

**NIST GCR 01-823**

# **A Guide to the EU Safety of Toys**

Helen Delaney  
Rene van de Zande  
Editors



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# **A Guide to the EU Safety of Toys Directive**

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*U.S. Department of Commerce  
Global Standards Program  
Office of Standards Services  
National Institute of Standards and Technology  
Gaithersburg, MD 20899-2100*

By  
Helen Delaney  
Rene van de Zande  
Editors  
DVZ Joint Ventures  
Bethesda, MD 20814

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*Donald L. Evans, Secretary*

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*Karen H. Brown, Acting Director*

## ABSTRACT

This guide (prepared under contract by Helen Delaney and Rene van de Zande, DVZ Joint Ventures) is an easy-to-use introductory reference for industry and government officials on the requirements of the European Union's (EU) *Safety of Toys Directive* [88/378/EEC]. It is designed to help business and government officials understand the purpose of the directive, its relationship to other directives, the essential requirements contained in the directive, and the basic steps necessary for compliance. The guide offers explanations of such requirements as: the products covered by the directive; particular risks associated with toys and specific guidelines for those risks; toy hygiene; radioactivity toys; warnings and indications of precautions; and the use of standards. The guide contains the text of the directive and a list of applicable standards. In addition, the guide references appropriate sections of *NIST Special Publication 951: A Guide to EU Standards and Conformity Assessment* for further information on some of the generic conformity assessment concepts and requirements of the EU's New Approach.

Key Words: CEN; CENELEC; conformity assessment; directives; European Union; games; New Approach directives; toys; technical construction files; user manuals



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# The Safety of Toys Directive<sup>1 2</sup>

## Directive 88/378/EEC

In force since May 1988, mandatory as of January 1990

### To Be Considered:

A. *The Safety of Toys Directive is not applicable to the following products (see Annex I):*

1. Christmas decorations.
2. Detailed scale models for adult collectors.
3. Equipment intended to be used collectively in playgrounds.
4. Sports equipment.
5. Aquatic equipment intended to be used in deep water.
6. Folk dolls and decorative dolls and other similar articles for adult collectors.
7. 'Professional' toys installed in public places (shopping centers, stations, etc.).
8. Puzzles with more than 500 pieces or without picture, intended for specialists.
9. Air guns and air pistols.
10. Fireworks, including percussion caps (With the exception of percussion caps specifically designed for use in toys without prejudice to more stringent provisions already existing in certain Member States).
11. Slings and catapults.
12. Sets of darts with metallic points.
13. Electric ovens, irons or other functional products operated at a nominal voltage exceeding 24 volts.
14. Products containing heating elements intended for use under the supervision of an adult in a teaching context.
15. Vehicles with combustion engines.
16. Toy steam engines.
17. Bicycles designed for sport or for travel on the public highway.
18. Video toys that can be connected to a video screen and operated at a nominal voltage exceeding 24 volts.
19. Babies' dummies (pacifiers).
20. Faithful reproductions of real fire arms.
21. Fashion jewelry for children.

B. *This directive has been partially amended by Directive 93/68/EEC, the CE Marking Directive. For an explanation of CE Marking, see NIST SP 951 A Guide to EU Standards and Conformity Assessment, Pages 17-19.*

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<sup>1</sup> "Toy" is defined as any product or material designed or clearly intended for use in play by children under the age of 14.

<sup>2</sup> Readers of this report may wish to refer to NIST SP 951: A Guide to EU Standards and Conformity Assessment, which is available on NIST's website at: <http://ts.nist.gov/ca>.

C. The Directive on General Product Safety (92/59/EEC) is legislation that is intended as a compliment to the Directive on the Safety of Toys. Although it does not address the safety requirements of toys, it does afford protection to consumers by providing other safeguards, such as a rapid alert system for unsafe products and European Community emergency measures. This was brought to bear in the case of toys containing phthalates.

## **Purpose of the Safety of Toys Directive**

The Safety of Toys Directive sets fundamental health and safety requirements relating to playthings. The directive defines “toys” broadly as “any product or material designed or clearly intended for use in play by children of less than 14 years of age.”

Since January 1990 (the date of effect of the directive), toys placed on the European Economic Area Market (EEA) See NIST SP 951, Page 1) have been required to bear the CE Marking.

The directive consists of Articles that cover definitions, scope, free movement, and standards. Annexes covering exemptions, essential requirements, and labeling information follow these articles.

Before Manufacturers can place the CE Marking on their toys (See NIST P 951, Page 17) and legally sell to, or within the EEA, they must be in compliance with the Safety of Toys Directive.

## **Basic Steps to Compliance**

- I. Determining Whether or Not the Product Has To Comply with the Safety of Toys Directive
- II. Compliance with the Essential Requirements of the Directive
- III. Harmonized standards
- IV. Technical File
- V. CE marking
- VI. Declaration of Conformity

### **I. Determining Whether or Not the Product Has To Comply with the Toys Directive**

The purpose of the Safety of Toys Directive is to protect children who play with toys, as well as the adults who supervise that play. Among other things, the directive addresses the appropriate labeling of toys for safe use, safety guidelines for specific toys, and inspection procedures.



A “toy” is defined as any product or material designed or clearly intended for use in play by children under the age of 14 (See *Article 1*). Some products should not be regarded as toys, either because they are not intended for children, or because they require supervision or special conditions of use. For the purposes of this directive, the products that are exempted and are not considered toys are listed in *Annex I*.

## **II. Compliance With the Essential Requirements of the Directive**

The Essential Requirements of the Safety of Toys Directive are contained in *Annex II* of the directive. Compliance with these requirements is mandatory, and is the underlying principle behind CE Marking (See *NIST SP 951, Page 17*).

