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**PROPOSAL**

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from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
dated:	28 January 2008
Subject:	Proposal for a Directive of the European Parliament and of the Council on the safety of toys

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Delegations will find attached a proposal from the Commission, submitted under a covering letter from Secretary-General of the European Commission to Mr Javier SOLANA, Secretary-General/High Representative.

Encl.: COM(2008) 9 final



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 25.1.2008

COM(2008) 9 final

2008/0018 (COD)

Proposal for a

**DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on the safety of toys**

(presented by the Commission)

{SEC(2008)38}

{SEC(2008)39}

## **EXPLANATORY MEMORANDUM**

### **1. CONTEXT OF THE PROPOSAL**

#### **General context**

The revision of Directive 88/378/EEC of 3 May 1988 on the approximation of the laws of the Member States concerning the safety of toys<sup>1</sup> (TSD) was announced in the Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions - Updating and simplifying the Community *acquis*.<sup>2</sup>

Directive 88/378/EEC was adopted in the context of the achievement of the Internal Market. The proliferation of different safety provisions across the Member States had led to barriers to trade and marketing. This went hand in hand with the recognition that a proliferation of different national safety regimes across the EU did not necessarily afford consumers in the EU, especially children, with effective protection against hazards arising from toys. The Directive was the first EC Directive applying the New Approach method – introduced in 1985 – to mass market consumer goods. The key New Approach concept consisted in laying down in the legislation the essential safety related requirements, leaving the technical specifications of products meeting the essential requirements in harmonised standards. Since 1988, the Directive has been amended only once in respect of the CE marking<sup>3</sup>.

Whilst the TSD has in general proven successful in providing safe products and eliminating trade barriers between the Member States, a number of deficiencies have been identified over time, which have triggered the need to assess the existing legal framework.

A thorough revision of the TSD seems appropriate, with a view to:

- Updating and completing the existing provisions to address safety issues that were unknown at the time of the TSD adoption;
- Improving the implementation and enforcement of the TSD throughout the European Union;
- Clarifying the scope and concepts of the Directive;
- Ensuring consistency with the general measures that have been tabled in the general legislative framework for the marketing of goods<sup>4</sup>.

#### **Consistency with other policies and objectives of the Union**

The proposal is a central element to ensure the free movement of toys within the European Union and contributes to the protection of the consumer by providing at the same time a uniform level of toy safety across the EU.

The objectives pursued by the revision are in line with the EU's strategy for jobs and growth and also fit into the Community policy of better regulation and simplification. The overall goal is to improve the quality and efficiency of the toys safety regulations and to simplify the current legislation for both economic operators and market surveillance authorities.

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

<sup>2</sup> COM/2003/0071 final.

<sup>3</sup> Council Directive 93/68/EEC of 22 July 1993, OJ L 220, 30.8.1993, p.1.

<sup>4</sup> Proposal for a Regulation on accreditation and market surveillance; COM(2007)37 final of 14/02/2007. Proposal for a Decision on a common framework for the marketing of goods; COM (2007) 53 final of 14/02/2007.

## **2. CONSULTATION OF INTERESTED PARTIES AND IMPACT ASSESSMENT**

### **Consultation of interested parties**

The revision has been under consideration since 2003 and has been the subject of a wide ranging consultation, namely in the framework of the Expert Group on toys safety with the Member States authorities and other stakeholders like industry, consumer- and standardisation organisations.

A public consultation was organised in May 2007 to invite all interested parties to send their observations on those questions which have been identified as potential objects for changes in the Expert Group discussions. The results of the public consultation are published at [http://ec.europa.eu/enterprise/toys/public\\_consultation.htm](http://ec.europa.eu/enterprise/toys/public_consultation.htm). More than 1500 replies were received: 91 percent responded as an individual and 9 percent on behalf of an organisation, institution or enterprise.

The public consultation confirmed the need to revise the Directive and, in particular, to improve its enforcement and implementation and to clarify its scope and concepts. There was also an agreement to update the essential safety requirements on certain hazards. Although the vast majority of reactions came from respondents qualifying themselves as individuals, because of the nature and or the focus of the comments it could be assumed that a part of these individual replies originates from individuals who are to various degrees involved in the toys business (distributors, retailers, company managers, etc.).

### **Collection and use of expertise**

Three studies have been established by independent consultants for the purposes of this revision: one general impact assessment study as well one specific impact assessment study on the revision of the chemical requirements as well as a specific study on certain chemicals used in toys to provide elements for the revision of the chemicals requirements of the Directive. The studies are available at: [http://ec.europa.eu.enterprise/toys/index\\_en.htm](http://ec.europa.eu.enterprise/toys/index_en.htm).

### **Impact assessment**

Five options for a revision have been identified:

- Repealing of Directive 88/378/EEC;
- No Commission action, i.e. maintaining the status quo;
- Non-regulatory approach; guidance documents; recommendations;
- A new Directive based on the “Old Approach”;
- A revised Directive to the extent necessary to ensure that safe toys can circulate in the EU internal market.

The fifth option was identified as the preferred option because it seems adequate and proportionate to cope with the identified problems without requiring a fundamental change of the system that has proved workable. Option 5 keeps an adequate balance between on the one hand new (compliance and administrative) costs for the industry concerned and on the other hand benefits for children’s health and safety.

Within the option to adapt the Directive to the extent necessary, a number of sub-options with various degrees of stringency have been identified and assessed in detail:

- To enhance safety requirements for toys
  - New provisions on the chemical requirements;

- More stringent requirements on warnings;
- Changes to the requirements concerning the choking risk;
- Clarifying the suffocation risk;
- Clarifying the criteria of essential safety requirements;
- Special requirements for toys in food;
- To improve the enforcement and efficiency of the Directive
- Changes to the technical file as regards information on chemicals;
- Changes to the CE marking and traceability information;
- Changes to the conformity assessment procedures.

The Commission has carried out a detailed impact assessment listed in the Work Programme.

### 3. LEGAL ELEMENTS OF THE PROPOSAL

#### Main elements of the revision

#### 3.1. Enhanced safety requirements

##### 3.1.1. Chemical substances used in toys

The revision focuses on enhanced safety requirements for toys, namely with regard to the use of chemicals in toys. The revision also aims at updating requirements on electrical properties and in physical and mechanical areas, as choking risks and suffocation.

As regards chemicals in toys, the Directive foresees that toys must comply with Community's general chemicals legislation, including Regulation EC No 1907/2006 (REACH).

Main novelty of the revision is the introduction of specific rules on **CMR** (carcinogenic, mutagenic, or toxic for reproduction) in toys. The proposal foresees that toys and components of toys or micro-structurally distinct parts of toys that are accessible to children shall not contain CMR of categories 1, 2 and 3<sup>5</sup>. This ban applies to CMR with a concentration above 0,1%, with the exception of some CMR substances for which a lower concentration is already foreseen in existing legislation. The proposal, however, provides for a possibility of granting an exemption from this ban, if the substance has been evaluated by the relevant Scientific Committee and found acceptable for use in toys, while for CMR 1 and 2 no suitable alternative substances must be available at the same time.

It is important to note that REACH imposes a duty on suppliers of articles containing substances, in particular CMRs 1 or 2, to communicate sufficient information to allow safe use of the article. These provisions are unaffected by the revision of the toys directive and so will continue to apply to toys

The Directive prohibits the use or requires the labelling of certain **allergenic substances and certain fragrances**. This approach also follows the regime of Directive 76/768/EEC on cosmetic products.

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<sup>5</sup> Substances CMR substances are categorised into categories 1, 2 and 3 based on the degree of evidence of their carcinogenic, mutagenic or reprotoxic properties. Category 1: "Substances known to be carcinogenic to man"; Category 2: "Substances which should be regarded as if they are carcinogenic to man"; Category 3: "Substances which cause concern for man owing to possible carcinogenic effects but in respect of which the available information is not adequate for making a satisfactory assessment".

In order to take into account new scientific knowledge, the Directive provides for an update of **certain chemical substances** to be used in toys and raises the limit values for these substances. The proposal replaces the reference to bioavailability (i.e. the soluble extract having toxicological significance) with “migration” in line with the Standard EN 71-3.

### 3.1.2. *Warnings*

According to the existing Directive toys must be accompanied by clearly legible warnings in order to reduce inherent risks of their use. The revision foresees to complement these provisions by requiring that warnings specify, where appropriate for safe use, user limitations such as minimum and maximum ages for users or the ability of the user of toys or maximum or minimum weight of the users as well as the need to ensure that the toy is used under adult supervision. It is furthermore proposed to require warnings at the point of sale specifying minimum and maximum ages for users. The new measures are meant to improve their effectiveness in the prevention of accident. More detailed practical instructions on warnings will be established in a guidance document to be drawn up together with the various stakeholders and Member States authorities taking into account developments of scientific and technical knowledge.

### 3.1.3. *Choking and suffocation risks*

The risk of choking, that is the risk of inhalation of small parts, is currently regulated in respect of toys intended for children under 36 months. The revised Directive foresees to extend the provisions to those toys that are intended to be put in the mouth, such as toy instruments, even when destined to children above 36 months.

The suffocation risk, defined as an *external* airway obstruction of the mouth and nose, is already covered by the current Directive. The proposed new measures provide for extending the definition in question to *internal* airway obstruction, to deal with the risk presented by new toys such as those with suction cups. The suffocation risk shall be covered in case of all toys and not only for those intended for children under 36 months.

### 3.1.4. *Toys in food*

Under the current Directive there are no specific provisions for toys in food. These products need to respect the general requirements of the Directive for small parts and for warnings. It is appropriate to proceed to an assessment of the hazard inherent in toys in food on the basis of the precautionary principle<sup>6</sup>. The Directive foresees the new requirement that i) toys should be marketed in a package separating them from the food items they are attached to, ii) the packaging itself should not present any choking hazard (namely that it passes the safety ‘small parts cylinder test’) and iii) to ban toys that are firmly coupled with foodstuffs in such a way that prior consumption of the food item is necessary to access to the toy itself.

### 3.1.5. *Definition of the general safety requirement*

The current safety requirements have created problems of interpretation, in particular because the general safety requirement refers to the obligation to cover “foreseeable” use of a toy taking into account the “normal behaviour of children”, which may result in a narrow consideration of safety issues.

