy is not in conformity with the requirements set out in Article 10 and Annex II, it shall not make the toy available on the market until the toy has been brought into conformity. Furthermore, where the toy presents a risk, the distributor shall inform the manufacturer or the importer, as well as the market surveillance authorities, to that effect.

3. Distributors shall ensure that, while a toy is under their responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in Article 10 and Annex II.

4. Distributors who consider or have reason to believe that a toy which they have made available on the market is not in conformity with the relevant Community harmonisation legislation shall make sure that the corrective measures necessary to bring that toy into conformity, to withdraw it or recall it, if appropriate, are taken. Furthermore, where the toy presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they made the toy available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.

5. Distributors shall, further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate

the conformity of the toy. They shall cooperate with that authority, at its request, as regards any action taken to eliminate the risks posed by toys which they have made available on the market.

#### Article 8

##### Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Directive and be subject to the obligations of the manufacturer under Article 4 where it places a toy on the market under its name or trademark or modifies a toy already placed on the market in such a way that compliance with the applicable requirements may be affected.

#### Article 9

##### Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance authorities:

- (a) any economic operator who has supplied them with a toy;
- (b) any economic operator to whom they have supplied a toy.

Economic operators shall be able to present the information referred to in the first paragraph for a period of 10 years after the toy has been placed on the market, in the case of the manufacturer, and for a period of 10 years after they have been supplied with the toy, in the case of other economic operators.

### CHAPTER III

#### CONFORMITY OF TOYS

##### Article 10

##### Essential safety requirements

1. Member States shall take all measures necessary to ensure that toys may not be placed on the market unless they comply with the essential safety requirements set out, as far as the general safety requirement is concerned, in paragraph 2, and, as far as the particular safety requirements are concerned, in Annex II.

2. Toys, including the chemicals they contain, shall not jeopardise the safety or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the behaviour of children.

The ability of the users and, where appropriate, their supervisors shall be taken into account, in particular, in the case of toys which are intended for use by children under 36 months or by other specified age groups.

Labels affixed in accordance with Article 11(2) and instructions for use which accompany toys shall draw the attention of users or their supervisors to the inherent hazards and risks of harm involved in using the toys, and to the ways of avoiding such hazards and risks.

3. Toys placed on the market shall comply with the essential safety requirements during their foreseeable and normal period of use.

#### Article 11

##### Warnings

1. Where appropriate for safe use, warnings made for the purposes of Article 10(2) shall specify appropriate user limitations in accordance with Part A of Annex V.

As regards the categories of toy listed in Part B of Annex V, the warnings set out therein shall be used. The warnings set out in points 2 to 10 of Part B of Annex V shall be used as worded therein.

Toys shall not bear one or more of the specific warnings set out in Part B of Annex V where that warning conflicts with the intended use of the toy, as determined by virtue of its function, dimension and characteristics.

2. The manufacturer shall mark the warnings in a clearly visible, easily legible and understandable and accurate manner on the toy, on an affixed label or on the packaging and, if appropriate, on the instructions for use which accompany the toy. Small toys which are sold without packaging shall have appropriate warnings affixed to them.

The warnings shall be preceded by the words 'Warning' or 'Warnings', as the case may be.

Warnings which determine the decision to purchase the toy, such as those specifying the minimum and maximum ages for users and the other applicable warnings set out in Annex V, shall appear on the consumer packaging or be otherwise clearly visible to the consumer before the purchase, including in cases where the purchase is made on-line.

3. In accordance with Article 4(7), a Member State may, within its territory, stipulate that those warnings and the safety instructions shall be written in a language or languages easily understood by consumers, as determined by that Member State.

#### Article 12

##### Free movement

Members States shall not impede the making available on the market in their territory of toys which comply with this Directive.

#### Article 13

##### Presumption of conformity

Toys which are in conformity with harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*, shall be presumed to be in conformity with the requirements covered by those standards or parts thereof set out in Article 10 and Annex II.

#### Article 14

##### Formal objection to a harmonised standard

1. When a Member State or the Commission considers that a harmonised standard does not entirely satisfy the requirements which it covers and which are set out in Article 10 and Annex II, the Commission or the Member State concerned shall bring the matter before the Committee set up by Article 5 of Directive 98/34/EC, giving its arguments. The Committee shall, having consulted the relevant European standardisation bodies, deliver its opinion without delay.

2. In the light of the Committee's opinion, the Commission shall decide to publish, not to publish, to publish with restriction, to maintain, to maintain with restriction or to withdraw the references to the harmonised standard concerned in or from the *Official Journal of the European Union*.

3. The Commission shall inform the European standardisation body concerned and, if necessary, request the revision of the harmonised standards concerned.

#### Article 15

##### EC declaration of conformity

1. The EC declaration of conformity shall state that the fulfilment of the requirements set out in Article 10 and Annex II has been demonstrated.

2. The EC declaration of conformity shall as a minimum contain the elements specified in Annex III to this Directive and the relevant modules set out in Annex II to Decision No 768/2008/EC and shall be continuously updated. It shall have the model structure set out in Annex III to this Directive. It shall be translated into the language or languages required by the Member State in whose market the toy is placed or made available.

3. By drawing up the EC declaration of conformity, the manufacturer shall assume responsibility for the compliance of the toy.

#### Article 16

##### General principles of the CE marking

1. Toys made available on the market shall bear the CE marking.

2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

3. Member States shall presume that toys bearing the CE marking comply with this Directive.

4. Toys not bearing a CE marking or which do not otherwise comply with this Directive may be shown and used at trade fairs and exhibitions, provided that they are accompanied by a sign which clearly indicates that they do not comply with this Directive and that they will not be made available in the Community before being brought into conformity.

#### Article 17

##### Rules and conditions for affixing the CE marking

1. The CE marking shall be affixed visibly, legibly and indelibly to the toy, to an affixed label or to the packaging. In the case of small toys and toys consisting of small parts, the CE marking may alternatively be affixed to a label or an accompanying leaflet. Where, in the case of toys sold in counter displays, that is not technically possible, and on condition that the counter display was originally used as packaging for the toy, the CE marking may be affixed to the counter display.

Where the CE marking is not visible from outside the packaging, if any, it shall as a minimum be affixed to the packaging.

2. The CE marking shall be affixed before the toy is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.

#### CHAPTER IV

##### CONFORMITY ASSESSMENT

#### Article 18

##### Safety assessments

Manufacturers shall, before placing a toy on the market, carry out an analysis of the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards that the toy may present, as well as an assessment of the potential exposure to such hazards.

#### Article 19

##### Applicable conformity assessment procedures

1. Before placing a toy on the market, manufacturers shall use the conformity assessment procedures referred to in paragraphs 2 and 3 to demonstrate that the toy complies with the requirements set out in Article 10 and Annex II.