### **A. General Requirements for Toys**

Users of toys must be protected against health hazards and risks presented by toys.

The risks are those that are:

- Connected with the design, construction, or composition of a toy;
- Inherent in the use of the toy and that cannot be completely eliminated by modifying the toy’s construction and composition without altering its function or depriving it of its essential requirements.

The degree of risk present in the use of a toy must be commensurate with the ability of the children, and their supervisors to cope with it. This applies in particular to toys that are intended for use by children younger than 36 months. To that end, when appropriate, there must be a minimum age for users of a toy and/or an explicit warning that the toy must only be used under adult supervision.

Toys must bear labels that draw attention to risks. Or, if that is not possible, the labels must be on packaging and instructions for use. These labels should also point out ways of avoiding risks.

### **B. Particular Risks and Specific Guidelines**

The following sections are guidelines for designing and constructing safe toys. In all cases, it is assumed that children or their adult supervisors will use the toys in normal, recommended ways.

#### **1. Physical and Mechanical Properties**

Toys, their parts, and, in the case of fixed toys, their anchorages, must be strong and stable enough to withstand the stresses to which they are subjected during use. They shouldn’t

break or become distorted so as to cause physical injury to users.

The risk of injury due to the movement of parts must be minimized.

The risk of injury due to contact with accessible edges, protrusions, cords, cables, and fastenings on toys must be reduced as much as possible.

Toys, their component parts, and detachable parts of toys that are clearly intended for use by children younger than 36 months must be made so that they cannot be swallowed and/or inhaled. Also, toys, their parts, and the packaging in which they are contained for retail sale should not present a risk of strangulation or suffocation.

Toys intended for use in shallow water, toys that can carry or support a child on the water, must be made so that the risk of losing buoyancy and support is reduced as far as possible.

Toys that allow children to get inside them must have an exit that the child can open easily from the inside.

Toys that children can ride must provide an adequate braking system that is easy for the child to operate. The system should not risk ejection of the user or physical harm to the user.

In the case of toys that can be fired, the form and composition of the projectiles should not pose an unreasonable risk of physical injury to the user.

Toys containing heating elements must be so constructed to ensure that:

- The maximum temperature of any accessible surfaces does not cause burns when touched; and
- Liquids and gases contained within toys do not reach temperatures or pressures that 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.

## **2. Flammability**

Toys must not constitute a dangerous flammable element in the child's environment. They must be composed of materials that:

- Do not burn if directly exposed to a flame or spark or other potential seat of fire;
- Are not readily flammable (i.e., the flame goes out as soon as the fire cause disappears);
- If they do ignite, burn slowly and present a low rate of spread of the flame; and
- Irrespective of the toy's chemical composition, are treated so as to delay the combustion process (and such combustible materials must not constitute a risk of ignition for other

materials used in the toy).

Toys that, for reasons essential to their functioning, contain dangerous substances or preparations as defined in Council Directive 67/548/EEC, and in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic molding, enameling, photography, or similar activities, must not contain substances or preparations that may become flammable with the loss of nonflammable volatile components.

Toys must not be explosive or contain elements or substances likely to explode or form explosive or flammable vapor/air mixtures. (This provision does not apply to toy percussion caps).

### **3. Chemical Properties**

Toys must be made so that they do not present health hazards or risks of physical injury by reason of ingestion, inhalation, or contact with the skin, mucous tissues, or eyes. They must, in fact, comply, with the relevant Community legislation relating to certain categories of products or to the prohibition, restriction of use, or labeling of certain dangerous substances and preparations.

In particular, for the protection of children's health, bioavailability resulting from the use of toys must not, as an objective, exceed the following levels (or such levels as may be laid down for these or other substances in Community legislation based on scientific evidence) per day. (The bioavailability of these substances means the soluble extract having toxicological significance):

- 0.2 mg for antimony.
- 0.1 mg for arsenic.
- 25.0 mg for barium.
- 0.6 mg for cadmium.
- 0.3 mg for chromium.
- 0.7 mg for lead.
- 0.5 mg for mercury.
- 5.0 mg for selenium.

Toys must not contain dangerous substances or preparations within the meaning of Directives 67/548/EEC and 88/379/EEC in amounts that may harm the health of children using them. In all cases, it is strictly forbidden to include dangerous substances or preparations in a toy if

they are going to be used while the toy is being used. But if a limited number of substances or preparations are essential to the functioning of certain toys, in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic molding, enameling, photography, or similar activities, they are permitted up to a maximum concentration level to be defined for each substance or preparation by the European standardization body CEN (See *Harmonized Standards on Page 8 of this report.*) And the permitted substances and preparations must also comply with Community classification rules for labeling.

#### **4. Electrical properties**

Electric toys must not be powered by electricity exceeding 24 volts and no part of the toy may exceed 24 volts.

Parts of toys that 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 conducted to such parts) must be properly insulated and mechanically protected to prevent the risk of such shock.

Electric toys must be made so that maximum temperatures reached by all directly accessible surfaces will not cause burns when touched.

#### **C. Hygiene Toys**

Hygiene toys must be so designed and manufactured as to meet the requirements of hygiene and cleanliness to avoid any risk of infection, sickness, and contamination.

#### **D. Radioactivity Toys**

Radioactivity toys must not contain radioactive elements or substances in forms or proportions likely to be detrimental to a child's health. Please refer to Council Directive 80/836/Euratom for the requirements that apply.

#### **E. Warnings and Indications of Precautions**

There are warnings and indications of precautions to be taken during use that must be given for certain toys. Some or all of these warnings and precautions, together with the information specified above, must be given in the appropriate national language or languages in states where the toys are placed on the market:

- *Toys that might be dangerous for children under 36 months of age* have to bear a warning, such as: “Not suitable for children under 36 months” or “Not suitable for children under three years,” along with a brief indication, which may also appear in the instructions for use, of the specific risks calling for this restriction. This provision does not apply to toys that are clearly unsuitable for children under 36 months.