Clarifying the general safety requirement is essential because it is the only legal basis for taking dangerous toys out of the market in cases where a new risk is discovered, that is, a risk which has previously not been known and which is therefore, not covered by specific

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<sup>6</sup> Commission Communication COM (2000) 1, 1.2.2000.

standards. A recent example of such risk which was previously not known and which is not yet covered by standards is the risk presented by certain powerful magnets.

It is, therefore, foreseen to refer in the general safety requirement to "behaviour" of children to ensure that the often unpredictable behaviour of children is taken into account when designing toys with a view to achieve greater safety benefits.

### **3.2. More efficient and coherent enforcement of the Directive**

#### *3.2.1. Reinforcement of the Member States market surveillance measures*

The proposal reinforces in Chapter VI the market surveillance obligations of the Member States under the General Product Safety Directive 2001/95/EC by granting certain specific powers to the market surveillance authorities (right of access to the premises of economic operators, right to request information from Notified bodies, right to give instructions to the Notified bodies, right to obtain mutual assistance from other Member States). It also foresees an obligation for the Member States to ensure a cooperation of their market surveillance authorities and those of the other Member States and between their own authorities and the Commission and the relevant Community Agencies.

#### *3.2.2. Information on chemicals in the technical file*

The proposal contains an update of the documentation which toy manufacturers and importers have to keep available for inspection by the market surveillance. It has been assessed which information besides a detailed description of the design and manufacture of the toy should be kept in the technical documentation. It is proposed that the technical file needs to contain information on components and materials used in toys.

#### *3.2.3. CE marking and its affixing*

The Directive takes into account the detailed rules on the CE-marking foreseen in the general legislative framework for the marketing of products.

In addition, the revision retains the provision of the existing Directive that the CE marking shall be marked either on the toy or the packaging or in case of small toys on a label or accompanying leaflet. It adds one novelty: the CE marking shall always be affixed on the packaging if the marking on the toy is not visible from outside the packaging. This provision which adds more visibility to the CE-marking is foreseen to facilitate market surveillance.

#### *3.2.4. Safety assessment*

A new obligation will be introduced to perform an analysis of the hazards that the toy may present, and to make it available - as part of the toy's technical file - to the market surveillance authorities for inspection. This new provision is designed to provide a reliable and systematic basis for the analysis of risk, which industry already performs as part of the process involved in the design and marketing of new products, with a view to evaluating their soundness and ensuring conformity with the essential safety requirements.

### **3.3. Alignment to the general legislative framework on the marketing of products**

On 14 February 2007, the Commission adopted its proposals for a Council and European Parliament Regulation and Decision for the marketing of goods<sup>7</sup>. The proposal for Regulation sets the requirements for accreditation and market surveillance relating to the marketing of products. The proposed Decision on a common framework for the marketing of products sets standard Articles to be used in future New Approach Directives.

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<sup>7</sup> See footnote 4.

According to the Commission proposal, the requirements of the Regulation for accreditation of conformity assessment bodies and the rules on market surveillance will apply also to the accreditation in the toys sector and to the market surveillance of toys at external frontiers. In order to ensure consistency with other sectoral product legislation, the revised Directive contains the following horizontal provisions of the above mentioned Decision: definitions, general obligations for economic operators, presumption of conformity, formal objection against harmonised standards, rules for the CE marking, requirements for conformity assessment bodies and the notification procedures as well as the provisions concerning procedures dealing with products presenting a risk. The conformity assessment procedures available to the manufacturer are also set by reference to the proposed horizontal Decision. Experience has shown that the two procedures (internal production control and EC type-examination combined with the conformity to type procedure) available under Directive 88/378/EEC and the conditions of their use are appropriate for the toy sector and should therefore be maintained.

### **3.4. Clarifying scope and concepts of the Directive**

In order to facilitate the application of the Directive by manufacturers and national authorities the scope of the Directive is 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. In addition to adopting the harmonised definitions laid down in the proposed standard Articles, it is appropriate to foresee certain new definitions specific to the toys sector: Functional toy, activity toy, trampoline, hazard, risk, harm, suffocation and design speed.

The proposal also aims at clarifying the relationship between the Toys Directive and the General Product Safety Directive. The General Product Safety Directive applies in accordance with its Article 1 (2) to toys in so far as there are no specific provisions with the same objective in the Toys Directive. For the sake of clarity and legal certainty the toys proposal enumerates the Articles of the Directive 2001/95/EC that apply to toys.

#### **Legal basis**

The proposal is based on Article 95 of the EC-Treaty.

#### **Subsidiarity principle**

Directive 88 /378/EEC is a total harmonisation directive adopted on the basis of Article 95 of the Treaty with the objective of the establishment and functioning of the internal market for toys. National legislation cannot impose additional provisions on the safety of toys which would require the modification of the product or affect the conditions for its placing on the market. Therefore, the revision of provisions of Directive 88/378/EEC is, as far as the safety requirements for toys or the conditions of their placing on the market are concerned, within the exclusive competence of the Community. The application of the principle of subsidiarity within the meaning of Article 5, second paragraph, of the EC-Treaty does not arise.

It is important to note that the revision aims at clarifying the scope of products covered by the Directive, but not at extending or changing it otherwise. Therefore the issue of subsidiarity within the meaning of Article 5, second paragraph, of the EC-Treaty does not arise in this respect either.

The respect of the subsidiarity principle, therefore, only arises with regard to the other areas of the revision, namely with regard to the improvement of effective enforcement of the Directive. Experience has shown that coherent and effective enforcement and market surveillance has not been sufficiently achieved by Member States acting alone. As a consequence, the issue of setting some mandatory common minimum requirements arises. As



a result of the proposal, this activity would remain within the authority of the national authorities but some general EU-wide requirements would be introduced to ensure equal treatment, a level playing field for economic operators, and a similar level of protection for the citizens in all the Member States.

### **Proportionality**

In accordance with the principle of proportionality, the proposed modifications do not go beyond what is necessary to achieve the objectives set. In order to protect the benefits of the single market in the toys sector, any changes to the existing directive have to be dealt with at the Community level. If Member States acted on their own, there would be a proliferation of safety requirements which would hamper and undermine the achievements of the single market, and very likely lead to confusion for consumers and producers alike. The consequences could be higher prices for consumers, as producers would have to revert to abiding by member state specific requirements, while there would be a lack of clarity regarding the safety of toys bought in another Member State.

All modifications of the Directive do not impose unnecessary burden and costs on industry, especially on small and medium sized enterprises, or administrations. A number of options concern the improvement of clarity of the existing Directive without introducing significant new requirements with cost implication. Where modifications have more significant impacts, the analysis of the impacts of the option serves to provide the most proportionate response to the problems identified.

## **4. BUDGETARY IMPLICATIONS**

The proposal foresees establishment of a Regulatory committee. Budgetary implications are discussed in the legislative financial statement annexed to this proposal.

## **5. ADDITIONAL INFORMATION**

### **Repeal of existing legislation**

The adoption of the proposal will lead to repeal of Directive 88/378/EEC on the safety of toys.

### **European Economic Area**

The proposal concerns the EEA and should therefore extended to the European Economic Area.

Proposal for a

**DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**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<sup>8</sup>,

Having regard to the opinion of the European Economic and Social Committee<sup>9</sup>,

Having regard to the opinion of the Committee of the Regions<sup>10</sup>,

Acting in accordance with the procedure laid down in Article 251 of the Treaty<sup>11</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>12</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. Thus, it sets out only the essential safety requirements with regard to toys, while 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<sup>13</sup>. Conformity with harmonised standards so set, the reference number of which is published in the *Official Journal of the European Union*, provides presumption of conformity to 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

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<sup>8</sup> OJ C [...], [...], p. [...].

<sup>9</sup> OJ C [...], [...], p. [...].

<sup>10</sup> OJ C [...], [...], p. [...].

<sup>11</sup> OJ C [...], [...], p. [...].

<sup>12</sup> OJ L 187, 16.7.1988, p. 1. Directive as amended by Directive 93/68/EEC (OJ L 220, 30.8.1993, p. 1).

<sup>13</sup> OJ L 204, 21.7.1998, p. 37.

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.

- (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>14</sup>, which applies in a complementary manner to specific sectoral legislation, and in particular are subject to the Community Rapid Information System (RAPEX) foreseen in that Directive.
- (5) Decision [...] of the European Parliament and of the Council of [...] on a common framework for the marketing of products<sup>15</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 for economic operators, presumption of conformity, formal objection against harmonised standards, rules for the CE marking, requirements for conformity assessment bodies and the notification procedures as well as the provisions concerning procedures dealing with products presenting a risk should be aligned to that Decision.
- (6) In order to facilitate the application of this Directive by manufacturers and national authorities, its scope 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.
- (7) 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.
- (8) All economic operators intervening in the supply and distribution chain should take the appropriate measures to ensure that they make available on the market only toys which are in conformity with the applicable legislation. This Directive provides a clear and proportionate distribution of obligations which correspond to the respective role of each operator in the supply and distribution process.
- (9) As certain tasks can only be executed by the manufacturer, it is necessary to clearly distinguish between the manufacturer and the operators further down the distribution chain. It is furthermore necessary to clearly distinguish the importer and the distributor, as the importer introduces toys from third countries on the Community market. He has thus to ensure that these toys comply with the applicable Community requirements.
- (10) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the complete conformity assessment procedure for toys. Importers and distributors perform a trading function and do not have any influence on the production process. The conformity assessment should therefore remain the obligation of the manufacturer alone.
- (11) Since importers and distributors are downstream operators they cannot in the normal course of events be obliged to ensure themselves that the design and production of the

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<sup>14</sup> OJ L 11, 15.1.2002, p. 4.

<sup>15</sup> OJ L [...], [...], p. [...].

toy is in compliance with the applicable requirements. Their obligations in relation to the compliance of the toy should be limited to certain control measures to ascertain whether the manufacturer has fulfilled his obligations, such as verifying whether the toys bears the required conformity marking and whether the required documents have been supplied. However, it can be expected of both importers and distributors to act with due care in relation to the applicable requirements when placing or making available products on the market.