2. If the manufacturer has applied harmonised standards, the reference number of which has been published in the *Official Journal of the European Union*, covering all relevant safety requirements for the toy, it shall use the internal production control procedure set out in Module A of Annex II to Decision No 768/2008/EC.

3. In the following cases, the toy shall be submitted to EC-type examination, as referred to in Article 20, together with the conformity to type procedure set out in Module C of Annex II to Decision No 768/2008/EC:

- (a) where harmonised standards, the reference number of which has been published in the *Official Journal of the European Union*, covering all relevant safety requirements for the toy, do not exist;
- (b) where the harmonised standards referred to in point (a) exist but the manufacturer has not applied them or has applied them only in part;
- (c) where one or more of the harmonised standards referred to in point (a) has been published with a restriction;
- (d) when the manufacturer considers that the nature, design, construction or purpose of the toy necessitate third party verification.

#### Article 20

##### EC-type examination

1. An application for EC-type examination, performance of that examination and issue of the EC-type examination certificate shall be carried out in accordance with the procedures set out in Module B of Annex II to Decision No 768/2008/EC.

EC-type examination shall be carried out in the manner specified in the second indent of point 2 of that Module.

In addition to those provisions, the requirements laid down in paragraphs 2 to 5 of this Article shall apply.

2. The application for an EC-type examination shall include a description of the toy and an indication of the place of manufacture, including the address.

3. When a conformity assessment body notified under Article 22 (hereinafter referred to as a 'notified body') carries out the EC-type examination, it shall evaluate, if necessary together with the manufacturer, the analysis of the hazards that the toy may present carried out by the manufacturer in accordance with Article 18.

4. The EC-type examination certificate shall include a reference to this Directive, a colour image, a clear description of the toy, including its dimensions, and a list of the tests performed, together with a reference to the relevant test report.

The EC-type examination certificate shall be reviewed whenever necessary, in particular in case of a change to the manufacturing process, the raw materials or the components of the toy, and, in any case, every five years.

The EC-type examination certificate shall be withdrawn if the toy fails to comply with the requirements set out in Article 10 and Annex II.

Member States shall ensure that their notified bodies do not grant an EC-type examination certificate for a toy in respect of which a certificate has been refused or withdrawn.

5. The technical documentation and correspondence relating to the EC-type examination procedures shall be drawn up in an official language of the Member State in which the notified body is established or in a language acceptable to that body.

#### Article 21

##### Technical documentation

1. The technical documentation referred to in Article 4(2) shall contain all relevant data or details of the means used by the manufacturer to ensure that toys comply with the requirements set out in Article 10 and Annex II. It shall, in particular, contain the documents listed in Annex IV.

2. The technical documentation shall be drawn up in one of the official languages of the Community, subject to the requirement set out in Article 20(5).

3. Following a reasoned request from the market surveillance authority of a Member State, the manufacturer shall provide a translation of the relevant parts of the technical documentation into the language of that Member State.

When a market surveillance authority requests the technical documentation or a translation of parts thereof from a manufacturer, it may fix a deadline for receipt of such file or translation, which shall be 30 days, unless a shorter deadline is justified in the case of serious and immediate risk.

4. If the manufacturer does not comply with the requirements of paragraphs 1, 2 and 3, the market surveillance authority may require it to have a test performed by a notified body at its own expense within a specified period in order to verify compliance with the harmonised standards and essential safety requirements.

#### CHAPTER V

##### NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

#### Article 22

##### Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under Article 20.

#### Article 23

##### Notifying authorities

1. Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies for the purposes of this Directive, and for the monitoring of notified bodies, including compliance with Article 29.

2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

3. Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 24(1) to (5). In addition, that body shall have arrangements to cover liabilities arising out of its activities.

4. The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

#### Article 24

##### Requirements relating to notifying authorities

1. Notifying authorities shall be established in such a way that no conflict of interest with a conformity assessment body occurs.

2. Notifying authorities shall be organised and operated so as to safeguard the objectivity and impartiality of their activities.

3. Notifying authorities shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4. Notifying authorities shall not offer or provide any activities that conformity assessment bodies perform, nor shall they offer or provide consultancy services on a commercial or competitive basis.

5. Notifying authorities shall safeguard the confidentiality of the information they obtain.

6. Notifying authorities shall have a sufficient number of competent personnel at their disposal for the proper performance of their tasks.



*Article 25***Information obligation of notifying authorities**

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

*Article 26***Requirements relating to notified bodies**

1. For the purposes of notification under this Directive, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2. Conformity assessment bodies shall be established under national law and shall have legal personality.

3. A conformity assessment body shall be a third-party body independent of the organisation or the toy it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of toys which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the toys which they assess, nor the authorised representative of any of those parties. This shall not preclude the use of assessed toys that are necessary for the operations of the conformity assessment body or the use of such toys for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design or manufacture, the marketing, installation, use or maintenance of those toys, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5. Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6. Conformity assessment bodies shall be capable of carrying out the conformity assessment tasks assigned to them by the provisions of Article 20 and in relation to which they have been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of toy in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

- (a) personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- (b) descriptions of procedures in accordance with which conformity assessment is carried out ensuring the transparency and ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;
- (c) procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the technology of the toy in question and the mass or serial nature of the production process.

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7. The personnel responsible for carrying out the conformity assessment activities shall have:

- (a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
- (b) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

(c) appropriate knowledge and understanding of the essential requirements, of the applicable harmonised standards and of the relevant Community harmonisation legislation and of its implementing regulations;

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8. The impartiality of conformity assessment bodies, their top level management and assessment personnel shall be ensured.

The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9. Conformity assessment bodies shall take out liability insurance unless liability is assumed by the Member State in accordance with its national law, or the Member State itself is directly responsible for the conformity assessment.

10. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Article 20 or any provision of national law giving effect to that Article, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11. Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under Article 38, and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

#### Article 27

##### **Presumption of conformity**

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*, it shall be presumed to comply with the requirements set out in Article 26 insofar as the applicable harmonised standards cover those requirements.

#### Article 28

##### **Formal objection to a harmonised standard**

Where a Member State or the Commission has a formal objection to the harmonised standards referred to in Article 27, Article 14 shall apply.

#### Article 29

##### **Subsidiaries of and subcontracting by notified bodies**

1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 26, and shall inform the notifying authority accordingly.

2. Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries, wherever these are established.

3. Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4. Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Article 20.

#### Article 30

##### **Application for notification**

1. A conformity assessment body shall submit an application for notification under this Directive to the notifying authority of the Member State in which it is established.

2. The application referred to in paragraph 1 shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the toy or toys for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 26.

3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 26.

#### Article 31

##### **Notification procedure**

1. Notifying authorities may only notify conformity assessment bodies which have satisfied the requirements laid down in Article 26.

2. Notifying authorities shall notify conformity assessment bodies to the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3. The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules, toy or toys concerned and the relevant attestation of competence.

