

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)

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;

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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.

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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.

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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.

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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.

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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

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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.

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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.

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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.

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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

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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.

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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.

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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