- *Slides, suspended swings and rings, trapezes, ropes, and similar toys attached to a crossbeam* must be accompanied by instructions that state the need to check and maintain the main parts (suspensions, fixings, anchorages, etc.) at intervals, and point out that, if these checks are not carried out, the toy may cause a fall or overturn. Instructions must also be given as to the correct assembly of the toy, indicating those parts that can present dangers if incorrectly assembled.
- *Functional toys* are those that are used in the same way as, and are often scale models of, appliances or installations intended for adults. Functional toys or their packaging must bear the marking, “Warning: To be used under the direct supervision of an adult.” In addition, these toys should be accompanied by directions giving working instructions as well as the precautions to be taken by the user, with the warning that failure to take these precautions will expose the user to the hazards—to be specified—normally associated with the appliance or product of which the toy is a scale model or an imitation. It must also state that the toy must be kept out of the reach of very young children.
- *Toys containing inherently dangerous substances or preparations* include chemical toys, skates and skateboards for children, and toys intended for use in water. They must warn of the dangerous elements and also provide precautions to be taken by the user to avoid the hazards associated with them. Additionally, first aid instructions to be followed in the event of a serious accident with the toy must be included, along with a warning to keep the toy out of the reach of very young children. Additional, specific warnings for all 3 groups are detailed below:
  - Chemical toys (*e.g., chemistry sets, plastic embedding sets, miniature workshops for ceramics, enameling, or photography and similar toys*) must bear the following marking on their packaging: “Warning: for children over [manufacturer fills in an appropriate age] years of age only. For use under adult supervision.”
  - Skates and skateboards for children *that are offered for sale as toys* shall bear the marking: “Warning: protective equipment should be worn.” Moreover, the instructions for use shall contain a reminder that the toy must be used with caution, since it requires great skill to avoid falls or collisions that may injure the user. Some indication should also be given as to recommended protective equipment (*i.e., helmets, gloves, knee-pads, elbow-pads, etc.*).
  - Toys intended for use in water must contain the admonition “Warning! Only to be used in water in which the child is within its depth and under supervision.”

### III. Harmonized Standards

Standards can be important guides to the Manufacturer. Standards interpret the safety objectives and also provide the technical route to compliance.

The most direct route to compliance through standards is the use of Harmonized Standards (See *NIST SP 951, Page 10*). A Manufacturer who uses Harmonized Standards in the design and production of devices is presumed in conformity with the Essential Requirements of the directive (See *NIST SP 951, Page 11*). The use of Harmonized Standards is the most direct route to compliance with any New Approach directive.

The principle of applying standards, therefore, is the following:

Harmonized Standards, which have been developed specifically to deal with the Essential Requirements of the Safety of Toys Directive, provide a presumption of conformity (See *NIST SP 951, Page 11*) and allow the manufacturer to self certify (See *NIST SP 951, Page 20*) the toys.

In the absence of Harmonized Standards, the Manufacturer is allowed to comply with any appropriate specifications that may demonstrate conformity with the safety objectives, or the Essential Requirements, of the directive. However, the Manufacturer must bear the burden of proof that the use of specifications other than Harmonized Standards brings the product into conformance.

This means that toys that do not conform in whole or in part to the applicable Harmonized Standards will require approval from a Notified Body (See *Article 8 (2), Article 10, and NIST SP 951, Page 20*). In other words, before the CE Marking can be affixed and the product placed on the EEA market, the Notified Body must confirm that the toy meets the essential requirements (See EC-Type Examination in *NIST SP 951, Page 22*) and See *Article 8 (2), Article 10* of the directive.

*Note: Notified Bodies are referred to as “Approved Bodies” within the text of the directive.*

#### **A. Harmonized Standard - EN 71**

The Harmonized Standard for the safety of toys is EN 71. It aims at reducing as much as possible risks that are not evident to users. It does not, however, cover inherent dangers (e.g. instability of scooters, sharp needles in a sewing kit, etc.) that should be obvious to children or the persons in charge of them.

*Note: The directive assumes that the toys will be used in the manner for which they are intended. Allowances should also be made for normal or foreseeable misuse, bearing in mind the normal behavior of children who do not generally share the same degree of care as the average adult user.*

The EN 71 consists of the following parts:

- Part 1: Mechanical and physical properties;
- Part 2: Flammability;

- Part 3: Migration of certain elements;
- Part 4: Experimental sets for chemistry and related activities;
- Part 5: Chemical toys (sets) other than experimental sets;
- Part 6: Graphical symbol for age warning labeling.

Harmonized Standards often contain language that parallels the language in the related directive. The “migration of elements” standard, EN 71-3, is an example of an attribute where the standard and related directive are in harmony. EN 71-3 prescribes the same elements and concentration that appear at Part II (3) (2) of Annex II of the Safety of Toys Directive. It also defines a test methodology.

*Note: The EN 71 family of standards may not meet every safety attribute mandated by the Essential Requirements of the directive. The Manufacturer may have to rely on other standards or specifications.*

#### **IV. The Technical File**

The Manufacturer must compile a Technical File (See NIST SP 951, Page 24). This file contains all the relevant information that is needed to demonstrate that the product meets the essential health and safety requirements of the Toy Directive.

The Manufacturer or his Authorized Representative (See NIST SP 951, Page 23) must make this documentation, including the Declaration of Conformity, available to the Surveillance Authorities (See NIST SP 951, Page 34) for inspection purposes.

Where neither the Manufacturer nor his Authorized Representative are established in the European Union, the obligation to keep the technical documentation available falls to the person(s) who place(s) the product on the European market.