4. Where a notification is not based on an accreditation certificate as referred to in Article 30(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 26.

5. The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of this Directive.

6. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

#### Article 32

##### Identification numbers and lists of notified bodies

1. The Commission shall assign an identification number to each notified body.

It shall assign a single identification number even where the same body is notified under several Community acts.

2. The Commission shall make publicly available a list of bodies notified under this Directive, including the identification numbers that have been allocated to them and the activities for which they have been notified.

The Commission shall ensure that the list is kept up to date.

#### Article 33

##### Changes to notifications

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 26, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2. In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available to the responsible notifying and market surveillance authorities, at their request.

#### Article 34

##### Challenge to the competence of notified bodies

1. The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2. The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned.

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including de-notification if necessary.

#### Article 35

##### Operational obligations of notified bodies

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedure provided for in Article 20.

2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the technology of the toy in question and the mass or serial nature of the production process.

In so doing, they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the toy with this Directive.

3. Where a notified body finds that the requirements set out in Article 10 and Annex II or in corresponding harmonised standards have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue the EC-type examination certificate as referred to in Article 20(4).

4. Where, in the course of the monitoring of conformity following the issue of a EC-type examination certificate, a notified body finds that a toy is no longer in compliance, it shall require the manufacturer to take appropriate corrective measures, and shall suspend or withdraw the EC-type examination certificate if necessary.

5. Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any EC-type examination certificates, as appropriate.

#### Article 36

##### Information obligation of notified bodies

1. Notified bodies shall inform the notifying authority of the following:

- (a) any refusal, restriction, suspension or withdrawal of an EC-type examination certificate;
- (b) any circumstances affecting the scope of and conditions for notification;
- (c) any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
- (d) on request, conformity assessment activities performed within the scope of their notification, and any other activity performed, including cross-border activities and subcontracting.

2. Notified bodies shall provide the other bodies notified under this Directive which carry out similar conformity assessment activities covering the same toys with relevant information on issues relating to negative and, on request, positive conformity assessment results.

#### Article 37

##### Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

#### Article 38

##### Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Directive are put in place and properly operated in the form of a sectoral group or groups of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that group or groups, directly or by means of designated representatives.

## CHAPTER VI

### OBLIGATIONS AND POWERS OF MEMBER STATES

#### Article 39

##### Precautionary principle

When competent authorities of the Member States take measures as provided for in this Directive, and in particular those referred to in Article 40, they shall take due account of the precautionary principle.

#### Article 40

##### General obligation to organise market surveillance

Member States shall organise and perform surveillance of toys placed on the market in accordance with Articles 15 to 29 of Regulation (EC) No 765/2008. In addition to those Articles, Article 41 of this Directive shall apply.

#### Article 41

##### Instructions to the notified body

1. Market surveillance authorities may request a notified body to provide information relating to any EC-type examination certificate which that body has issued or withdrawn, or which relates to any refusal to issue such a certificate, including the test reports and technical documentation.

2. If a market surveillance authority finds that a toy is not in conformity with the requirements set out in Article 10 and Annex II, it shall, where appropriate, instruct the notified body to withdraw the EC-type examination certificate in respect of that toy.

3. Where necessary, and in particular in the cases specified in the second subparagraph of Article 20(4), the market surveillance authority shall instruct the notified body to review the EC-type examination certificate.

#### Article 42

##### Procedure for dealing with toys presenting a risk at national level

1. Where the market surveillance authorities of one Member State have taken action pursuant to Article 20 of Regulation (EC) No 765/2008, or where they have sufficient reason to believe that a toy covered by this Directive presents a risk to the health or safety of persons, they shall carry out an evaluation in relation to the toy concerned covering all the requirements laid down in this Directive. The relevant economic operators shall cooperate as necessary with the market surveillance authorities.



Where, in the course of that evaluation, the market surveillance authorities find that the toy does not comply with the requirements laid down in this Directive, they shall without delay require the relevant economic operator to take appropriate corrective action to bring the toy into compliance with those requirements, to withdraw the toy from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred in the second subparagraph of this paragraph.

2. Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the relevant economic operator to take.

3. The relevant economic operator shall ensure that appropriate corrective action is taken in respect of toys which that operator has made available on the Community market.

4. Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take appropriate provisional measures to prohibit or restrict the toy being made available on their national market, to withdraw the toy from that market or to recall it.

They shall inform the Commission and the other Member States, without delay, of those measures.

5. The information referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant toy, the origin of the toy, the nature of the alleged non-compliance and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either:

- (a) failure of the toy to meet requirements relating to the health or safety of persons; or
- (b) shortcomings in the harmonised standards referred to in Article 13 conferring a presumption of conformity.

6. Member States other than the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the toy concerned, and, in the event of disagreement with the notified national measure, of their objections.

7. Where, within three months of receipt of the information referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed to be justified.

8. Member States shall ensure that appropriate restrictive measures are taken in respect of the toy concerned, such as withdrawal of the toy from their market, without delay.

#### Article 43

#### Community safeguard procedure

1. Where, on completion of the procedure set out in Article 42(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Community legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure.

On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

2. If the national measure is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant toy is withdrawn from their market, and shall inform the Commission accordingly.

If the national measure is considered unjustified, the Member State concerned shall withdraw it.

3. Where the national measure is considered to be justified and the non-compliance of the toy is attributed to shortcomings in the harmonised standards referred to in Article 42(5)(b), the Commission shall inform the relevant European standardisation body or bodies and shall bring the matter before the Committee set up by Article 5 of Directive 98/34/EC. That Committee shall consult the relevant European standardisation body or bodies and deliver its opinion without delay.

#### Article 44

#### Exchange of information — Community Rapid Information Exchange System

If a measure referred to in Article 42(4) is a type of measure which is required under Article 22 of Regulation (EC) No 765/2008 to be notified through the Community Rapid Information Exchange System, it shall not be necessary to make a separate notification under Article 42(4) of this Directive, provided that the following conditions are met:

- (a) the Community Rapid Information Exchange notification indicates that the notification of the measure is also required by this Directive;
- (b) the supporting evidence referred to in Article 42(5) is enclosed with the Community Rapid Information Exchange notification.

#### Article 45

##### Formal non-compliance

1. Without prejudice to Article 42, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:
  - (a) that the CE marking has been affixed in violation of Article 16 or 17;
  - (b) that the CE marking has not been affixed;
  - (c) that the EC declaration of conformity has not been drawn up;
  - (d) that the EC declaration of conformity has not been drawn up correctly;
  - (e) that technical documentation is either not available or not complete.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take appropriate measures to restrict or prohibit the toy being made available on the market, or shall ensure that it is recalled or withdrawn from the market.

