



TOY SAFETY DIRECTIVE 2009/48/EC



European Commission
Enterprise and Industry

Directive 2009/48/EC on the safety of toys

**Replaces Directive 88/378/EEC
(20 years old)**

**Allows for free movement of safe toys in all
EU Member States**

**Contains essential safety requirements (= general
principles)**

**Technical details are provided in harmonised
standards (EN 71 series and EN 62115)**

Directive 2009/48/EC

Scope

Scope (Article 2.1):

“products designed or intended, whether or not exclusively, for use in play by children under 14 years of age”

Products not considered as toys: Annex I

Toys excluded from the scope: Article 2.2





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Guidance documents from the Expert Group on Toy Safety - Toys - Enterprise and Industry - Microsoft Internet Explorer provided

http://ec.europa.eu/enterprise/sectors/toys/documents/guidance/index_en.htm

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Guidance documents from the Expert Group on Toy Safety

These documents are non-binding documents intended to provide guidelines in order to help Member States and stakeholders on interpretation issues related to the Toy Safety Directive. These documents express the views of the majority of Members in the Expert Group on Toys Safety. The images appearing in the documents constitute examples intended to facilitate the decision-making on classification. They do not presuppose the conformity of the represented products.

N° 1	Community legislation applicable to "scooters" [7 MB] de fr	09/01/09
N° 2	Community legislation applicable to "floating seats" [9 KB] de fr	26/04/01
N° 3	The guidance document on the relationship between the Safety of Toys Directive and the Cadmium Directive (Directive 91/338/EEC) has become obsolete after the Court of Justice has given its judgment in case C-9/04	03/02/03
N° 4	Guidelines on the treatment of "grey zone" products - is a specific product covered by Directive 88/378/EEC or not? [26 KB] de fr	14/03/07
N° 5	Guidelines on the treatment of "grey zone" products - criteria to classify products consisting of miniatures to be assembled and painted and their support products [11 KB] de fr	13/02/03
N° 6	Guidelines on the treatment of "grey zone" products - criteria for differentiating dolls for adult collectors from toys [9 KB] de fr	13/02/03
N° 7	Guidelines on the treatment of "aquatic toys" - are certain aquatic devices/equipment covered by the Safety of Toys Directive (88/378/CEE) or not? [2 MB] de fr	21/06/07
N° 8	Guidance document on pools covered by the Toys Safety Directive [12 MB] de fr	30/06/08

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Safety requirements

ESSENTIAL SAFETY REQUIREMENTS

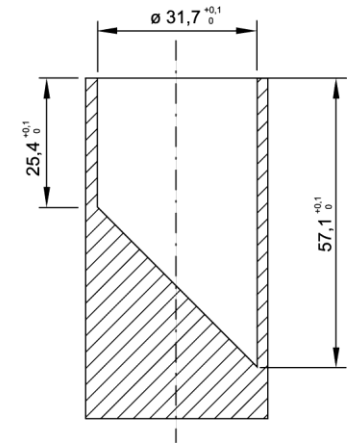
- **General safety requirement: Article 10.2**
- **Particular safety requirements: Annex II**
 - *Physical and mechanical properties*
 - *Flammability*
 - *Chemical properties*
 - *Electrical properties*
 - *Hygiene*
 - *Radioactivity*



PHYSICAL AND MECHANICAL PROPERTIES

Choking risk

= inhalation of small parts



Small parts are banned in toys for children under 36 months and in toys which are intended to be put in the mouth (for example music instruments)

CHEMICAL PROPERTIES (1)

BAN OF CMRs CATEGORY 1A, 1B AND 2

- 1) Substances that are classified as carcinogenic, mutagenic and toxic for reproduction, cat. 1A, 1B or 2, can in principle not be used in toys, components of toys or micro-structurally distinct parts of toys
- 2) Use of nickel in stainless steel permitted
- 3) Other uses can be permitted by the Commission