The technical file in which the manufacturer offers proof of conformity with the essential requirements of the Safety of Toys Directive must include:

- A general description of the product, including any variants planned;
- Design drawings, methods of manufacture envisaged and diagrams of components, sub-assemblies, circuits, etc.;
- The descriptions and explanations necessary to understand the above-mentioned drawings and diagrams and the operations of the product;
- Test reports;
- Toxicity reports;
- Instructions for use;
- Packaging and labeling;
- Marketing materials;
- Declaration of Conformity;
- Address of the manufacturer, his Authorized Representative, or the importer.

## **V. CE Marking**

The Manufacturer is obliged to place the CE Marking on the toy (See *NIST SP 951, Page 17*).

## **VI. Declaration of Conformity**

**Declaration of Conformity** (See *NIST SP 951, Page 26*.)

The Manufacturer must draw up a Declaration of Conformity and keep a copy with the Technical File. The Declaration of Conformity must contain the following elements:

- Name and address of the Manufacturer and/or his Authorized Representative;
- Product name of the toy;
- Reference to the applicable directive(s)
- Reference to applied Harmonized Standards;
- Where appropriate, references to the specifications with which conformity is declared;
- Identification of the signatory who has been empowered to enter into commitments on behalf of the Manufacturer or his Authorized Representative established within the Community.

For a sample of a Declaration of Conformity, see *NIST SP 951, Page 28*.

**FOR FURTHER INFORMATION, PLEASE REFER TO THE TEXT OF THE DIRECTIVE, WHICH FOLLOWS.**



## Text of Directive on the Safety of Toys 88/378/EEC

The following text of the Directive on the Safety of Toys was taken from the Web Site <http://www.newapproach.org>

*Only European Community's legislation printed in the Official Journal of the European Communities is deemed to be authentic.*

### **COUNCIL DIRECTIVE** **Of 3 May 1988** **On The Approximation Of The Laws Of The Member States Concerning The** **Safety Of Toys (88/378/EEC)**

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100A thereof,

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee(3),

Whereas the laws, regulations and administrative provisions in force in the various Member States relating to the safety characteristics of toys differ in scope and content;

Whereas such disparities are liable to create barriers to trade and unequal conditions of competition within the internal market without necessarily affording consumers in the common market, especially children, effective protection against the hazards arising from the products in question;

Whereas these obstacles to the attainment of an internal market in which only sufficiently safe products would be sold should be removed;

Whereas, for this purpose, the marketing and free movement of toys should be made subject to uniform rules based on the objectives regarding protection of consumer health and

safety as set out in the Council resolution of 23 June 1986 concerning the future orientation of the policy of the European Economic Community for the protection and promotion of consumer interests (4);

Whereas, to facilitate proof of conformity with the essential requirements, it is necessary to have harmonized standards at European level which concern, in particular, the design and composition of toys so that products complying with them may be assumed to conform to the essential requirements;

Whereas these standards harmonized at European level are drawn up by private bodies and must remain non-mandatory texts;

Whereas for that purpose the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) are recognized as the competent bodies for the adoption of harmonized standards in accordance with the general guidelines for cooperation between the Commission and those two bodies signed on 13 November 1984;

Whereas, for the purposes of this Directive, a harmonized standard is a technical specification (European standard or harmonization document) adopted by one or both of those bodies upon a remit from the Commission in accordance with the provisions of Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards and regulations (5), as last amended by the Act of Accession of Spain and

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Portugal, and on the basis of the general guidelines;

Whereas, in accordance with the Council resolution of 7 May 1985 on a new approach to technical harmonization and standards (6), the harmonization to be achieved should consist in establishing the essential safety requirements to be satisfied by all toys if they are to be placed on the market;

Whereas, in view of the size and mobility of the toy market and the diversity of the products concerned, the scope of this Directive should be determined on the basis of a sufficiently broad definition of 'toys';

Whereas, nevertheless, it should be made clear that some products are not to be regarded as toys for the purposes of this Directive either because they are not in fact intended for children or because they call for supervision or special conditions of use;

Whereas toys placed on the market should not jeopardize the safety and/or health either of users or of third parties;

Whereas the standard of safety of toys should be determined in relation to the criterion of the use of the product as intended, but allowance should also be made for any foreseeable use, bearing in mind the normal behaviour of children who do not generally show the same degree of care as the average adult user;

Whereas the standard of safety of the toy must be considered when it is marketed, bearing in mind the need to ensure that this standard is maintained throughout the foreseeable and normal period of use of the toy;

Whereas compliance with the essential requirements is likely to guarantee consumer health and safety;

Whereas all toys placed on the market must comply with these requirements and, if they do, no obstacle must be put in the way of their free movement;

Whereas toys may be presumed to comply with these essential requirements where they are in conformity with the harmonized standards, reference numbers of which have been published in the Official Journal of the

European Communities;

Whereas toys that conform to a model approved by an approved body may also be regarded as complying with the essential requirements;

Whereas such conformity must be certified by the affixing of a European mark;

Whereas certification procedures must be established to define the way in which national approved bodies have to approve models of toys not in conformity with standards and issue type-examination certificates for them and for toys in conformity with standards, a model of which is submitted to them for approval;

Whereas adequate information for the Member States, the Commission and all the approved bodies must be provided for at the various stages of the certification and inspection procedures;

Whereas Member States must appoint bodies, called 'approved bodies', for the purposes of applying the system introduced for toys;

Whereas adequate information on these bodies must be provided and they must all comply with minimum criteria for their approval;

Whereas cases might arise where a toy does not satisfy the essential safety requirements;

Whereas, in such cases, the Member State which ascertains this fact must take all appropriate measures to withdraw the products from the market or to prohibit their being placed on the market;