#### CHAPTER VII

##### COMMITTEE PROCEDURES

#### Article 46

##### Amendments and implementing measures

1. The Commission may, for the purposes of adapting them to technical and scientific developments, amend the following:
  - (a) Annex I;
  - (b) points 11 and 13 of Part III of Annex II;
  - (c) Annex V.

Those measures, designed to amend non-essential elements of this Directive, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 47(2).

2. The Commission may adopt specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth, taking into account the packaging requirements for food as laid

down in Regulation (EC) No 1935/2004 and the related specific measures for particular materials, as well as the differences between toys and materials which come into contact with food. The Commission shall amend Appendix C to Annex II to this Directive accordingly. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 47(2) of this Directive.

3. The Commission may decide upon the use in toys of substances or mixtures that are classified as carcinogenic, mutagenic or toxic for reproduction of the categories laid down in Section 5 of Appendix B to Annex II and have been evaluated by the relevant Scientific Committee, and may amend Appendix A to Annex II accordingly. Those measures, designed to amend non-essential elements of this Directive by supplementing it, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 47(2).

#### Article 47

##### Committee procedure

1. The Commission shall be assisted by a committee.
2. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

#### CHAPTER VIII

##### SPECIFIC ADMINISTRATIVE PROVISIONS

#### Article 48

##### Reporting

By 20 July 2014 and every five years thereafter, Member States shall send the Commission a report on the application of this Directive.

That report shall contain an evaluation of the situation concerning the safety of toys and of the effectiveness of this Directive, as well as a presentation of the market surveillance activities performed by that Member State.

The Commission shall draw up and publish a summary of the national reports.

#### Article 49

##### Transparency and confidentiality

When the competent authorities of the Member States and the Commission adopt measures under this Directive, the requirements of transparency and confidentiality provided for in Article 16 of Directive 2001/95/EC shall apply.

*Article 50***Motivation of measures**

Any measure taken pursuant to this Directive to prohibit or restrict the placing on the market of a toy, to withdraw a toy or to recall a toy from the market shall state the exact grounds on which it is based.

Such a measure shall be notified without delay to the party concerned, which shall at the same time be informed of the remedies available to it under the laws in force in the Member State in question and of the time limits applicable to them.

*Article 51***Penalties**

Member States shall lay down rules on penalties for economic operators, which may include criminal sanctions for serious infringements, applicable to infringements of the national provisions adopted pursuant to this Directive, and shall take all measures necessary to ensure that they are implemented.

The penalties provided for shall be effective, proportionate and dissuasive and may be increased if the relevant economic operator has previously committed a similar infringement of this Directive.

The Member States shall notify the Commission of those rules by 20 July 2011, and shall notify it without delay of any subsequent amendment to them.

## CHAPTER IX

**FINAL AND TRANSITIONAL PROVISIONS***Article 52***Application of Directives 85/374/EEC and 2001/95/EC**

1. This Directive is without prejudice to Directive 85/374/EEC.
2. Directive 2001/95/EC shall apply to toys in accordance with Article 1(2) thereof.

*Article 53***Transitional periods**

1. Member States shall not impede the making available on the market of toys which are in accordance with Directive 88/378/EEC and which were placed on the market before 20 July 2011.
2. In addition to the requirement of paragraph 1, Member States shall not impede the making available on the market of toys which are in accordance with the requirements of this Directive, except those set out in Part III of Annex II, provided that such toys meet the requirements set out in Part

3 of Annex II to Directive 88/378/EEC and were placed on the market before 20 July 2013.

*Article 54***Transposition**

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 20 January 2011. They shall forthwith inform the Commission thereof.

They shall apply those measures with effect from 20 July 2011.

When Member States adopt those measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

Member States shall communicate to the Commission the provisions of national law which they adopt in the field covered by this Directive.

*Article 55***Repeal**

Directive 88/378/EEC, except Article 2(1) and Part 3 of Annex II, is repealed with effect from 20 July 2011. Article 2(1) thereof and Part 3 of Annex II thereto are repealed with effect from 20 July 2013.

References to the repealed Directive shall be construed as references to this Directive.

*Article 56***Entry into force**

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

*Article 57***Addressees**

This Directive is addressed to the Member States.

Done at Brussels, 18 June 2009.

*For the European Parliament*  
The President  
H.-G. PÖTTERING

*For the Council*  
The President  
Š. FÜLE

## ANNEX I

**List of products that, in particular, are not considered as toys within the meaning of this Directive**

(as referred to in Article 2(1))

1. Decorative objects for festivities and celebrations
2. Products for collectors, provided that the product or its packaging bears a visible and legible indication that it is intended for collectors of 14 years of age and above. Examples of this category are:
  - (a) detailed and faithful scale models;
  - (b) kits for the assembly of detailed scale models;
  - (c) folk dolls and decorative dolls and other similar articles;
  - (d) historical replicas of toys; and
  - (e) reproductions of real fire arms.
3. Sports equipment, including roller skates, inline skates, and skateboards intended for children with a body mass of more than 20 kg
4. Bicycles with a maximum saddle height of more than 435 mm, measured as the vertical distance from the ground to the top of the seat surface, with the seat in a horizontal position and with the seat pillar set to the minimum insertion mark
5. Scooters and other means of transport designed for sport or which are intended to be used for travel on public roads or public pathways
6. Electrically driven vehicles which are intended to be used for travel on public roads, public pathways, or the pavement thereof
7. Aquatic equipment intended to be used in deep water, and swimming learning devices for children, such as swim seats and swimming aids
8. Puzzles with more than 500 pieces
9. Guns and pistols using compressed gas, with the exception of water guns and water pistols, and bows for archery over 120 cm long
10. Fireworks, including percussion caps which are not specifically designed for toys
11. Products and games using sharp-pointed missiles, such as sets of darts with metallic points
12. Functional educational products, such as electric ovens, irons or other functional products operated at a nominal voltage exceeding 24 volts which are sold exclusively for teaching purposes under adult supervision
13. Products intended for use for educational purposes in schools and other pedagogical contexts under the surveillance of an adult instructor, such as science equipment
14. Electronic equipment, such as personal computers and game consoles, used to access interactive software and their associated peripherals, unless the electronic equipment or the associated peripherals are specifically designed for and targeted at children and have a play value on their own, such as specially designed personal computers, key boards, joy sticks or steering wheels
15. Interactive software, intended for leisure and entertainment, such as computer games, and their storage media, such as CDs
16. Babies' soothers
17. Child-appealing luminaires
18. Electrical transformers for toys
19. Fashion accessories for children which are not for use in play