- (12) Where an importer or a distributor either places a toy on the market under his own name or trademark or modifies a toy in such a way that compliance with applicable requirements may be affected, he should be considered to be the manufacturer.
- (13) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by national authorities, and should be prepared to participate actively, providing the competent authorities with all necessary information relating to the toy concerned.
- (14) Ensuring traceability of a toy throughout the whole supply chain contributes to rendering market surveillance simpler and more efficient. An efficient traceability system facilitates the task of market surveillance authorities to trace the economic operator responsible for supplying non-compliant toys.
- (15) 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.
- (16) In order to ensure protection of children against recently discovered risks, it is also necessary to adopt new essential safety requirements. In particular, it is necessary to complete and update provisions on chemical substances in toys. These provisions should specify that toys should comply with the 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), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC<sup>16</sup>. These provisions should, however, also be adapted to the particular needs of children, who are a vulnerable group of consumers. Therefore, new restrictions on substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) according to 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>17</sup> and fragrances in toys should be provided for on account of the special risks that these substances may entail for human health. The specific limit values laid down in Directive 88/378/EEC for certain substances should be updated to take into account of the development of scientific knowledge.

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<sup>16</sup> OJ L 396, 30.12.2006, p. 1. Regulation as amended by Council Regulation (EC) No 1354/2007 (OJ L 304, 22.11.2007, p. 1).

<sup>17</sup> OJ 196, 16.8.1967, p. 1. Directive as last amended by Directive 2006/121/EC of the European Parliament and of the Council (OJ L 396, 30.12.2006, p. 850).

- (17) The general and specific chemical requirements in this Directive should aim at protecting the health of children from dangerous substances in toys, while environmental concerns presented by toys are addressed in horizontal environmental legislation applying also to toys, in particular in Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 on waste<sup>18</sup>, 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>19</sup>, in Directive 2002/96/EC of the European Parliament and of the Council of 27 January 2003 on waste electrical and electronic equipment<sup>20</sup>, in Directive 94/62/EC of the European Parliament and of the Council of 20 December 1994 on packaging and packaging waste<sup>21</sup> and in Directive 2006/66/EC of the European Parliament and of the Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC<sup>22</sup>.
- (18) It is appropriate to lay down specific safety requirements to cover the potential specific hazard presented by toys inside food in line with the precautionary principle, 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 measures at Community level.
- (19) Since toys may exist or be developed which present hazards which are not covered by a particular safety requirement laid down in this Directive, it is necessary to set a general requirement of safety as the legal base for taking action against such toys. In this respect safety of toys should be determined by reference to the intended use of the product while taking into account the foreseeable use, bearing in mind behaviour of children, who do not generally show the same degree of care as the average adult user.
- (20) In order to further promote safe conditions for use of toys, there is a need to supplement the provisions on warnings which should accompany the toy.
- (21) The CE marking, materialising conformity of a toy, is the visible consequence of a whole process comprising conformity assessment in a broad sense. General principles governing the use of the CE marking, and rules as to its affixing should therefore be set in this Directive.
- (22) 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 product is in conformity with all applicable requirements and that he takes full responsibility thereof.
- (23) It is appropriate to lay down rules on the affixing of CE-marking which ensure enough visibility for the marking in order to facilitate market surveillance of toys.
- (24) In order to ensure that the essential requirements are complied with 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 assessment of the various hazards that the toy may present and an assessment of the potential exposure to them should be included in this Directive, and the manufacturers should be obliged

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<sup>18</sup> OJ L 114, 27.4.2006, p. 9.

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

<sup>20</sup> OJ L 37, 13.2.2003, p. 24.

<sup>21</sup> OJ L 365, 31.12.1994, p. 10.

<sup>22</sup> OJ L 266, 26.9.2006, p. 1.

to keep this safety assessment in the technical file to allow market surveillance authorities to perform efficiently their tasks. Internal production control based on the manufacturer's own responsibility for the conformity assessment has proven adequate in cases where he 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 a third party verification (EC type examination). The same should apply if such standards or one of them has been published with a restriction in the *Official Journal of the European Union*, or the manufacturer has not followed such standards completely or in part. The manufacturer should submit the toy to the EC-type-examination in cases where he considers that the nature, design, construction or purpose of the toys necessitates third party verification.

- (25) Since it is necessary to ensure throughout the Community a uniform level of performance of bodies performing conformity assessment of toys and since all such bodies should perform their functions to the same level and under conditions of fair competition, requirements should be set for conformity assessment bodies seeking to be notified for the purposes of this Directive. Provision should also be made for the provision of adequate information about such bodies and for their monitoring.
- (26) In order to ensure a coherent level of quality in the performance of conformity assessment of toys, it is also necessary to make provision about the requirements to be fulfilled by the authorities responsible for notifying conformity assessment bodies to the Commission and the other Member States.
- (27) Market surveillance of toys in the Member States is subject to the provisions of Directive 2001/95/EC. In order to ensure a satisfactory level of market surveillance in all Member States, the provisions on market surveillance measures laid down in Directive 2001/95/EC should, however, be enhanced and certain other obligations and powers should be added to those already existing.
- (28) Directive 88/378/EEC already provides for a safeguard procedure allowing the Commission to examine the justification of a measure taken by a Member States 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 clause procedure, with the aim of making it more efficient and of drawing on expertise available in Member States.
- (29) The existing system should be complemented by a procedure allowing interested parties to be informed of measures intended with regard to toys presenting a risk for the health and safety of persons or for other issues of public interest protection. It also allows market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such products.
- (30) In a case in which Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required.
- (31) 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>23</sup>.

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<sup>23</sup> OJ L184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L200, 22/7/2006, p.11).

- (32) In particular power should be conferred on the Commission in order to adapt the chemical requirements in certain well defined cases and 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 toys. Since those measures are of general scope and are designed to amend non-essential elements of this Directive and/ or to supplement this Directive by the addition of 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.
- (33) Member States should provide for penalties applicable to infringements of the provisions of this Directive. Those penalties should be effective, proportionate and dissuasive.
- (34) Since the objectives of the proposed action, namely to ensure a high level of safety of toys 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 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 this Article, this Directive does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS DIRECTIVE:

## ***CHAPTER I***

### **GENERAL PROVISIONS**

#### *Article 1*

##### *Subject-matter and scope*

1. This Directive lays down rules on the safety, and the free movement in the Community, of products designed or intended, whether or not exclusively, for use in play by children under 14 years of age, hereinafter "toys".  
  
The products listed in Annex I shall not be considered 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;
  - (e) slings and catapults.

#### *Article 2*

##### *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 designs and manufactures a toy or who has such a toy designed or manufactured, under his name or trademark;
- (4) "distributor" means any natural or legal person in the supply chain, who makes a toy available on the market;
- (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) "economic operators" means the manufacturer, the importer, the distributor and the authorised representative;
- (7) "harmonised standard" means a standard adopted by one of the European standardisation bodies listed in Annex I to Directive 98/34/EC of the European Parliament and of the Council in accordance with Article 6 of Directive 98/34/EC;
- (8) "accreditation" has the meaning assigned to it by Regulation (EC) No [...] of the European Parliament and of the Council of [...] setting out the requirements for accreditation and market surveillance relating to the marketing of products<sup>24</sup>;
- (9) "withdrawal" means any measure aimed at preventing the making available on the market of a toy in the supply chain;
- (10) "recall" means any measure aimed at achieving the return of a toy that has already been made available to the end user;
- (11) "activity toy" means a toy which is intended for domestic use and designed to bear the weight of one or more children, excluding ride-on vehicles, and is intended for children to play on or in, such as swings, slides, carousels, climbing frames, trampolines, paddling pools and non aquatic inflatable toys;
- (12) "suffocation" means the result of airway obstruction external to the mouth and nose or internal airway obstruction by closing off the flow of air from the mouth and nose by objects wedged in the mouth or pharynx or lodged over the entrance to the lower airways.
- (13) "harm" means the physical injury or damage to health;
- (14) "hazard" means a potential source of harm;
- (15) "risk" means the probable rate of occurrence of a hazard causing harm and the degree of severity of the harm.

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<sup>24</sup>

OJ L [...], [...], p. [...].



## **CHAPTER II**

### **OBLIGATIONS OF ECONOMIC OPERATORS**

#### *Article 3*

#### *Obligations of manufacturers*

1. Manufacturers shall ensure that their toys are designed and manufactured in accordance with the essential safety requirements set out in Article 9 and in Annex II.
2. Manufacturers shall draw up technical documentation in accordance with Article 20 and carry out or have carried out the conformity assessment procedure applicable in accordance with Article 18.

Where the compliance of the toy with the applicable requirements has been demonstrated by such procedure, manufacturers shall draw up an EC declaration of conformity, as referred to in Article 14 and affix the conformity marking set out in Article 16 (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 to ensure the continued conformity of series production. Changes in the product design or characteristics and changes in the harmonised standards by reference to which conformity of a toy is stated shall be adequately taken into account.

Manufacturers shall, in all cases where appropriate, carry out sample testing of marketed toys, investigating, and, if necessary, keeping a register of complaints, and keeping distributors informed of such monitoring.

5. Manufacturers shall ensure that their toys bear a type, batch or serial or model number or any 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 and the address at which they can be contacted on the toy or, where the size or nature of the toy does not allow it, on its packaging or in a document accompanying the toy.
7. Manufacturers who consider or have reason to believe that a toy which they have placed on the market is not in conformity with the applicable Community legislation shall take the necessary corrective measures to bring that toy into conformity or withdraw it from the market and recall it from end users, if appropriate. They shall immediately inform the national authorities of the Member States where they made the toy available to this effect, giving details, in particular, of the non-compliance and of the corrective measures taken.
8. Manufacturers shall, on request from the competent national authorities, provide them with all the information and documentation necessary to demonstrate the conformity of the toy. They shall cooperate with those authorities, at the request of the latter, on any action to avoid the risks posed by toys which they have placed on the market.

*Article 4*  
*Authorised representatives*

1. Manufacturers may appoint, by a written mandate, any natural or legal person established within the Community, ("the authorised representative"), to act on their behalf for specified tasks with regard to the obligations of manufacturers under this Directive.
2. The obligations under Article 3 (1) and the drawing up of technical documentation may not form part of the authorised representative's mandate.
3. Where a manufacturer has appointed an authorised representative, the latter shall at least do 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;
  - (b) on request from the competent national authorities, provide them with all the information and documentation necessary to demonstrate the conformity of the toy;
  - (c) cooperate with the competent authorities, at the request of the latter, on any action to avoid the risks posed by toys covered by their mandate.