Whereas a reason must be given for this decision and, where the reason is a shortcoming in the harmonized standards, these, or a part thereof, must be withdrawn from the list published by the Commission;

Whereas the Commission is to ensure that the harmonized European standards in all the areas covered by the essential requirements listed in Annex II are drawn up in sufficient time to enable Member States to adopt and publish the necessary provisions by 1 July 1989;

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Whereas the national provisions adopted on the basis of this Directive should consequently become effective on 1 January 1990;

Whereas provision must be made for suitable action to be taken against anyone wrongfully affixing a mark of conformity;

Whereas checks on the safety of toys already on the market must be carried out by the competent authorities of the Member States;

Whereas, for some categories of toys that are particularly dangerous or intended for very young children, warnings or details of precautions to be taken must also be given;

Whereas the Commission must receive regular information on activities carried out under this Directive by the approved bodies;

Whereas those to whom any decision taken under this Directive is addressed must know the reason for that decision and the remedies open to them;

Whereas the opinion of the Scientific Advisory Committee for the evaluation of the toxicity and ecotoxicity of chemical compounds has been taken into account with respect to the health-based limits of bioavailability of metallic compounds in toys to children,

HAS ADOPTED THIS DIRECTIVE:

#### Article 1

1. This Directive shall apply to toys. A 'toy' shall mean any product or material designed or clearly intended for use in play by children of less than 14 years of age.
2. The products listed in Annex I shall not be regarded as toys for the purposes of this Directive.

#### Article 2

1. Toys may be placed on the market only if they do not jeopardize the safety and/or health of users or third parties when they are used as intended or in a foreseeable way, bearing in mind the normal behaviour of children.
2. In the condition in which it is placed on the

market, taking account of the period of foreseeable and normal use, a toy must meet the safety and health conditions laid down in this Directive.

3. For the purposes of this Directive, the expression 'placed on the market' shall cover both sale and distribution free of charge.

#### Article 3

Member States shall take all steps necessary to ensure that toys cannot be placed on the market unless they meet the essential safety requirements set out in Annex II.

#### Article 4

Member States shall not impede the placing on the market on their territory of toys which satisfy the provisions of this Directive.

#### Article 5

1. Member States shall presume compliance with the essential requirements referred to in Article 3 in respect of toys bearing the EC mark provided for in Article 11, hereinafter referred to as 'EC mark', denoting conformity with the relevant national standards which transpose the harmonized standards the reference numbers of which have been published in the Official Journal of the European Communities. Member States shall publish the reference numbers of such national standards.
2. Member States shall presume that toys in respect of which the manufacturer has not applied the standards referred to in paragraph 1, or has applied them only in part, or for which no such standards exist, satisfy the essential requirements referred to in Article 3 where, after receipt of an EEC type-examination certificate, their conformity with the approved model has been certified by the affixation of the EC mark.

#### Article 6

1. Where a Member State or the Commission considers that the harmonized standards referred to in Article

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5 (1) do not entirely satisfy the essential requirements referred to in Article 3, the Commission or the Member State shall refer the matter to the Standing Committee set up under Directive 83/189/EEC, hereinafter referred to as 'the committee', setting out its reasons. The committee shall issue an opinion as a matter of urgency. After receiving the committee's opinion, the Commission shall notify the Member States whether or not the standards concerned or a part thereof have to be withdrawn from the publications referred to in Article 5 (1).

2. The Commission shall inform the European standardization body concerned and, if necessary, issue a new standardization brief.

#### Article 7

1. Where a Member State ascertains that toys bearing the EC mark which are used as intended or in accordance with Article 2 are likely to jeopardize the safety and/or health of consumers and/or third parties, it shall take all appropriate measures to withdraw the products from the market, or to prohibit or restrict their placing on the market. The Member State shall inform the Commission immediately of this measure and indicate the reasons for its decision, stating in particular whether the non-compliance results from:
  - (a) failure to meet the essential requirements referred to in Article 3, if the toy does not meet the standards referred to in Article 5 (1);
  - (b) incorrect application of the standards referred to in Article 5 (1);
  - (c) shortcomings in the standards referred to in Article 5 (1).
2. The Commission shall enter into consultation with the parties concerned as soon as possible. Where, after such consultation, the Commission finds that any measure as referred to in paragraph 1 is justified, it shall forthwith so inform the Member State that took the action and the other Member States. Where the decision referred to in paragraph 1 is attributed to shortcomings in the standards, the

Commission, after consulting the parties concerned, shall bring the matter before the Committee within two months if the Member State which has taken the measures intends to maintain them and shall initiate the procedures referred to in Article 6.

3. Where the toy which does not comply with the requirements bears the EC mark, the competent Member State shall take appropriate measures and inform the Commission, which shall inform the other Member States.
4. The Commission shall ensure that the Member States are kept informed of the progress and outcome of this procedure.

#### Article 8

1.
  - (a) Before being placed on the market, toys manufactured in accordance with the harmonized standards referred to in Article 5 (1) must have affixed to them the EC mark by which the manufacturer or his authorized representative established within the Community confirms that the toys comply with those standards;
  - (b) The manufacturer or his authorized representative established within the Community shall keep the following information available for inspection: - a description of the means (such as the use of a test report or technical file) whereby the manufacturer ensures conformity of production with the standards referred to in Article 5 (1) and, as appropriate: an EC type-certificate drawn up by an approved body; copies of the documents the manufacturer has submitted to the approved body; a description of the means whereby the manufacturer ensures conformity with the approved model, - the addresses of the places of manufacture and storage, - detailed information concerning the design and manufacture. Where neither the manufacturer nor his authorized representative are established within the Community, the above obligation to keep a dossier available shall be the responsibility of the person who places the toy on the Community market.