## ANNEX II

## PARTICULAR SAFETY REQUIREMENTS

## I. Physical and Mechanical Properties

1. Toys and their parts and, in the case of fixed toys, their anchorages, must have the requisite mechanical strength and, where appropriate, stability to withstand the stresses to which they are subjected during use without breaking or becoming liable to distortion at the risk of causing physical injury.
2. Accessible edges, protrusions, cords, cables and fastenings on toys must be designed and manufactured in such a way that the risks of physical injury from contact with them are reduced as far as possible.
3. Toys must be designed and manufactured in such a way as not to present any risk or only the minimum risk inherent to their use which could be caused by the movement of their parts.
4.
  - (a) Toys and their parts must not present a risk of strangulation.
  - (b) Toys and their parts must not present a risk of asphyxiation by closing off the flow of air as a result of airway obstruction external to the mouth and nose.
  - (c) Toys and their parts must be of such dimensions as to not present a risk of asphyxiation by closing off the flow of air as a result of internal airway obstruction by objects wedged in the mouth or pharynx or lodged over the entrance to the lower airways.
  - (d) Toys, which are clearly intended for use by children under 36 months, and their component parts and any of their detachable parts must be of such dimensions as to prevent their being swallowed or inhaled. This also applies to other toys which are intended to be put in the mouth, and to their component parts and any of their detachable parts.
  - (e) The packaging in which toys are contained for retail sale must not present a risk of strangulation or asphyxiation caused by airway obstruction external to the mouth and nose.
  - (f) Toys contained within food or co-mingled with food must have their own packaging. This packaging, as it is supplied, must be of such dimensions as to prevent its being swallowed and/or inhaled.
  - (g) Toy packaging, as referred to in points (e) and (f), which is spherical, egg-shaped or ellipsoidal, and any detachable parts of this or of cylindrical toy packaging with rounded ends, must be of such dimensions as to prevent it from causing airway obstruction by being wedged in the mouth or pharynx or lodged over the entrance to the lower airways.
  - (h) Toys firmly attached to a food product at the moment of consumption, in such a way that the food product needs to be consumed in order to get direct access to the toy, shall be prohibited. Parts of toys otherwise directly attached to a food product shall fulfil the requirements set out in points (c) and (d).
5. Aquatic toys must be designed and manufactured so as to reduce as far as possible, taking into account the recommended use of the toy, any risk of loss of buoyancy of the toy and loss of support afforded to the child.
6. Toys which it is possible to get inside and which thereby constitute an enclosed space for occupants must have a means of exit which the intended user can open easily from the inside.
7. Toys conferring mobility on their users must, as far as possible, incorporate a braking system which is suited to the type of toy and is commensurate with the kinetic energy generated by it. Such a system must be easy for the user to operate without risk of ejection or physical injury for the user or for third parties.

The maximum design speed of electrically driven ride-on toys must be limited so as to minimise the risk of injury.

8. The form and composition of projectiles and the kinetic energy they may generate when fired from a toy designed for that purpose must be such that, taking into account the nature of the toy, there is no risk of physical injury to the user or to third parties.
9. Toys must be manufactured so as to ensure that:
  - (a) the maximum and minimum temperature of any accessible surfaces does not cause injury when touched; and
  - (b) liquids and gases contained within the toy do not reach temperatures or pressures which are such that their escape from the toy, other than for reasons essential to the proper functioning of the toy, might cause burns, scalds or other physical injury.
10. Toys which are designed to emit a sound shall be designed and manufactured in such a way in terms of the maximum values for impulse noise and continuous noise that the sound from them is not able to impair children's hearing.
11. Activity toys shall be manufactured so as to reduce the risk of crushing or trapping of body parts or trapping of clothing and of falls, impacts and drowning as far as possible. In particular, any surface of such a toy accessible for one or more children to play on shall be designed to bear their load.

## II. Flammability

1. Toys must not constitute a dangerous flammable element in the child's environment. They must therefore be composed of materials which fulfil one or more of the following conditions:
  - (a) they do not burn if directly exposed to a flame or spark or other potential source of fire;
  - (b) they are not readily flammable (the flame goes out as soon as the fire cause disappears);
  - (c) if they do ignite, they burn slowly and present a low rate of spread of the flame;
  - (d) irrespective of the toy's chemical composition, they are designed so as to mechanically delay the combustion process.

Such combustible materials must not constitute a risk of ignition for other materials used in the toy.
2. Toys which, for reasons essential to their functioning, contain substances or mixtures that meet the classification criteria laid down in Section 1 of Appendix B, in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, must not contain, as such, substances or mixtures which may become flammable due to the loss of non-flammable volatile components.
3. Toys other than toy percussion caps must not be explosive or contain elements or substances likely to explode when used as specified in the first subparagraph of Article 10(2).
4. Toys and, in particular, chemical games and toys, must not contain as such substances or mixtures:
  - (a) which, when mixed together, may explode through chemical reaction or through heating;
  - (b) which may explode when mixed with oxidizing substances; or
  - (c) which contain volatile components which are flammable in air and liable to form a flammable or explosive vapour/air mixture.

### III. Chemical Properties

1. Toys shall be designed and manufactured in such a way that there are no risks of adverse effects on human health due to exposure to the chemical substances or mixtures of which the toys are composed or which they contain when the toys are used as specified in the first subparagraph of Article 10(2).

Toys shall comply with the relevant Community legislation relating to certain categories of products or to restrictions for certain substances and mixtures.

2. Toys that are themselves substances or mixtures must comply also with Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances <sup>(1)</sup>, Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations <sup>(2)</sup> and 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 <sup>(3)</sup>, as applicable, relating to the classification, packaging and labelling of certain substances and mixtures.
3. Without prejudice to the restrictions referred to in the second paragraph of point 1, substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Regulation (EC) No 1272/2008 shall not be used in toys, in components of toys or in micro-structurally distinct parts of toys.
4. By way of derogation from point 3, substances or mixtures classified as CMR of the categories laid down in Section 3 of Appendix B may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that one or more of the following conditions is met:
  - (a) these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in Section 2 of Appendix B for the classification of mixtures containing these substances;
  - (b) these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in the first subparagraph of Article 10(2);
  - (c) a decision in accordance with Article 46(3) has been taken to permit the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in Appendix A.

That decision may be taken if the following conditions are met:

- (i) the use of the substance or mixture has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure;
- (ii) there are no suitable alternative substances or mixtures available, as documented in an analysis of alternatives; and
- (iii) the substance or mixture is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006.

The Commission shall mandate the relevant Scientific Committee to re-evaluate those substances or mixtures as soon as safety concerns arise and at the latest every five years from the date that a decision in accordance with Article 46(3) was taken.

5. By way of derogation from point 3, substances or mixtures classified as CMR of the categories laid down in Section 4 of Appendix B may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that one of the following conditions is met:
  - (a) these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in Section 2 of Appendix B for the classification of mixtures containing these substances;
  - (b) these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as specified in the first subparagraph of Article 10(2); or

<sup>(1)</sup> OJ 196, 16.8.1967, p. 1.

<sup>(2)</sup> OJ L 200, 30.7.1999, p. 1.