*Article 5*  
*Obligations of Importers*

1. When placing a toy on the market, importers shall act with due care in relation to the applicable requirements.
2. Before placing a toy on the market importers shall verify that the appropriate conformity assessment procedure has been carried out by the manufacturer.

They shall verify that the manufacturer has drawn up the technical documentation, that the toy bears the required conformity marking(s), is accompanied by the required documents and that the manufacturer has respected the requirements set out in Article 3 (5) and (6).

Where an importer discovers that the toy is not in conformity with the essential safety requirements set out in Article 9 and in Annex II, he may place the toy on the market only after it has been brought into conformity with those requirements.
3. Importers shall indicate their name and the address at which they can be contacted on the toy or, where the size or nature of the toy does not allow it, on its packaging or in a document accompanying the toy.
4. 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 9 and in Annex II.
5. Importers who consider or have reason to believe that a toy which they have placed on the market is not in conformity with the applicable Community legislation shall take the necessary corrective measures to bring that toy into conformity or withdraw it from the market and recall it from end users, if appropriate. They shall immediately inform the national authorities of the Member States where they made the toy available to this effect, giving details, in particular, of the non-compliance and of the corrective measures taken.

6. Importers shall, for a period of 10 years, 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.
7. Importers shall, on request from the competent national authorities, provide them with all the information and documentation necessary to demonstrate the conformity of the toy. They shall cooperate with those authorities, at the request of the latter, on any action to avoid the risks posed by toys which they have placed on the market.

#### *Article 6* *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(s) and is accompanied by the required documents and that the manufacturer and the importer have complied with the requirements set out in Article 3 (5) and (6) and Article 5 (3) respectively.

Where a distributor discovers that a toy is not in conformity with the essential safety requirements set out in Article 9 and in Annex II, he may make the toy available on the market only after it has been brought into conformity with those requirements. The distributor shall inform the manufacturer or the importer to this effect.

3. A distributor shall ensure that, while a toy is under his responsibility, storage or transport conditions do not jeopardise its compliance with the requirements set out in Article 9 and in 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 applicable Community legislation shall take the necessary corrective measures to bring that toy in conformity or withdraw it from the market and recall it from end users, if appropriate. They shall immediately inform the national authorities of the Member States where they made the toy available to this effect, giving details, in particular, of the non-compliance and of the corrective measures taken.
5. Distributors shall, on request from the competent national authorities, provide them with all the information and documentation necessary to demonstrate the conformity of the toy. They shall cooperate with those authorities, at the request of the latter, on any action to avoid the risks posed by toys which they have made available on the market.

#### *Article 7* *Cases in which obligations of manufacturers apply to importers and distributors*

An importer or distributor who places a toy on the market under his name or trademark shall be subject to the obligations of the manufacturer under Article 3.

An importer or a distributor, who modifies a toy in such a way that compliance with the essential safety requirements set out in Article 9 and in Annex II may be affected, shall be subject to the obligations of the manufacturer under Article 3 in respect of these modifications.

*Article 8*  
*Identification of economic operators*

Economic operators shall be able to identify the following:

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

They shall have in place appropriate systems and procedures which allow for this information to be made available to the market surveillance authorities on request, for a period of 10 years.

**CHAPTER III**  
**CONFORMITY OF THE TOY**

*Article 9*  
*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 shall not jeopardize the safety or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind 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, by virtue of their functions, dimensions and characteristics, are intended for use by children of under 36 months.

Labels on toys or on their packaging and the instructions for use which accompany them shall draw the attention of users or their supervisors to the inherent hazards and risks of harms involved in using the toys and to the ways of avoiding them.

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

*Article 10*  
*Warnings*

1. Where appropriate for safe use, warnings made for the purposes of Article 9 (2) shall specify appropriate user limitations, in accordance with Part A of Annex V.

As regards the categories of toys listed in Part B of Annex V, the warnings set out therein shall be used.

2. The manufacturer shall mark the warnings in a visible, clearly legible 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 that are sold without packaging shall have appropriate warnings affixed to them.

Warnings specifying the minimum and maximum ages for users shall be visible, legible and conspicuously displayed at the point of sale.

3. Member States may require warnings and safety instructions, or some of them, to be presented in their own official language or languages when the toys are placed on the market in their territory.

*Article 11*  
*Free movement*

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

*Article 12*  
*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 9 and in Annex II.

*Article 13*  
*Formal objection against harmonised standards*

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 9 and in 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, hereinafter the "Committee", giving its arguments. The Committee shall 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 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 14*  
*EC declaration of conformity*

1. The EC declaration of conformity shall state that the fulfilment of the requirements specified in Article 9 and in Annex II has been demonstrated.
2. The EC declaration of conformity shall as a minimum contain the elements specified in Annex III and shall continuously be updated. The EC declaration of conformity shall have the model structure set out in Annex III.
3. By drawing up the EC declaration of conformity, the manufacturer shall assume the responsibility for the compliance of the toy.

*Article 15*  
*General principles of the CE marking*

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

2. The CE marking may only be affixed by the manufacturer or his authorised representative.

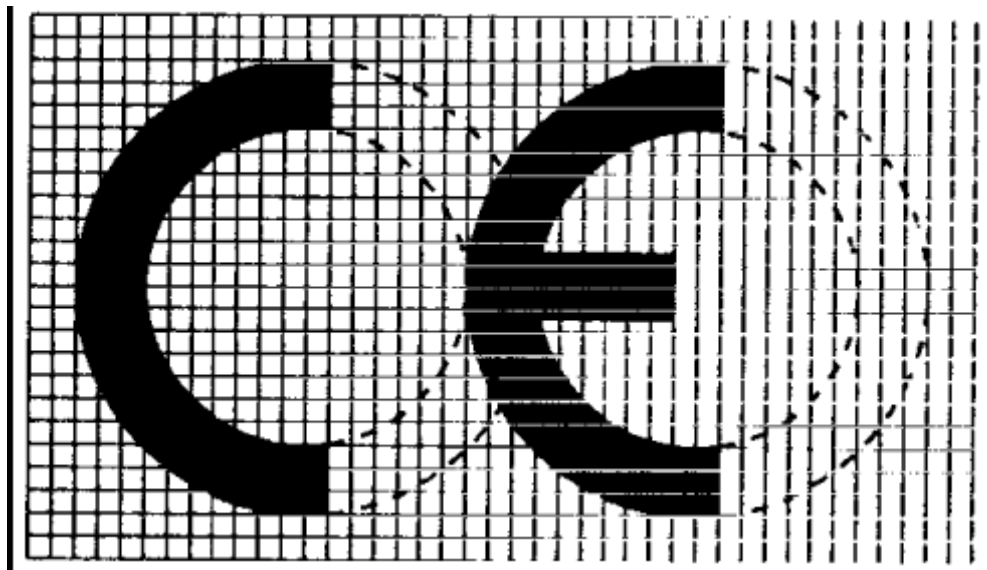
By affixing or having affixed the CE marking the manufacturer shall assume the responsibility for the conformity of the toy with the requirements laid down in this Directive.

3. Member States shall presume that toys bearing the CE marking comply with the provisions of this Directive.
4. The CE marking shall be the only marking which attests conformity of the toy with the applicable requirements.
5. Member States shall refrain from introducing into their national regulations, or shall withdraw any reference to, a conformity marking other than the CE marking in connection with conformity to the provisions of this Directive.
6. The affixing on a toy of markings, signs and inscriptions which are likely to mislead third parties as to the meaning or form of the CE marking, or both, shall be prohibited. Any other marking may be affixed to the toy provided that the visibility, legibility and meaning of the CE marking are not thereby impaired.
7. Toys not bearing a CE-marking and which do not comply with the provisions of this Directive may feature in trade fairs and exhibitions, provided that they are accompanied by a sign which clearly indicates that the toys do not comply with the requirements of this Directive and are not for sale or for distribution free of charge.

#### *Article 16*

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

1. The CE marking shall consist of the initials “CE” taking the following form:



2. If the CE marking is reduced or enlarged the proportions given in the graduated drawing in paragraph 1 must be respected.
3. Where specific legislation does not impose specific dimensions, the CE marking shall have a height of at least 5 mm.
4. The CE marking shall be marked visibly, legibly and indelibly either on the toy, on an affixed label, or on the packaging.

5. In the case of small toys and toys consisting of small parts the CE-marking may alternatively be affixed on a label or an accompanying leaflet. If that is not technically possible in the case of toys sold in counter displays, the information shall be affixed to the counter display.
6. If the CE-marking is not visible from outside the packaging, if any, it shall at least be affixed on the packaging.
7. 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 17* *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 and an assessment of the potential exposure to them.

#### *Article 18* *The applicable conformity assessment procedures*

1. Before placing the toys on the market, manufacturers shall use the conformity assessment procedures identified in paragraphs 2 and 3 to demonstrate that the toys comply with the essential safety requirements set out in Article 9 and Annex II.
2. If the manufacturer has applied the harmonised standards the reference number of which has been published in the *Official Journal of the European Union* covering all the relevant safety requirements for the toy, the manufacturer shall use the procedure of internal production control as set out in Module A of Annex I to Decision [...].
3. The toy shall be submitted for EC-type-examination as referred to in Article 19 combined with the conformity to type procedure set out in Module C of Annex I to Decision [...] in the following cases:
  - (a) when 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) when standards as referred to in point (a) exist but the manufacturer has not applied them or has applied them only in part;
  - (c) when standards as referred to in point (a) or any of them have 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 19*  
*EC type-examination*

1. 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 laid down in Annex I to Decision [...].

The EC type-examination shall be carried out in the manner specified in paragraph 2, second indent, of Module B (combination of production type and design type).

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 21, hereinafter "notified body", carries out the EC type-examination, it shall evaluate, if necessary, jointly with the manufacturer, the analysis performed by the manufacturer in accordance with Article 17 of the hazards that the toy may present.
4. The EC type-examination certificate shall include a reference to this Directive, a colour image and a clear description of the toy including dimensions, and a list of the tests performed with a reference to the relevant test report.