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- 2.
- (a) Toys which do not conform in whole or in part to the standards referred to in Article 5 (1) must have affixed to them, before being placed on the market, the EC mark by which the manufacturer or his authorized representative established within the Community confirms that the toy concerned conforms to the model examined in accordance with the procedures laid down in Article 10 which an approved body has stated complies with the essential requirements referred to in Article 3;
- (b) the manufacturer or his authorized representative established within the Community shall keep the following information available for inspection: - a detailed description of manufacture, - a description of the means (such as the use of a test report or technical file) whereby the manufacturer ensures conformity with the approved model, - the addresses of the places of manufacture and storage, - copies of the documents the manufacturer has submitted to an approved body in accordance with Article 10 (2), - the test certificate for the sample or a certified copy thereof. Where neither the manufacturer nor his authorized representative is established within the Community, the above obligation to keep a dossier available shall be the responsibility of the person who places the toy on the market in the Community.
3. In the event of non-observance of the obligations laid down in paragraphs 1 (b) and 2 (b), the competent Member State shall take appropriate measures to ensure that those obligations are observed. Where non-observance of the obligations is obvious, it may in particular require the manufacturer or his authorized representative established within the Community to have a test performed at his own expense within a specified period by an approved body in order to verify compliance with the harmonized standards and essential safety requirements.

#### Article 9

1. The minimum criteria which Member States must meet in order to appoint the

approved bodies referred to in this Directive are contained in Annex III.

2. Each Member State shall notify the Commission of the approved bodies responsible for carrying out the EC type-examination referred to in Articles 8 (2) and 10. The Commission shall publish a list of these bodies, with the distinguishing numbers it has given them, in the Official Journal of the European Communities for information and shall be responsible for updating it.
3. A Member State which has approved a body shall withdraw approval if it finds that the body no longer meets the criteria listed in Annex III. It shall forthwith inform the Commission thereof.

#### Article 10

1. EC type-examination is the procedure by which an approved body ascertains and certifies that a model of a toy satisfies the essential requirements referred to in Article 3.
2. The application for EC type-examination shall be lodged with an approved body by the manufacturer or by his authorized representative established within the Community. The application shall include: - a description of the toy, - the name and address of the manufacturer or of his authorized representative or representatives, and the place of manufacture of the toy, - comprehensive manufacturing and design data; and shall be accompanied by a model of the toy to be manufactured.
3. The approved body shall carry out the EC type-examination in the manner described below: - it shall examine the documents supplied by the applicant and establish whether they are in order, - it shall check that the toy would not jeopardize safety and/or health, as provided for in Article 2, - it shall carry out the appropriate examinations and tests - using as far as possible the harmonized standards referred to in Article 5 (1) - in order to check whether the model meets the essential requirements referred to in Article 3, - it may ask for further examples

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of the model.

4. If the model complies with the essential requirements referred to in Article 3, the approved body shall draw up an EC type-examination certificate which shall be notified to the applicant. This certificate shall state the conclusions of the examination, indicate any conditions attaching to it and be accompanied by the descriptions and drawings of the approved toy. The Commission, the other approved bodies and the other Member States may obtain on request a copy of the certificate and, on reasoned request, a copy of the design and manufacturing schedule and the reports on the examinations and tests carried out.
5. An approved body which refuses to issue an EC type-examination certificate shall so inform the Member State which approved it and the Commission, giving the reasons for refusal.

#### Article 11

1. The EC mark referred to in Articles 5, 7 and 8 and the name and/or trade name and/or mark and address of the manufacturer or his authorized representative or the importer into the Community shall as a rule be affixed either to the toy or on the packaging in a visible, easily legible and indelible form. In the case of small toys and toys consisting of small parts these particulars may be affixed in the same way to the packaging, to a label or to a leaflet. Where the said particulars are not affixed to the toy, the consumer's attention must be drawn to the advisability of keeping them.
2. The EC mark shall consist of the symbol 'CE'.
3. The affixing to toys of marks or inscriptions that are likely to be confused with the EC mark shall be prohibited.
4. The particulars referred to in paragraph 1 may be abbreviated provided that the abbreviation enables the manufacturer, his authorized representative or the importer into the Community to be identified.

5. Annex IV sets out the warnings and indications of precautions to be taken during use that have to be given for certain toys. Member States may require that these warnings and precautions, or some of them, together with the information specified in paragraph 4, be given in their own national language or languages when the toys are placed on the market.

#### Article 12

1. Member States shall take the necessary measures to ensure that sample checks are carried out on toys which are on their market, so as to verify their conformity with this Directive. The authority responsible for inspection: - shall obtain access, on request, to the place of manufacture or storage and to the information referred to in Article 8 (1) (b) and (2) (b), - may ask the manufacturer, his authorized representative or the person responsible for marketing the toy established within the Community to supply the information as provided for in Article 8 (1) (b) and (2) (b) within a period specified by the Member State, - may select a sample and take it away for examination and testing.
2. Every three years, Member States shall send the Commission a report on the application of this Directive.
3. The Member States and the Commission shall take the necessary measures to guarantee confidentiality with regard to the forwarding of the copies relating to the EC type-examination referred to in Article 10 (4).

#### Article 13

Member States shall regularly inform the Commission of the activities carried out in pursuance of this Directive by the bodies they have approved so that the Commission may ensure that the inspection procedures are implemented correctly and without discrimination.

#### Article 14

Any decision taken pursuant to this Directive and involving restrictions on the placing of the toy on the market shall state the exact grounds

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on which it is based. It shall be notified at the earliest opportunity 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 15

1. Member States shall adopt and publish by 30 June 1989 the provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof. They shall apply these provisions from 1 January 1990.
2. Member States shall communicate to the Commission the texts of the provisions of national law which they adopt in the field covered by this Directive.