<sup>(3)</sup> OJ L 353, 31.12.2008, p. 1.

- (c) a decision in accordance with Article 46(3) has been taken to permit the substance or mixture and its use, and the substance or mixture and its permitted uses have been listed in Appendix A.

That decision may be taken if the following conditions are met:

- (i) the use of the substance or mixture has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure; and
- (ii) the substance or mixture is not prohibited for use in consumer articles under Regulation (EC) No 1907/2006.

The Commission shall mandate the relevant Scientific Committee to re-evaluate those substances or mixtures as soon as safety concerns arise and at the latest every five years from the date that a decision in accordance with Article 46(3) was taken.

6. Points 3, 4 and 5 shall not apply to nickel in stainless steel.
7. Points 3, 4 and 5 shall not apply to materials that comply with the specific limit values set out in Appendix C, or, until such provisions have been laid down, but not later than 20 July 2017, to materials covered by and complying with the provisions for food contact materials set out in Regulation (EC) No 1935/2004 and the related specific measures for particular materials.
8. Without prejudice to the application of points 3 and 4, nitrosamines and nitrosable substances shall be prohibited for use in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth if the migration of the substances is equal to or higher than 0,05 mg/kg for nitrosamines and 1 mg/kg for nitrosable substances.
9. The Commission shall systematically and regularly evaluate the occurrence of hazardous substances of materials in toys. These evaluations shall take into account reports of market surveillance bodies and concerns expressed by Member States and stakeholders.
10. Cosmetic toys, such as play cosmetics for dolls, shall comply with the compositional and labelling requirements laid down in Council Directive 76/768/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to cosmetic products <sup>(1)</sup>.
11. Toys shall not contain the following allergenic fragrances:

No	Name of the allergenic fragrance	CAS number
(1)	Alanroot oil ( <i>Inula helenium</i> )	97676-35-2
(2)	Allylthiocyanate	57-06-7
(3)	Benzyl cyanide	140-29-4
(4)	4 tert-Butylphenol	98-54-4
(5)	Chenopodium oil	8006-99-3
(6)	Cyclamen alcohol	4756-19-8
(7)	Diethyl maleate	141-05-9
(8)	Dihydrocoumarin	119-84-6
(9)	2,4-Dihydroxy-3-methylbenzaldehyde	6248-20-0

<sup>(1)</sup> OJ L 262, 27.9.1976, p. 169.



No	Name of the allergenic fragrance	CAS number
(10)	3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol)	40607-48-5
(11)	4,6-Dimethyl-8-tert-butylcoumarin	17874-34-9
(12)	Dimethyl citraconate	617-54-9
(13)	7,11-Dimethyl-4.6,10-dodecatrien-3-one	26651-96-7
(14)	6,10-Dimethyl-3.5,9-undecatrien-2-one	141-10-6
(15)	Diphenylamine	122-39-4
(16)	Ethyl acrylate	140-88-5
(17)	Fig leaf, fresh and preparations	68916-52-9
(18)	trans-2-Heptenal	18829-55-5
(19)	trans-2-Hexenal diethyl acetal	67746-30-9
(20)	trans-2-Hexenal dimethyl acetal	18318-83-7
(21)	Hydroabietyl alcohol	13393-93-6
(22)	4-Ethoxy-phenol	622-62-8
(23)	6-Isopropyl-2-decahydronaphthalenol	34131-99-2
(24)	7-Methoxycoumarin	531-59-9
(25)	4-Methoxyphenol	150-76-5
(26)	4-(p-Methoxyphenyl)-3-butene-2-one	943-88-4
(27)	1-(p-Methoxyphenyl)-1-penten-3-one	104-27-8
(28)	Methyl trans-2-butenolate	623-43-8
(29)	6-Methylcoumarin	92-48-8
(30)	7-Methylcoumarin	2445-83-2
(31)	5-Methyl-2,3-hexanedione	13706-86-0
(32)	Costus root oil (Saussurea lappa Clarke)	8023-88-9
(33)	7-Ethoxy-4-methylcoumarin	87-05-8
(34)	Hexahydrocoumarin	700-82-3
(35)	Peru balsam, crude (Exudation of Myroxylon pereirae (Royle) Klotzsch)	8007-00-9
(36)	2-Pentylidene-cyclohexanone	25677-40-1
(37)	3.6,10-Trimethyl-3.5,9-undecatrien-2-one	1117-41-5
(38)	Verbena oil (Lippia citriodora Kunth)	8024-12-2
(39)	Musk ambrette (4-tert-Butyl-3-methoxy-2,6-dinitrotoluene)	83-66-9
(40)	4-Phenyl-3-buten-2-one	122-57-6

No	Name of the allergenic fragrance	CAS number
(41)	Amyl cinnamal	122-40-7
(42)	Amylcinnamyl alcohol	101-85-9
(43)	Benzyl alcohol	100-51-6
(44)	Benzyl salicylate	118-58-1
(45)	Cinnamyl alcohol	104-54-1
(46)	Cinnamal	104-55-2
(47)	Citral	5392-40-5
(48)	Coumarin	91-64-5
(49)	Eugenol	97-53-0
(50)	Geraniol	106-24-1
(51)	Hydroxy-citronellal	107-75-5
(52)	Hydroxy-methylpentylcyclohexenecarboxaldehyde	31906-04-4
(53)	Isoeugenol	97-54-1
(54)	Oakmoss extracts	90028-68-5
(55)	Treemoss extracts	90028-67-4

However, the presence of traces of these fragrances shall be allowed provided that such presence is technically unavoidable under good manufacturing practice and does not exceed 100 mg/kg.

In addition, the names of the following allergenic fragrances shall be listed on the toy, on an affixed label, on the packaging or in an accompanying leaflet, if added to a toy, as such, at concentrations exceeding 100 mg/kg in the toy or components thereof:

No	Name of the allergenic fragrance	CAS number
(1)	Anisyl alcohol	105-13-5
(2)	Benzyl benzoate	120-51-4
(3)	Benzyl cinnamate	103-41-3
(4)	Citronellol	106-22-9
(5)	Farnesol	4602-84-0
(6)	Hexyl cinnamaldehyde	101-86-0
(7)	Lilial	80-54-6
(8)	d-Limonene	5989-27-5
(9)	Linalool	78-70-6
(10)	Methyl heptine carbonate	111-12-6
(11)	3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one	127-51-5

12. The use of the fragrances set out in points 41 to 55 of the list set out in the first paragraph of point 11 and of the fragrances set out in points 1 to 11 of the list set out in the third paragraph of that point shall be allowed in olfactory board games, cosmetic kits and gustative games, provided that:

- (i) those fragrances are clearly labelled on the packaging, and the packaging contains the warning set out in point 10 of Part B of Annex V;
- (ii) if applicable, the resulting products made by the child in accordance with the instructions comply with the requirements of Directive 76/768/EEC; and
- (iii) if applicable, those fragrances comply with the relevant legislation on food.