The certificate shall be reviewed at any time where necessary, in particular in case of a modification in the manufacturing process, in the raw materials or the components of the toy and, in any case, every 5 years.

It shall be withdrawn if the toy fails to comply with the essential safety requirements set out in Article 9 and Annex II.

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

5. The file 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 the body.

*Article 20*  
*Technical documentation*

1. The technical documentation referred to in Article 3 (2) shall contain all relevant data or details of the means used by the manufacturer to ensure that toys comply with the relevant essential requirements set out in Article 9 and in Annex II and, in particular, it shall contain the documents listed in Annex IV.
2. The technical documentation shall be drafted in one of the official languages of the Community, subject to the requirement laid down in Article 19 (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 of it from a manufacturer, it may fix a deadline for doing so which shall be 30 days unless a shorter deadline is justified because there is a serious and immediate risk.



4. If the manufacturer does not observe the obligations foreseen in paragraphs 1, 2 and 3, the market surveillance authority may require him to have a test performed by a notified body at his 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 21*

##### *Notification*

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

Bodies which were notified according to Directive 88/378/EEC shall be presumed notified for the purposes of this Directive.

#### *Article 22*

##### *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 the provisions of Article 27.
2. Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by their national accreditation bodies within the meaning of and in accordance with Regulation (EC) No [...].
3. Where the notifying authority delegates, subcontracts or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, the delegated, sub-contracted or otherwise entrusted body shall be a legal entity and shall have arrangements to cover liabilities arising from its activities.

#### *Article 23*

##### *Requirements relating to notifying authorities*

- (1) The notifying authority shall meet the requirements set out in paragraphs 2 to 7
- (2) The notifying authority shall be established in such a way that no conflicts of interest with conformity assessment bodies occur
- (3) The notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities
- (4) The notifying authority shall be organised in such a way that each decision relating to notification of the conformity assessment body is taken by competent persons different from those who carried out the assessment;
- (5) The notifying authority shall not offer or provide any activities that conformity assessment bodies perform, or consultancy.

- (6) The notifying authority shall have adequate arrangements to safeguard the confidentiality of the information obtained.
- (7) The notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

#### *Article 24*

##### *Information obligation for the notifying authorities*

Member States shall inform the Commission and the other Member States of their national procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes to that information.

The Commission shall make that information publicly available.

#### *Article 25*

##### *Requirements for notified bodies*

1. For the purposes of notification under this Directive, a conformity assessment body shall meet the requirements set out in paragraphs 2 to 11.
2. The conformity assessment body shall be established under national law and have legal personality.
3. The conformity assessment body shall be a third-party body independent from the organisation or the product it assesses.
4. The 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 products which they assess, nor the authorised representative of any of those parties. Nor shall they become directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of those products, nor represent the parties engaged in those activities.

They shall not provide consultancy related to the conformity assessment activities for which they are notified and relating to products intended to be placed on the Community market. This shall not preclude the possibility of exchanges of technical information between the manufacturer and the conformity assessment body and the use of assessed products that are necessary for the operations of the conformity assessment body.

The conformity assessment body shall ensure that activities of its subsidiaries or subcontractors do not affect the confidentiality, objectivity and impartiality of its conformity assessment activities.

5. The conformity assessment body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and requisite technical competence in the specific field and must be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially from persons or groups of persons with an interest in the results of those activities.
6. The conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to such a body by the provisions of Article 19 and for

which it has 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 for each kind or category of products for which it is notified, the conformity assessment body shall have at its disposal the necessary personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks. It 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 the following:
  - (a) sound technical and vocational training covering all the conformity assessment activities of the relevant scope for 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 such operations;
  - (c) appropriate knowledge and understanding of the essential requirements, of the applicable harmonised standards and of the relevant provisions of the relevant Community legislation and relevant implementing regulations
  - (d) the ability required to draw up the certificates, records and reports to demonstrate that the assessments have been carried out.
8. The impartiality of the conformity assessment body, its top level management and assessment personnel shall be guaranteed.

The remuneration of the conformity assessment body's top level management and assessment personnel shall not depend on the number of assessments carried out or on the results of such assessments.
9. The conformity assessment body shall take out liability insurance unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.
10. The personnel of the conformity assessment body shall be bound to observe professional secrecy with regard to all information gained in carrying out its tasks under Article 19 or any provision of national law giving effect to it, except in relation to the competent administrative authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.
11. The conformity assessment body shall participate in, or ensure that its assessment personnel is informed of, the relevant standardisation activities and the activities of the notified body co-ordination group established under Article 36 and apply as general guidance the administrative decisions and documents produced as a work result of that group.

#### *Article 26* *Presumption of conformity*

Where a conformity assessment body can demonstrate its conformity with the criteria laid down in the harmonised standards, 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 25

#### *Article 27*

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

1. Where the conformity assessment body subcontracts specific tasks connected with the assessment of conformity or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 25.
2. The conformity assessment body 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. The conformity assessment body shall keep at the disposal of the national authorities the relevant documents concerning the assessment of the subcontractor's or subsidiary's qualifications and the work carried out by the subcontractor or the subsidiary under Article 19.

#### *Article 28*

##### *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 shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the product or products for which the body claims to be competent, as well as by an accreditation certificate, where it exists, delivered by a national accreditation body within the meaning of Regulation (EC) No [...], attesting that the conformity assessment body meets the requirements laid down in Article 25 of this Directive.
3. Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 25.

#### *Article 29*

##### *Notification procedure*

1. Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 25.
2. They shall notify 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 and product or products concerned and the relevant attestation of competence.
4. Where a notification is not based on an accreditation certificate referred to in Article 28 (2), the notifying authority shall provide the Commission and the other Member States with all documentary evidence necessary for the verification of the conformity assessment body's competence.

5. The body concerned may perform the activities of a notified body only where no objections have been raised by the Commission and the other Member States within two months following that notification.  
Only such a body shall be considered as a notified body for the purpose of this Directive.
6. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

#### *Article 30*

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

1. The Commission shall assign an identification number to a notified body. It shall assign a single such number even where the body is notified under several Community acts.
2. The Commission shall make publicly available the list of the bodies notified under this Directive, including the identification numbers that have been assigned to them and the activities for which they have been notified.

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

#### *Article 31*

##### *Changes to the notification*

1. Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements set out in Article 25, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw the notification as appropriate. It shall immediately inform the Commission and the other Member States thereof.
2. In the case of withdrawal, restriction or suspension of notification or where the notified body has ceased activity, the notifying Member State concerned shall take the appropriate steps to ensure that the files are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities on request.

#### *Article 32*

##### *Challenge of the competence of notified bodies*

1. The Commission shall investigate all cases where it doubts or doubt is brought to its attention as to the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities placed on it.
2. The notifying Member State shall provide the Commission, on request, with all information related to the basis for notification or the maintenance of the competence of the body concerned.
3. The Commission shall ensure that all 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 its notification, it shall inform the notifying Member

State thereof and request it to take the necessary corrective measures, including de-notification, if necessary.

### *Article 33*

#### *Operational obligations for notified bodies*

1. Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedure provided for in Article 19.
2. Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burden for economic operators, in particular taking into consideration the size of companies and the relative complexity of the technology used by the toys.
3. Where a notified body finds that the requirements laid down in Article 9 and in Annex II have not been met by the manufacturer, it shall require the manufacturer to take appropriate corrective measures and it shall not deliver the EC type-examination certificate as referred to in Article 19(4).
4. Where, in the course of the monitoring of conformity following the delivery of certificate, a notified body finds that a toy no longer complies, it shall require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the 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 certificates, as appropriate.

### *Article 34*

#### *Information obligation for notified bodies*

1. Notified bodies shall inform the notifying authority of the following:
  - (a) any refusal, restriction, suspension or withdrawal of EC type-examination certificates;
  - (b) any circumstances affecting the scope of and conditions for notification;
  - (c) any request for information which they have received from market surveillance authorities;
  - (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 carrying out similar conformity assessment activities and covering the same products with relevant information on issues relating to negative and, on request, positive conformity assessment results.

### *Article 35*

#### *Exchange of experience*

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

*Article 36*  
*Coordination of notified bodies*

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

Member States shall ensure that the bodies notified by them participate in the work of that group.

## **CHAPTER VI**

### **MARKET SURVEILLANCE**

*Article 37*  
*General obligation to organise market surveillance*

Member States shall organise and perform surveillance in accordance with Articles 6, 8 and 9 of Directive 2001/95/EC of toys placed on the market. In addition to those provisions, Articles 38, 39 and 40 of this Directive shall apply.

*Article 38*  
*Powers of market surveillance authorities*

1. The market surveillance authorities may require from the economic operators concerned any information considered necessary for the purposes of effective market surveillance, including the technical documentation referred to in Article 20.
2. The market surveillance authorities may ask 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.
3. The market surveillance authorities shall be entitled to enter the premises of the economic operators concerned where it appears necessary for the purposes of carrying out the surveillance of toys in accordance with Article 37.

*Article 39*  
*Instructions to the notified body*

1. If the market surveillance authority finds that a particular toy is not in conformity with the essential safety requirements set out in Article 9 and Annex II, it shall, where appropriate, instruct the notified body to withdraw the EC type-examination certificate in respect of such products.
2. Where necessary, and in particular in cases specified in the second subparagraph of Article 19 (4), the market surveillance authority shall instruct the notified body to review the EC type-examination certificate.

*Article 40*  
*Co-operation for market surveillance*

1. Member States shall ensure efficient co-operation and exchange of information on all issues relating to toys presenting a risk between their market surveillance authorities and those of the other Member States and between their own authorities and the Commission and the relevant Community Agencies.

2. For the purposes of paragraph 1, the market surveillance authorities of one Member State shall provide, on request, assistance to market surveillance authorities of other Member States by supplying information or documentation, by carrying out appropriate investigations or any other appropriate measure or by participating in investigations initiated in other Member States.

## **CHAPTER VII**

### **SAFEGUARD PROCEDURES**

#### *Article 41*

#### *Safeguard clause*

#### *Procedure to deal with toys presenting a risk at national level*

1. Where the market surveillance authorities of one Member State have taken action referred to in Article 12 of Directive 2001/95/EC or where they have sufficient reason to believe that a toy covered by this Directive presents a risk for the health or safety of persons they shall, together with the relevant economic operators, perform an evaluation in relation to the toy concerned covering all the requirements laid down by this Directive.