#### Article 16

This Directive is addressed to the Member States.

Done at Brussels, 3 May 1988.

For the Council

The President

M. BANGEMANN

(1) OJ No C 282, 8. 11. 1986, p. 4. (2) OJ No C 246, 14. 9. 1987, p. 91 and Decision of 9 March 1988 (not yet published in the Official Journal). (3) OJ No C 232, 31. 8. 1987, p. 22. (4) OJ No C 167, 5. 7. 1986, p. 1. (5) OJ No L 109, 26. 4. 1983, p. 8. (6) OJ No C 136, 4. 6. 1985, p.1.

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**ANNEX I PRODUCTS NOT REGARDED AS TOYS FOR THE PURPOSE OF THIS DIRECTIVE**  
**(Article 1 (1))**

1. Christmas decorations
2. Detailed scale models for adult collectors
3. Equipment intended to be used collectively in playgrounds
4. Sports equipment
5. Aquatic equipment intended to be used in deep water
6. Folk dolls and decorative dolls and other similar articles for adult collectors
7. Professional' toys installed in public places (shopping centres, stations, etc.)
8. Puzzles with more than 500 pieces or without picture, intended for specialists
9. Air guns and air pistols
10. Fireworks, including percussion caps (1)
11. Slings and catapults
12. Sets of darts with metallic points
13. Electric ovens, irons or other functional products operated at a nominal voltage exceeding 24 volts
14. Products containing heating elements intended for use under the supervision of an adult in a teaching context
15. Vehicles with combustion engines
16. Toy steam engines
17. Bicycles designed for sport or for travel on the public highway
18. Video toys that can be connected to a video screen, operated at a nominal voltage exceeding 24 volts
19. Babies' dummies
20. Faithful reproductions of real fire arms
21. Fashion jewellery for children

(1) With the exception of percussion caps specifically designed for use in toys without prejudice to more stringent provisions already existing in certain Member States.



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## ANNEX II ESSENTIAL SAFETY REQUIREMENTS FOR TOYS

### I. GENERAL PRINCIPLES

1. In compliance with the requirements of Article 2 of the Directive, the users of toys as well as third parties must be protected against health hazards and risk of physical injury when toys are used as intended or in a foreseeable way, bearing in mind the normal behaviour of children. Such risks are those: (a) which are connected with the design, construction or composition of the toy; (b) which are inherent in the use of the toy and cannot be completely eliminated by modifying the toy's construction and composition without altering its function or depriving it of its essential properties.
2.
  - (a) The degree of risk present in the use of a toy must be commensurate with the ability of the users, and where appropriate their supervisors, to cope with it. This applies in particular to toys which, by virtue of their functions, dimensions and characteristics, are intended for use by children of under 36 months.
  - (b) To observe this principle, a minimum age for users of toys and/or the need to ensure that they are used only under adult supervision must be specified where appropriate.
3. Labels on toys and/or their packaging and the instructions for use which accompany them must draw the attention of users or their supervisors fully and effectively to the risks involved in using them and to the ways of avoiding such risks.

### II. PARTICULAR RISKS

1. Physical and mechanical properties
  - (a) 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.
  - (b) 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.
  - (c) 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.
  - (d) Toys, and their component parts, and any detachable parts of toys which are clearly intended for use of toys which are clearly intended for use by children under 36 months must be of such dimensions as to prevent their being swallowed and/or inhaled.
  - (e) Toys, and their parts and the packaging in which they are contained for retail sale must not present risk of strangulation or suffocation.
  - (f) 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.
  - (g) 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 latter can open easily from the inside.

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- (h) 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.
  - (i) 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 unreasonable risk of physical injury to the user or to third parties.
  - (j) Toys containing heating elements must be so constructed as to ensure that: - the maximum temperature of any accessible surfaces does not cause burns when touched, - 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.

## 2. Flammability

- (a) Toys must not constitute a dangerous flammable element in the child's environment. They must therefore be composed of materials which: 1. do not burn if directly exposed to a flame or spark or other potential seat of fire; or 2. are not readily flammable (the flame goes out as soon as the fire cause disappears); or 3. if they do ignite, burn slowly and present a low rate of spread of the flame; or 4. irrespective of the toy's chemical composition, are treated so as to delay the combustion process. Such combustible materials must not constitute a risk of ignition for other materials used in the toy.
- (b) Toys which, for reasons essential to their functioning, contain dangerous substances or preparations as defined in Council Directive 67/548/EEC (1), 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.
- (c) Toys must not be explosive or contain elements or substances likely to explode when used as specified in Article 2 (1) of the Directive. This provision does not apply to toy percussion caps, for which reference should be made to point 10 of Annex I and the related footnote.
- (d) Toys and, in particular, chemical games and toys, must not contain as such substances or preparations: - which, when mixed, may explode: - through chemical reaction, or through heating, - when mixed with oxidizing substances, - which contain volatile components which are flammable in air and liable to form flammable or explosive vapour/air mixture.

## 3. Chemical properties

- (a) Toys must be so designed and constructed that, when used as specified in Article 2 (1) of the Directive, they do not present health hazards or risks of physical injury by ingestion, inhalation or contact with the skin, mucous tissues or eyes. They must in all cases comply with the relevant Community legislation relating to certain categories of products or to the prohibition, restriction of use or labelling of certain dangerous substances and preparations.
- (b) In particular, for the protection of children's health, bioavailability resulting from the use of toys must not, as an objective, exceed the following levels per day: 0,2 mg for antimony, 0,1 mg for arsenic, 25,0 mg for barium, 0,6 mg for cadmium, 0,3 mg for chromium, 0,7 mg for lead, 0,5 mg for mercury, 5,0 mg for selenium, (1) OJ No 196, 16. 8. 1967, p. 1/67. or such other values as may be laid down for these or other substances in Community legislation based on scientific evidence. The bioavailability of these substances means the soluble extract having toxicological

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significance.