Such olfactory board games, cosmetic kits and gustative games shall not be used by children under 36 months and shall comply with point 1 of Part B of Annex V.

13. Without prejudice to points 3, 4 and 5, the following migration limits, from toys or components of toys, shall not be exceeded:

Element	mg/kg in dry, brittle, powder-like or pliable toy material	mg/kg in liquid or sticky toy material	mg/kg in scraped-off toy material
Aluminium	5 625	1 406	70 000
Antimony	45	11,3	560
Arsenic	3,8	0,9	47
Barium	4 500	1 125	56 000
Boron	1 200	300	15 000
Cadmium	1,9	0,5	23
Chromium (III)	37,5	9,4	460
Chromium (VI)	0,02	0,005	0,2
Cobalt	10,5	2,6	130
Copper	622,5	156	7 700
Lead	13,5	3,4	160
Manganese	1 200	300	15 000
Mercury	7,5	1,9	94
Nickel	75	18,8	930
Selenium	37,5	9,4	460
Strontium	4 500	1 125	56 000
Tin	15 000	3 750	180 000
Organic tin	0,9	0,2	12
Zinc	3 750	938	46 000

These limit values shall not apply to toys or components of toys which, due to their accessibility, function, volume or mass, clearly exclude any hazard due to sucking, licking, swallowing or prolonged contact with skin when used as specified in the first subparagraph of Article 10(2).

#### IV. Electrical Properties

1. Toys shall not be powered by electricity of a nominal voltage exceeding 24 volts direct current (DC) or the equivalent alternating current (AC) voltage, and their accessible parts shall not exceed 24 volts DC or the equivalent AC voltage.

Internal voltages shall not exceed 24 volts DC or the equivalent AC voltage unless it is ensured that the voltage and the current combination generated do not lead to any risk or harmful electric shock, even when the toy is broken.

2. Parts of toys which are connected to, or liable to come into contact with, a source of electricity capable of causing electric shock, together with the cables or other conductors through which electricity is conveyed to such parts, must be properly insulated and mechanically protected so as to prevent the risk of such shock.
3. Electric toys must be designed and manufactured in such a way as to ensure that the maximum temperatures reached by all directly accessible surfaces are not such as to cause burns when touched.
4. Under foreseeable fault conditions, toys must provide protection against electrical hazards arising from an electrical power source.
5. Electric toys must provide adequate protection against fire hazards.
6. Electric toys must be designed and manufactured in such a way that electric, magnetic and electromagnetic fields and other radiations generated by the equipment are limited to the extent necessary for the operation of the toy, and must operate at a safe level in compliance with the generally acknowledged state of the art, taking account of specific Community measures.
7. Toys which have an electronic control system must be designed and manufactured in such a way that the toy operates safely even when the electronic system starts malfunctioning or fails due to failure of the system itself or an outside factor.
8. Toys must be designed and manufactured in such a way that they do not present any health hazards or risk of injury to eyes or skin from lasers, light-emitting diodes (LEDs) or any other type of radiation.
9. The electrical transformer of a toy shall not be an integral part of the toy.

#### V. Hygiene

1. Toys must be designed and manufactured in such a way as to meet hygiene and cleanliness requirements in order to avoid any risk of infection, sickness or contamination.
2. A toy intended for use by children under 36 months must be designed and manufactured in such a way that it can be cleaned. A textile toy shall, to this end, be washable, except if it contains a mechanism that may be damaged if soak washed. The toy shall fulfil the safety requirements also after having been cleaned in accordance with this point and the manufacturer's instructions.

#### VI. Radioactivity

Toys shall comply with all relevant measures adopted under Chapter III of the Treaty establishing the European Atomic Community.

*Appendix A***List of CMR substances and their permitted uses in accordance with points 4, 5 and 6 of Part III**

Substance	Classification	Permitted use
Nickel	CMR 2	In stainless steel



## Appendix B

**CLASSIFICATION OF SUBSTANCES AND MIXTURES**

As a result of the timing of the application of Regulation (EC) No 1272/2008, there are equivalent ways of referring to a given classification that should be used at different points in time.

**1. Criteria for classifying substances and mixtures for the purposes of point 2 of Part II**

A. Criteria to be applied from 20 July 2011 until 31 May 2015:

*Substances*

The substance fulfils the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:

- (a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;
- (b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;
- (c) hazard class 4.1;
- (d) hazard class 5.1.

*Mixtures*

The mixture is dangerous within the meaning of Directive 67/548/EEC.

B. Criteria to be applied from 1 June 2015:

The substance or mixture fulfils the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:

- (a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;
- (b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;
- (c) hazard class 4.1;
- (d) hazard class 5.1.

**2. Community legal acts governing the use of certain substances for the purposes of points 4(a) and 5(a) of Part III**

From 20 July 2011 until 31 May 2015, the relevant concentrations for the classification of mixtures containing the substances shall be those established in accordance with Directive 1999/45/EC.

From 1 June 2015, the relevant concentrations for the classification of mixtures containing the substances shall be those established in accordance with Regulation (EC) No 1272/2008.

**3. Categories of substances and mixtures classified as carcinogenic, mutagenic or toxic for reproduction (CMR) for the purposes of point 4 of Part III***Substances*

Point 4 of Part III concerns substances classified as CMR category 1A and 1B under Regulation (EC) No 1272/2008.

*Mixtures*

From 20 July 2011 until 31 May 2015, point 4 of Part III concerns mixtures classified as CMR category 1 and 2 under Directive 1999/45/EC and Directive 67/548/EEC as applicable.

From 1 June 2015, point 4 of Part III concerns mixtures classified as CMR category 1A and 1B under Regulation (EC) No 1272/2008.

**4. Categories of substances and mixtures classified as carcinogenic, mutagenic or toxic for reproduction (CMR) for the purposes of point 5 of Part III**

*Substances*

Point 5 of Part III concerns substances classified as CMR category 2 under Regulation (EC) No 1272/2008.

*Mixtures*

From 20 July 2011 until 31 May 2015, point 5 of Part III concerns mixtures classified as CMR category 3 under Directive 1999/45/EC and Directive 67/548/EEC as applicable.

From 1 June 2015, point 5 of Part III concerns mixtures classified as CMR category 2 under Regulation (EC) No 1272/2008.

**5. Categories of substances and mixtures classified as carcinogenic, mutagenic or toxic for reproduction (CMR) for the purposes of Article 46(3)**

*Substances*

Article 46(3) concerns substances classified as CMR category 1A, 1B and 2 under Regulation (EC) No 1272/2008.

*Mixtures*

From 20 July 2011 until 31 May 2015, Article 46(3) concerns mixtures classified as CMR category 1, 2, 1999 and 3 under Directive 1999/45/EC and Directive 67/548/EEC as applicable.