Where, in the course of that evaluation, the market surveillance authorities find that the toy does not comply with the requirements laid down by this Directive, they shall require the relevant economic operator to take all appropriate corrective actions to bring the toy into compliance with those requirements or to withdraw the toy from the market or recall it within such reasonable period, commensurate with the nature of the risk, as they may prescribe.

2. Where the market surveillance authorities consider that the non-compliance is not limited to the 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 economic operator to take.
3. The economic operator shall ensure that any corrective actions are taken in respect of all the toys concerned which he has made available on the market throughout the Community.
4. Where the relevant economic operator, within the period referred to in the second subparagraph of paragraph 1, does not take adequate corrective actions, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the making available of the toy on the national market or to withdraw the toy from that market or to recall it.

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

5. The information referred to in paragraph 4 shall provide all available details, in particular as regards the necessary data for the identification of the non-compliant toy, the origin of the toy, the nature of the risk involved, the nature and duration of national measures taken. In particular, the market surveillance authorities shall indicate whether the non compliance is due to either of the following:
  - (a) failure of the toy to meet the requirements related to the health or safety of persons;



- (b) shortcomings in the harmonised standards referred to in Article 12 (1) as conferring presumption of conformity.
- 6. Member States other than the Member State which initiated the procedure shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information relating to the non-compliance of the toy concerned at their disposal, 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 in relation to the toy concerned, the measure shall be deemed justified.

#### *Article 42* *Community safeguard procedure*

- 1. Where, on completion of the procedure set out in Article 41 (3) and (4), objections are raised against a national measure of a Member State or where the Commission considers the 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(s) and shall proceed to the evaluation of the national measure.  
  
On the basis of the results of that evaluation, the Commission shall take a decision, indicating whether the measure is justified or not.  
  
The Commission shall address its decision to all Member States and shall immediately communicate it to them and to the relevant economic operator(s).
- 2. If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant toy is withdrawn from their markets. Member States shall inform the Commission thereof.  
  
If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.
- 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 as referred to in Article 41(5)(b), the Commission or the Member State shall bring the matter before the Standing Committee set up under Article 5 of Directive 98/34/EC.

#### *Article 43* *RAPEX notifications*

If a measure referred to in Article 41 (4) is a type of measure which is required under Article 12 of Directive 2001/95/EC to be notified through the Community Rapid Information Exchange System (RAPEX), it shall not be necessary to make a separate notification under Article 41(4) of this Directive, provided that the following conditions are met:

- (a) the RAPEX notification indicates that the notification of the measure is also required by this Directive;
- (b) the supporting evidence referred to in Article 41 (5) is enclosed with the RAPEX notification.

*Article 44*  
*Formal non-compliance*

1. Without prejudice to Article 41, 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) the conformity marking has been affixed in violation of Article 15 or Article 16,
  - (b) the conformity marking has not been affixed;
  - (c) the EC declaration of conformity has not been drawn up;
  - (d) the EC declaration of conformity has not been drawn up correctly.
2. Where the non-compliance referred to in paragraph 1 continues, the Member State shall take all appropriate measures to restrict or prohibit the making available on the market of the toy or ensure that it is recalled or withdrawn from the market.

## **CHAPTER VIII**

### **COMMITTEE PROCEDURES**

*Article 45*  
*Amendments and implementing measures*

1. The Commission may, for the purposes of adapting them to technical and scientific developments, amend the following:
  - (a) Points 7 and 8 in Part III of Annex II;
  - (b) Annex V.

Those measures, designed to amend non-essential elements of this Regulation, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 46 (2).
2. The Commission may decide upon the use in toys of substances or preparations classified as carcinogenic, mutagenic or toxic for reproduction, of category 1, 2 and 3, under Annex I to Directive 67/548/EEC.

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 46 (2).

*Article 46*  
*Committee*

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 IX**

### **SPECIFIC ADMINISTRATIVE PROVISIONS**

#### *Article 47*

##### *Reporting*

Three years following the date of application of this Directive referred to in the second paragraph of Article 53 and every five years thereafter, Member States shall send the Commission a report on the application of this Directive.

This 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 the Member State.

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

#### *Article 48*

##### *Transparency and confidentiality*

When the 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 49*

##### *Motivation of measures*

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

Such measures shall be notified without delay to the party concerned, who shall at the same time be informed of the remedies available to him under the laws in force in the Member State in question and of the time limits applying to such remedies.

#### *Article 50*

##### *Penalties*

Member States shall lay down the rules on penalties, which may include criminal sanctions for serious infringements, applicable to infringements to 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.

The Member States shall notify those provisions to the Commission by the date specified in Article 53 at the latest and shall notify it without delay of any subsequent amendment affecting them.

## **CHAPTER X**

### **FINAL AND TRANSITIONAL PROVISIONS**

#### *Article 51*

##### *Application of Directives 85/374/EEC and 2001/95/EC*

1. This Directive is without prejudice to the application of Directive 85/374/EEC.

2. Directive 2001/95/EC shall apply to toys in accordance with Article 1(2) thereof. The applicable Articles of Directive 2001/95/EC are those mentioned in Articles 37, 43 and 48 of this Directive as well as Articles 10, 11 and 13 of Directive 2001/95/EC.

*Article 52*  
*Transitional period*

Member States shall not impede the placing on the market of toys which are in accordance with Directive 88/378/EEC and which were placed on the market before this Directive entered into force or at the latest 2 years after this Directive entered into force.

*Article 53*  
*Transposition*

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

They shall apply those provisions with effect from [...]

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

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

*Article 54*  
*Repeal*

Directive 88/378/EEC is repealed from the date set out in the second paragraph of Article 53. References to the repealed Directive shall be construed as references to this Directive.

*Article 55*  
*Entry into force*

This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

*Article 56*  
*Addressees*

This Directive is addressed to the Member States.

Done at Brussels,

*For the European Parliament*  
*The President*

*For the Council*  
*The President*

## **ANNEX I**

### **LIST OF PRODUCTS THAT, IN PARTICULAR, ARE NOT CONSIDERED AS TOYS WITHIN THE MEANING OF THIS DIRECTIVE (ARTICLE 2 (1))**

1. Decorative objects for festivities and celebrations;
2. Products for adult 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,
  - (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, scooters and other means of transport designed for sport or which are intended to be used for travel on public roads or public pathways;
5. Electrically driven vehicles which are intended to be used for travel on public roads, public pathways, or on the pavement of these.
6. Aquatic equipment intended to be used in deep water and swimming learning devices for children, such as swim seats and swimming aids;
7. Puzzles with more than 500 pieces;
8. Guns and pistols using compressed gas, with the exception of water guns, and bows for archery over 120 cm long;
9. Fireworks, including percussion caps which are not specifically designed for toys;
10. Products and games using sharp-pointed missiles, such as sets of darts with metallic points;
11. 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;

“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 may be a scale model of such a product, appliance or installation.
12. Products intended for use for educational purposes in schools and in other pedagogical framework under the surveillance of an adult instructor, such as science equipment;
13. 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;

14. Interactive software, intended for leisure and entertainment, such as computer games, and their storage media, such as CD;
15. Babies' soothers;
16. Child-appealing luminaires;
17. Electrical transformers for toys.

## **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 so designed and constructed that the risks of physical injury from contact with them are reduced as far as possible.
3. Toys must be so designed and constructed as to minimize the risk of physical injury which could be caused by the movement of their parts.
4. Toys and their parts must not present risk of asphyxiation caused, in particular, by strangulation or suffocation.

The packaging in which toys are contained for retail sale must not present risk of strangulation or asphyxiation caused by airway obstruction external to the mouth and nose.

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 and/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.

Toys contained within food or co-mingled with a food must have their own packaging. This packaging, in its supplied condition, must be of such dimensions as to prevent it being swallowed and/or inhaled.

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.

5. Toys intended for use in shallow water which are capable of carrying or supporting a child on the water must be designed and constructed 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

developed 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.

"Design speed" means representative potential operating speed that is determined by the design and correlation of the physical features.

8. The form and composition of projectiles and the kinetic energy they may develop 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 so constructed as to ensure that:
  - (a) the maximum and minimum temperature of any accessible surfaces does not cause injury when touched;
  - (b) liquids and gases contained within toys do not reach temperatures or pressures which are such that their escape from a 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 should be so designed and constructed so that the sound from them is not able to impair children's hearing.
11. Activity toys shall be constructed so as to reduce the risk of crushing or trapping of body parts or trapping of clothing and the risk of falls, impacts and drowning as far as possible.

## **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 seat 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 treated mechanically so as to delay the combustion process
  - (e) 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 dangerous substances or preparations as defined in Council Directive 67/548/EEC, 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 preparations 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 9(2).
4. Toys and, in particular, chemical games and toys, must not contain as such substances or preparations:
  - (a) which, when mixed, may explode:- through chemical reaction, or through heating,- when mixed with oxidizing substances;
  - (b) which contain volatile components which are flammable in air and liable to form flammable or explosive vapour/air mixture.

### **III. CHEMICAL PROPERTIES**

1. Toys shall be so designed and constructed that there are no risks of adverse effects on human health due to exposure to the chemical substances or preparations of which the toys are composed or which they contain, when the toys are used as specified in the first subparagraph of Article 9 (2).
2. Toys shall comply with relevant Community legislation relating to certain categories of products or to the prohibition of use of certain dangerous substances and preparations.

Toys that are themselves substances or preparations must comply also with Directives 67/548/EEC and 1999/45/EC<sup>25</sup> relating to the classification, packaging and labelling of dangerous substances and dangerous preparations.
3. Without prejudice to the application of the restrictions under the first sentence of point 2, the use in toys of substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) according to Directive 67/548/EEC in individual concentrations equal to or greater than the relevant concentrations established for the classification of preparations containing the substances in accordance with the provisions of Directive 1999/45/EC shall be prohibited, except if the substances are contained in components of toys or micro-structurally distinct parts of toys that are not accessible to any physical contact by children.
4. Substances or preparations classified as CMR category 1 and 2 according to Directive 67/548/EEC may be used in toys provided that the following conditions are met:
  - 4.1. use of the substance has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure, and a Decision as referred to in Article 45 (2) has been taken;
  - 4.2. there are no suitable alternative substances available, as documented in an analysis of alternatives,
  - 4.3. they are not prohibited for uses in consumer articles under Regulation (EC) No 1907/2006 (REACH).