- (c) Toys must not contain dangerous substances or preparations within the meaning of Directives 67/548/EEC and 88/379/EEC <sup>(1)</sup> in amounts which may harm the health of children using them. At all events it is strictly forbidden to include, in a toy, dangerous substances or preparations if they are intended to be used as such while the toy is being used. However, where a limited number of substances or preparations are essential to the functioning of certain toys, in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, they are permitted up to a maximum concentration level to be defined for each substance or preparation by mandate to the European Committee for Standardization (CEN) according to the procedure of the committee set up by Directive 83/189/EEC, provided the permitted substances and preparations comply with the Community classification rules in respect of labelling, without prejudice to point 4 of Annex IV.

#### 4. Electrical properties

- (a) Electric toys must not be powered by electricity of a nominal voltage exceeding 24 volts and no part of the toy may exceed 24 volts.
- (b) 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.
- (c) 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.

5. Hygiene 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.

6. Radioactivity Toys must not contain radioactive elements or substances in forms or proportions likely to be detrimental to a child's health. Council Directive 80/836/Euratom shall apply <sup>(2)</sup>.

<sup>(1)</sup> See page 14 of this Official Journal. <sup>(2)</sup> OJ No L 246, 17. 9. 1980, p. 1.

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### **ANNEX III CONDITIONS TO BE FULFILLED BY THE APPROVED BODIES (Article 9 (1))**

The bodies designated by the Member States must fulfil the following minimum conditions:

1. availability of personnel and of the necessary means and equipment;
2. technical competence and professional integrity of personnel;
3. independence, in carrying out the tests, preparing the reports, issuing the certificates and performing the surveillance provided for in this Directive, of staff and technical personnel in relation to all circles, groups or persons directly or indirectly concerned with toys;
4. maintenance of professional secrecy by personnel;
5. subscription of a civil liability insurance unless that liability is covered by the state under national law. Fulfilment of the conditions under 1 and 2 shall be verified at intervals by the competent authorities of the Member States.

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## ANNEX IV WARNINGS AND INDICATIONS OF PRECAUTIONS TO BE TAKEN WHEN USING TOYS (Article 11 (5))

Toys must be accompanied by appropriate clearly legible warnings in order to reduce inherent risks in their use as described in the essential requirements, and specifically:

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: 'Not suitable for children under 36 months' or 'Not suitable for children under three years' together with a brief indication, which may also appear in the instructions for use, of the specific risks 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 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.
3. Functional toys. 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 will also be indicated that the toy must be kept out of the reach of very young children. 'Functional toys' means toys which are used in the same way as, and are often scale models of, appliances or installations intended for adults.
4. Toys containing inherently dangerous substances or preparations.

### Chemical toys

- (a) 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.
  - (b) In addition to the instructions provided for in (a), chemical toys shall bear the following marking on their packaging: 'Warning: for children over XX (Age to be decided by the manufacturer) years of age only. 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.
5. Skates and skateboards for children

If these products are offered for sale as toys they shall bear the marking: 'Warning: protective equipment should be worn'. 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.).

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6. Toys intended for use in water

The toys intended for use in water defined in Section II.1 (f) of Annex II shall contain the warning in accordance with CEN's brief to adapt standard EN/71, parts 1 and 2: 'Warning! Only to be used in water in which the child is within its depth and under supervision'.

## Harmonized Standards for Toys

Note: This list of Toys Harmonized Standards is from the Web Site:  
<http://www.newapproach.org>

| European Standards Bodies  | Standard reference                 | Titles   | Ratification date | Publication OJ      |
|--|------------------------------------|--|-------------------|---------------------|
| CEN  | EN 71                              | Safety of toys:  |                   |                     |
| CEN  | EN 71-1:1988                       | Part 1: Mechanical and physical properties                     | 1988              | C 340 of 1999-11-27 |
| CEN  | EN 71-1:1998                       | Part 1: Mechanical and physical properties                     | 1998              | C 340 of 1999-11-27 |
| <p>This publication does not concern the C-weighted peak emission sound pressure level produced by a toy using percussion caps, as referred to standards EN 71-1:1998 in Clause 4.20(d), in respect of which it grants no presumption of conformity to the provisions of Directive 88/378/EEC.</p> |                                    |  |                   |                     |
| CEN  | EN 71-2:1993                       | Part 2: Flammability   | 1993              | C 340 of 1999-11-27 |
| CEN  | EN 71-3:1994                       | Part 3: Migration of certain element                           | 1994              | C 340 of 1999-11-27 |
| CEN  | EN 71-4:1990                       | Part 4: Experimental sets for chemistry and related activities | 1990              | C 340 of 1999-11-27 |
| CEN  | EN 71-4:1990/A1                    | Part 4: Experimental sets for chemistry and related activities | 1998              | C 340 of 1999-11-27 |
| CEN  | EN 71-5:1993                       | Part 5: Chemical toys (sets) other than experimental sets      | 1993              | C 340 of 1999-11-27 |
| CEN  | EN 71-6:1994                       | Part 6: Graphical symbol for age warning labeling              | 1994              | C 340 of 1999-11-27 |
| CENELEC  | EN 50088:1966                      | Safety of electric toys  | 1995              | C 340 of 1999-11-27 |
| CENELEC  | Amendment A1:1996 at EN 50088:1996 | Safety of electric toys  | 1995              | C 340 of 1999-11-27 |
| CENELEC  | Amendment A2:1997 at EN 50088:1996 | Safety of electric toys  | 1997              | C 340 of 1999-11-27 |