From 1 June 2015, Article 46(3) concerns mixtures classified as CMR category 1A, 1B and 2 under Regulation (EC) No 1272/2008.

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*Appendix C*

**Specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth adopted in accordance with Article 46(2)**

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## ANNEX III

**EC DECLARATION OF CONFORMITY**

1. No ... (unique identification of the toy(s))
2. Name and address of the manufacturer or his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer:
4. Object of the declaration (identification of toy allowing traceability). It shall include a colour image of sufficient clarity to enable the identification of the toy.
5. The object of the declaration described in point 4 is in conformity with the relevant Community harmonisation legislation:
6. References to the relevant harmonised standards used, or references to the specifications in relation to which conformity is declared:
7. Where applicable: the notified body ... (name, number) ... performed ... (description of intervention) ... and issued the certificate:
8. Additional information:

Signed for and on behalf of:

(place and date of issue)

(name, function)(signature)

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## ANNEX IV

**TECHNICAL DOCUMENTATION**

The technical documentation referred to in Article 21 shall contain, in particular, so far as relevant for assessment:

- (a) a detailed description of the design and manufacture, including a list of components and materials used in the toy as well as the safety data sheets on chemicals used, to be obtained from the chemical suppliers;
  - (b) the safety assessment(s) carried out in accordance with Article 18;
  - (c) a description of the conformity assessment procedure followed;
  - (d) a copy of the EC declaration of conformity;
  - (e) the addresses of the places of manufacture and storage;
  - (f) copies of documents that the manufacturer has submitted to a notified body, if involved;
  - (g) test reports and description of the means whereby the manufacturer ensured conformity of production with the harmonised standards, if the manufacturer followed the internal production control procedure referred to in Article 19(2); and
  - (h) a copy of the EC-type examination certificate, a description of the means whereby the manufacturer ensured conformity of the production with the product type as described in the EC-type examination certificate, and copies of the documents that the manufacturer submitted to the notified body, if the manufacturer submitted the toy to EC-type examination and followed the conformity to type procedure referred to in Article 19(3).
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## ANNEX V

**WARNINGS**

(as referred to in Article 11)

## PART A

**GENERAL WARNINGS**

The user limitations referred to in Article 11(1) shall include at least the minimum or maximum age of the user and, where appropriate, the abilities of the user, the maximum or minimum weight of the user and the need to ensure that the toy is used only under adult supervision.

## PART B

**SPECIFIC WARNINGS AND INDICATIONS OF PRECAUTIONS TO BE TAKEN WHEN USING CERTAIN CATEGORIES OF TOYS****1. Toys not intended for use by children under 36 months**

Toys which might be dangerous for children under 36 months of age shall bear a warning such as 'Not suitable for children under 36 months' or 'Not suitable for children under three years' or a warning in the form of the following graphic:



These warnings shall be accompanied by a brief indication, which may appear in the instructions for use, of the specific hazard calling for this precaution.

This point shall not apply to toys which, on account of their function, dimensions, characteristics or properties, or on other cogent grounds, are manifestly unsuitable for children under 36 months.

**2. Activity toys**

Activity toys shall bear the following warning:

'Only for domestic use'.

Activity toys attached to a crossbeam as well as other activity toys, where appropriate, shall be accompanied by instructions drawing attention to the need to carry out checks and maintenance of the main parts (suspensions, fixings, anchorages, etc.) at intervals, and pointing out that, if these checks are not carried out, the toy may cause a fall or overturn.

Instructions must also be given as to the correct assembly of the toy, indicating those parts which can present a danger if incorrectly assembled. Specific information regarding a suitable surface on which to place the toy shall be given.

**3. Functional toys**

Functional toys shall bear the following warning:

'To be used under the direct supervision of an adult'.

In addition, these toys shall be accompanied by directions giving working instructions as well as the precautions to be taken by the user, with the warning that failure to take these precautions will expose the user to the hazards – to be specified – normally associated with the appliance or product of which the toy is a scale model or imitation. It shall also be indicated that the toy must be kept out of the reach of children under a certain age, which shall be specified by the manufacturer.

#### 4. Chemical toys

Without prejudice to the application of the provisions laid down in applicable Community legislation on the classification, packaging and labelling of certain substances or mixtures, the instructions for use of toys containing inherently dangerous substances or mixtures shall bear a warning of the dangerous nature of these substances or mixtures and an indication of the precautions to be taken by the user in order to avoid hazards associated with them, which shall be specified concisely according to the type of toy. The first aid to be given in the event of serious accidents resulting from the use of this type of toy shall also be mentioned. It shall also be stated that the toy must be kept out of reach of children under a certain age, which shall be specified by the manufacturer.

In addition to the instructions provided for in the first subparagraph, chemical toys shall bear the following warning on their packaging:

'Not suitable for children under (\*) years. For use under adult supervision'.

In particular, the following are regarded as chemical toys: chemistry sets, plastic embedding sets, miniature workshops for ceramics, enamelling or photography and similar toys which lead to a chemical reaction or similar substance alteration during use.

#### 5. Skates, roller skates, inline skates, skateboards, scooters and toy bicycles for children

Where these toys are offered for sale as toys, they shall bear the following warning:

'Protective equipment should be worn. Not to be used in traffic'.

Moreover, the instructions for use shall contain a reminder that the toy must be used with caution, since it requires great skill, so as to avoid falls or collisions causing injury to the user or third parties. Some indication shall also be given as to recommended protective equipment (helmets, gloves, knee-pads, elbow-pads, etc.).

#### 6. Aquatic toys

Aquatic toys shall bear the following warning:

'Only to be used in water in which the child is within its depth and under adult supervision'.

#### 7. Toys in food

Toys contained in food or co-mingled with food shall bear the following warning:

'Toy inside. Adult supervision recommended'.

#### 8. Imitations of protective masks and helmets

Imitations of protective masks and helmets shall bear the following warning:

'This toy does not provide protection'.

#### 9. Toys intended to be strung across a cradle, cot or perambulator by means of strings, cords, elastics or straps

Toys intended to be strung across a cradle, cot or perambulator by means of strings, cords, elastics or straps shall carry the following warning on the packaging, which shall also be permanently marked on the toy:

'To prevent possible injury by entanglement, remove this toy when the child starts trying to get up on its hands and knees in a crawling position'.

(\*) Age to be specified by the manufacturer.

**10. Packaging for fragrances in olfactory board games, cosmetic kits and gustative games**

Packaging for fragrances in olfactory board games, cosmetic kits and gustative games that contain the fragrances set out in points 41 to 55 of the list set out in the first paragraph of point 11 of Part III of Annex II and of the fragrances set out in points 1 to 11 of the list set out in third paragraph of that point shall contain the following warning:

'Contains fragrances that may cause allergies'.

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