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<sup>25</sup> OJ No L 200, 30.7. 1999, p. 1-68



The Commission shall mandate the relevant Scientific Committee to re-evaluate those substances or preparations as soon as safety concerns arise and at the latest every 5 years from the date that a decision in accordance with Article 45 (2) was taken.

5. Substances or preparations classified as CMR category 3 according to Directive 67/548/EEC may be used in toys if use of the substance has been evaluated by the relevant Scientific Committee and found to be safe, in particular in view of exposure, and following a Decision as referred to in Article 45 (2) and provided that they are not prohibited for uses in consumer articles under Regulation (EC) No 1907/2006 (REACH).
6. Cosmetic toys, such as play cosmetics for dolls, shall comply with the compositional and labelling requirements provided for in Directive 76/768/EEC.
7. Toys shall not contain the following allergenic fragrances:
  - (1) Alanroot (*Inula helenium*)
  - (2) Allylisothiocyanate
  - (3) Benzyl cyanide
  - (4) 4 tert-Butylphenol
  - (5) Chenopodium oil
  - (6) Cyclamen alcohol
  - (7) Diethyl maleate
  - (8) Dihydrocoumarin
  - (9) 2,4-Dihydroxy-3-methylbenzaldehyde
  - (10) 3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol)
  - (11) 4,6-Dimethyl-8-tert-butylcoumarin
  - (12) Dimethyl citraconate
  - (13) 7,11-Dimethyl-4,6,10-dodecatrien-3-one
  - (14) 6,10-Dimethyl-3,5,9-undecatrien-2-one
  - (15) Diphenylamine
  - (16) Ethyl acrylate
  - (17) Fig leaf, fresh and preparations
  - (18) trans-2-Heptenal
  - (19) trans-2-Hexenal diethyl acetal
  - (20) trans-2-Hexenal dimethyl acetal
  - (21) Hydroabietyl alcohol
  - (22) 4-Ethoxy-phenol
  - (23) 6-Isopropyl-2-decahydronaphthalenol
  - (24) 7-Methoxycoumarin
  - (25) 4-Methoxyphenol

- (26) 4-(p-Methoxyphenyl)-3-butene-2-one
- (27) 1-(p-Methoxyphenyl)-1-penten-3-one
- (28) Methyl trans-2-butenolate
- (29) 6-Methylcoumarin
- (30) 7-Methylcoumarin
- (31) 5-Methyl-2,3-hexanedione
- (32) Costus root oil (*Saussurea lappa* Clarke)
- (33) 7-Ethoxy-4-methylcoumarin
- (34) Hexahydrocoumarin
- (35) Peru balsam (*Myroxylonpereirae* Klotzsch)
- (36) 2-Pentylidene-cyclohexanone
- (37) 3,6,10-Trimethyl-3,5,9-undecatrien-2-one
- (38) Verbana oil (*Lippia citriodora* Kunth).

However, the presence of traces of these substances shall be allowed provided that such presence is technically unavoidable in good manufacturing practice.

In addition the following allergenic fragrances shall be listed if added to toys, as such, at concentrations exceeding 0,01 % by weight:

- (1) Amyl cinnamal
- (2) Amylcinnamyl alcohol
- (3) Anisyl alcohol
- (4) Benzyl alcohol
- (5) Benzyl benzoate
- (6) Benzyl cinnamate
- (7) Benzyl salicylate
- (8) Cinnamal
- (9) Cinnamyl alcohol
- (10) Citral
- (11) Citronellol
- (12) Coumarin
- (13) Eugenol
- (14) Farnesol
- (15) Geraniol
- (16) Hexyl cinnamaldehyde
- (17) Hydroxy-citronellal
- (18) Hydroxy-methylpentylcyclohexenecarboxaldehyde
- (19) Isoeugenol

- (20) Lilial (referred to in the Cosmetics Directive in entry 83 as: 2-(4-tert-Butylbenzyl) propionaldehyde
- (21) d-Limonene
- (22) Linalool
- (23) Methyl heptine carbonate
- (24) 3-methyl-4-(2,6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one
- (25) Oakmoss extracts
- (26) Treemoss extracts

8. The following migration limits, from toys or components of toys that are accessible to children during use as specified in the first subparagraph of Article 9 (2), shall not be exceeded:

Element	mg/kg in dry, brittle, powder-like or pliable toy material	mg/kg in liquid or sticky toy material
Aluminium	5625	1406
Antimony	45	11.3
Arsenic	7.5	1.9
Barium	4500	1125
Boron	1200	300
Cadmium	3.8	0.9
Chromium (III)	37.5	9.4
Chromium (VI)	0.04	0.01
Cobalt	10.5	2.6
Copper	622.5	156
Lead	27	6.8
Manganese	1200	300
Mercury	15	3.8
Nickel	75	18.8
Selenium	37.5	9.4
Strontium	4500	1125
Tin	15000	3750

Organic tin	1.9	0.5
Zinc	3750	938

These limit values do not apply to 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 9 (2).

#### **IV. ELECTRICAL PROPERTIES**

1. Toys shall not be powered by electricity exceeding 24 volts and their accessible parts shall not exceed 24 volts.

Internal voltages shall not exceed 24 volts 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 so designed and constructed 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 its operation, and 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 shall be designed and manufactured in such a way that the toy operates safely even when the electronic system starts malfunctioning or fails due to the failure in the system itself or due to an outside factor.
8. Toys must be so designed and constructed 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 for toys shall not be integral part of the toy.

#### **V. HYGIENE**

1. Toys must be so designed and manufactured as to meet the requirements of hygiene and cleanliness in order to avoid any risk of infection, sickness and contamination.
2. Textile toys for children under 36 months shall be washable and shall fulfil the safety requirements also after washing.

## **VI. RADIOACTIVITY**

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

### **ANNEX III** **EC DECLARATION OF CONFORMITY**

1. No xxxxxx (unique identification of the toy(s))
2. Name and address of (authorised representative of the) manufacturer:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer:
4. Object of the declaration (identification of toy allowing traceability):
5. The object of the declaration described above 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. 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)

### **ANNEX IV** **TECHNICAL DOCUMENTATION**

The technical documentation referred to in Article 20 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 toys as well as the safety data sheets on chemicals used to be obtained from chemical suppliers;
- b) the safety assessment(s) carried out in accordance with Article 17;
- 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 ensures conformity of production with the harmonised standards if the manufacturer has followed the internal production control referred to in Article 18 (2).
- h) a copy of the EC type-examination certificate, a description of the means whereby the manufacturer ensures conformity of the production with the product-type as described in the EC type-examination certificate and copies of the documents that the

manufacturer has submitted to the notified body, if the manufacturer has followed the EC type-examination and type conformity –declaration referred to in Articles 18 (3).

i) Colour image of the toy.

**ANNEX V**  
**WARNINGS**  
**(Article 10)**

**PART A – GENERAL WARNINGS**

The user limitations referred to in Article 10 (1) shall include at least the minimum or maximum age of the user and, where appropriate, the ability of the users of toys, the maximum or minimum weight of the users 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 children under 36 months**

Toys which might be dangerous for children under 36 months of age shall bear a warning, for example: 'Warning: Not suitable for children under 36 months' or 'Warning: Not suitable for children under three years' or the word “Warning” together with the following graphic:

[Pictogram]

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

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

**2. Slides, suspended swings and rings, trapezes, ropes and similar toys attached to a crossbeam**

Such toys shall bear a marking “Warning: only for domestic use”.

They 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 correct assembly of the toy, indicating those parts which can present dangers if it is incorrectly assembled. Specific information regarding suitable surface shall be given.

**3. Functional toys**

“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 may be a scale model of such a product, appliance or installation.

Functional toys or their packaging shall bear the marking '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 would 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 an imitation. It shall also be indicated that the toy must be kept out of the reach of very young children.

**4. Toys containing inherently dangerous substances or preparations. Chemical toys**

Without prejudice to the application of the provisions laid down in Community directives on the classification, packaging and labelling of dangerous substances or preparations, the instructions for use of toys containing inherently dangerous substances or preparations shall bear a warning of the dangerous nature of these substances or preparations 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 toys must be kept out of reach of very young children.

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

'Warning: Not suitable for children under <sup>(1)</sup> 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, online skates, skateboards, scooters and toy bicycles for children**

If these toys are offered for sale as toys they shall bear the following markings:

'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 and third parties. Some indication shall also be given as to recommended protective equipment (helmets, gloves, knee-pads, elbow-pads, etc.).

**6. Toys intended for use in water**

The toys intended for use in water defined in Section 1 (5) of Annex II shall contain the warning:

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

<sup>(1)</sup> Age to be decided by the manufacturer.

**7. Toys in food**

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

“Adult supervision recommended”.

## LEGISLATIVE FINANCIAL STATEMENT

**1. NAME OF THE PROPOSAL:**

*Proposal for a Directive of the European Parliament and of the Council on the safety of toys*

**2. ABM / ABB FRAMEWORK**

Policy Area(s) concerned and associated Activity/Activities: *Simplification of existing legislation.*

*Policy area 02 "Enterprise"*

*Activity: "Administrative expenditure of Enterprise Policy area"*

**3. BUDGET LINES**

**3.1. Budget lines (operational lines and related technical and administrative assistance lines (ex- B.A lines) including headings:**

**3.2. Duration of the action and of the financial impact:**

2009-2013

**3.3. Budgetary characteristics (add rows if necessary):**

Budget line	Type of expenditure		New	EFTA contribution	Contributions from applicant countries	Heading in financial perspective
	Diff/ Non-diff	Diff <sup>26</sup> / Non-diff <sup>27</sup>	YES/ NO	YES/NO	YES/NO	No [...]
	Comp/ Non-comp	Diff/ Non-diff	YES/ NO	YES/NO	YES/NO	No [...]

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<sup>26</sup> Differentiated appropriations

<sup>27</sup> Non-differentiated appropriations hereafter referred to as NDA



## 4. SUMMARY OF RESOURCES

### 4.1. Financial Resources

#### 4.1.1. Summary of commitment appropriations (CA) and payment appropriations (PA)

*Not applicable*

EUR million (to 3 decimal places)

Expenditure type	Section no.		Year n	n + 1	n + 2	n + 3	n + 4	n + 5 and later	Total
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#### Operational expenditure<sup>28</sup>

Commitment Appropriations (CA)	8.1.	a							
Payment Appropriations (PA)		b							

#### Administrative expenditure within reference amount<sup>29</sup>

Technical & administrative assistance (NDA)	8.2.4.	c							
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#### TOTAL REFERENCE AMOUNT

Commitment Appropriations		a+c							
Payment Appropriations		b+c							

Administrative expenditure not included in reference amount<sup>30</sup>: no new expenditure for HR is contemplated as a result of the proposal

*Not applicable*

Human resources and associated expenditure (NDA)	8.2.5.	d							
Administrative costs, other than human resources and associated costs, not included in reference amount (NDA)	8.2.6.	e	0,120	0,120	0,120	0,120	0,120	0,120	0,600

#### Total indicative financial cost of intervention

*Not applicable*

TOTAL CA including cost of Human Resources		a+c+d+e	0,120	0,120	0,120	0,120	0,120	0,120	0,600
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<sup>28</sup> Expenditure that does not fall under Chapter xx 01 of the Title xx concerned.

<sup>29</sup> Expenditure within article xx 01 04 of Title xx.

<sup>30</sup> Expenditure within chapter xx 01 other than articles xx 01 04 or xx 01 05.

<b>TOTAL PA including cost of Human Resources</b>		b+c +d+ e	0,120	0,120	0,120	0,120	0,120	0,120	0,120
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### Co-financing details

If the proposal involves co-financing by Member States, or other bodies (please specify which), an estimate of the level of this co-financing should be indicated in the table below (additional lines may be added if different bodies are foreseen for the provision of the co-financing):

*No co-financing is envisaged within the scope of the revision of this existing legislation.*

EUR million (to 3 decimal places)

Co-financing body		Year n	n + 1	n + 2	n + 3	n + 4	n + 5 and later	Total
.....	f							
<b>TOTAL CA including co-financing</b>	a+c +d+ e+f							

#### 4.1.2. Compatibility with Financial Programming

- ☒ Proposal is compatible with existing financial programming.
- ☐ Proposal will entail reprogramming of the relevant heading in the financial perspective.
- ☐ Proposal may require application of the provisions of the Interinstitutional Agreement<sup>31</sup> (i.e. flexibility instrument or revision of the financial perspective).

#### 4.1.3. Financial impact on Revenue

- ☒ Proposal has no financial implications on revenue
- ☐ Proposal has financial impact – the effect on revenue is as follows:

**NB: All details and observations relating to the method of calculating the effect on revenue should be shown in a separate annex.**

EUR million (to one decimal place)

Budget line	Revenue	Prior to action [Year n-1]	Situation following action					
			[Year n]	[n+1]	[n+2]	[n+3]	[n+4]	[n+5] <sup>32</sup>
	a) Revenue in absolute terms							
	b) Change in revenue	Δ						

<sup>31</sup> See points 19 and 24 of the Interinstitutional agreement.

<sup>32</sup> Additional columns should be added if necessary i.e. if the duration of the action exceeds 6 years

(Please specify each revenue budget line involved, adding the appropriate number of rows to the table if there is an effect on more than one budget line.)

**4.2. Human Resources FTE (including officials, temporary and external staff) – see detail under point 8.2.1.**

Annual requirements	Year n	n + 1	n + 2	n + 3	n + 4	n + 5 and later
Total number of human resources						

**5. CHARACTERISTICS AND OBJECTIVES**

**5.1. Need to be met in the short or long term**

Only the creation of a ‘comitology’ committee is introduced by the proposal, to meet the need to revise the legislation in a timely and convenient manner.

**5.2. Value-added of Community involvement and coherence of the proposal with other financial instruments and possible synergy**

Not relevant

**5.3. Objectives, expected results and related indicators of the proposal in the context of the ABM framework**

?

**5.4. Method of Implementation (indicative)**

☐ ***Centralised Management***

☒ directly by the Commission

☐ indirectly by delegation to:

☐ executive Agencies

☐ bodies set up by the Communities as referred to in art. 185 of the Financial Regulation

☐ national public-sector bodies/bodies with public-service mission

☐ ***Shared or decentralised management***

☐ with Member states

☐ with Third countries

☐ ***Joint management with international organisations (please specify)***

Relevant comments: None

## **6. MONITORING AND EVALUATION**

### **6.1. Monitoring system**

The monitoring will be managed through the expert group on toy safety (already existing prior to the revision that is the object of the proposal), and the feedback provided by the national authorities, consistently with the arrangements in place for the legislation in force.

### **6.2. Evaluation**

#### *6.2.1. Ex-ante evaluation*

A thorough evaluation of the proposal has been done on the basis of several studies and a comprehensive Impact Assessment that is annexed to the proposal.

#### *6.2.2. Measures taken following an intermediate/ex-post evaluation (lessons learned from similar experiences in the past)*

Not relevant

#### *6.2.3. Terms and frequency of future evaluation*

Five years after entering into force.

## **7. ANTI-FRAUD MEASURES**

## 8. DETAILS OF RESOURCES

### 8.1. Objectives of the proposal in terms of their financial cost:

Not relevant (please refer to the information above on the limited scope of the financial incidence of the proposal).

Commitment appropriations in EUR million (to 3 decimal places)

(Headings of Objectives, actions and outputs should be provided)	Type of output	Av. cost	Year n		Year n+1		Year n+2		Year n+3		Year n+4		Year n+5 and later		TOTAL	
			No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost
OPERATIONAL OBJECTIVE No.1 <sup>33</sup> .....																
Action 1.....																
- Output 1																
- Output 2																
Action 2.....																
- Output 1																
Sub-total Objective 1																
OPERATIONAL OBJECTIVE No.2 <sup>1</sup> .....																
Action																

<sup>33</sup> As described under Section 5.3

1.....																
- Output 1																
Sub-total Objective 2																
OPERATIONAL OBJECTIVE No.n 1																
Sub-total Objective n																
<b>TOTAL COST</b>																

## 8.2. Administrative Expenditure

8.2.1. Number and type of human resources: *no immediate change to the current HR staffing is envisaged; the possibility of adding new staff will be assessed once the proposal will have been adopted, on the basis of the provisions that will have been finally introduced as a result of the legislative process.*

Types of post		Staff to be assigned to management of the action using existing and/or additional resources ( <b>number of posts/FTEs</b> )					
		Year <b>n</b>	Year <b>n+1</b>	Year <b>n+2</b>	Year <b>n+3</b>	Year <b>n+4</b>	Year <b>n+5</b>
Officials or temporary staff <sup>34</sup> (XX 01 01)	A*/AD						
	B*, C*/AST						
Staff financed <sup>35</sup> by art. XX 01 02							
Other staff <sup>36</sup> financed by art. XX 01 04/05							
<b>TOTAL</b>							

8.2.2. *Description of tasks deriving from the action*

**See explanatory memorandum.**

8.2.3. *Sources of human resources (statutory):*

- ☒ Posts currently allocated to the management of the programme to be replaced or extended: ***1 administrator***
- ☐ Posts pre-allocated within the APS/PDB exercise for year n
- ☐ Posts to be requested in the next APS/PDB procedure
- ☐ Posts to be redeployed using existing resources within the managing service (internal redeployment)
- ☐ Posts required for year n although not foreseen in the APS/PDB exercise of the year in question

<sup>34</sup> Cost of which is NOT covered by the reference amount

<sup>35</sup> Cost of which is NOT covered by the reference amount

<sup>36</sup> Cost of which is included within the reference amount

8.2.4. *Other Administrative expenditure included in reference amount (XX 01 04/05 – Expenditure on administrative management):*

*Not relevant*

EUR million (to 3 decimal places)

Budget line (number and heading)	Year <i>n</i>	Year <i>n+1</i>	Year <i>n+2</i>	Year <i>n+3</i>	Year <i>n+4</i>	Year <i>n+5</i> and later	TOTAL
<b>1 Technical and administrative assistance (including related staff costs)</b>							
Executive agencies <sup>37</sup>							
Other technical and administrative assistance							
- <i>intra muros</i>							
- <i>extra muros</i>							
<b>Total Technical and administrative assistance</b>							

8.2.5. *Financial cost of human resources and associated costs not included in the reference amount: EUR million (to 3 decimal places)*

Type of human resources	Year <i>n</i>	Year <i>n+1</i>	Year <i>n+2</i>	Year <i>n+3</i>	Year <i>n+4</i>	Year <i>n+5</i> and later
Officials and temporary staff (XX 01 01)						
Staff financed by Art XX 01 02 (auxiliary, END, contract staff, etc.) (specify budget line)						
<b>Total cost of Human Resources and associated costs (NOT in reference amount)</b>						

Calculation– *Officials and Temporary agents*

See above, 8.2.1.

Calculation– Staff financed under art. XX 01 02

<sup>37</sup> Reference should be made to the specific legislative financial statement for the Executive Agency(ies) concerned.



8.2.6. Other administrative expenditure not included in reference amount

EUR million (to 3 decimal places)

	Year n	Year n+1	Year n+2	Year n+3	Year n+4	Year n+5 and later	TOTAL
XX 01 02 11 01 – Missions							
XX 01 02 11 02 – Meetings & Conferences							
XX 01 02 11 03 – Committees <sup>38</sup>	0	0,120	0,120	0,120	0,120	0,120	0,600
XX 01 02 11 04 – Studies & consultations							
XX 01 02 11 05 - Information systems							
<b>2 Total Other Management Expenditure (XX 01 02 11)</b>							
<b>3 Other expenditure of an administrative nature</b> (specify including reference to budget line)							
<b>Total Administrative expenditure, other than human resources and associated costs (NOT included in reference amount)</b>							

Calculation - *Other administrative expenditure not included in reference amount*

None

<sup>38</sup> Specify the type of committee and the group to which it belongs.