Amendment for permitting further nickel use in the pipeline

CHEMICAL PROPERTIES (2)

ALLERGIC FRAGRANCES

- 1) Ban for 55 allergenic fragrances
- 2) Labelling for 11 fragrances that are susceptible to be allergenic for certain persons

CHEMICAL PROPERTIES (3)

LIMIT VALUES FOR CERTAIN DANGEROUS SUBSTANCES

1) Migration limits for 19 "heavy elements"

2) Can be amended by the Commission
when new scientific evidence is available

Two amendments so far:

- Cadmium (Commission Directive 2012/7/EU)
- Barium (Commission Regulation (EU) No 681/2013)

Amendment for lead in the pipeline

CHEMICAL PROPERTIES (4)

LIMIT VALUES FOR CERTAIN DANGEROUS SUBSTANCES

Specific limit values can be set by the Commission for chemicals used in toys intended for use by children under 36 months or other toys intended to be placed in the mouth

- No specific limit values so far
- Amendments about to be adopted for TCEP/TCPP/TDCP and bisphenol A
- More amendments in the pipeline for kathon, BIT, formamide, phenol, ...

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*Safety assessment and
conformity assessment*

CONFORMITY ASSESSMENT

Choice of the **conformity assessment procedure**

- 1) **Self-verification** (Article 19.2) if
 - harmonised standard covering all safety aspects are complied with
- 2) **Third party verification** ("EC-type examination" - Article 19.3) if
 - harmonised standards do not exist
 - harmonised standards are not applied or only in part
 - harmonised standards are published with a restriction
 - manufacturer considers that toy necessitates third party verification

In both cases:

Explicit obligation to carry out an **analysis of hazards as well as the potential exposure to such hazards** ("safety assessment" – Article 18)

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Technical documentation

TECHNICAL DOCUMENTATION

- **Contains all relevant data of the means used by the manufacturer to ensure the compliance of the toy**
- **Drawn up in one of the EU official languages**
- **Needs to be kept 10 years after the toy is placed on the market**

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Declaration of conformity

EC DECLARATION OF CONFORMITY

- **Must state that the fulfilment of the requirements has been demonstrated**
- **The manufacturer assumes responsibility for the compliance of the toy**
- **To be translated into the language or languages required by the Member State in whose market the toy is placed or made available**

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CE marking

CE MARKING

- **Toys on the EU market must bear CE marking**
- **Affixed visibly, legibly and indelibly**
- **On the toy, affixed label or packaging**
- **If not visible from outside, it has to be on the packaging**

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Warnings

WARNINGS

Marking of the warnings

- **In a clearly visible, easily legible and understandable and accurate manner**
- **In a language(s) easily understood by consumers, as requested by the Member State on whose market the toy is placed**

WARNINGS

Specific warnings

- **For specific categories of toys: Annex V**
- **Specific warnings cannot appear where that warning conflicts with the intended use of the toy, as determined by virtue of its function, dimension and characteristics**



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Obligations for economic operators

OBLIGATIONS OF ECONOMIC OPERATORS

Economic operators are responsible for the compliance of the toy in relation to their role in the supply and distribution chain

Manufacturer

Design and manufacture in accordance with the requirements

Importer

Place only compliant toys on the European market

Distributor

Act with due care in relation to the applicable requirements

Authorised Representative

↑
level of responsibility

Draw up the technical documentation

Exclusively the manufacturer

Carry out safety and conformity assessments

Exclusively the manufacturer

The Authorised Representative may carry out parts of the conformity assessment procedure

Keep the technical documentation

Manufacturer

- **10 years after the toy has been placed on the market (same for the Authorised Representative)**

Importer

- **No obligation**

Distributor

- **No obligation**

Make available the **technical documentation upon request**

Manufacturer (and his Authorised Representative)

Importer

Distributor

- **Upon reasoned request, 10 years after the toy has been placed on the market**

Draw up the declaration of conformity

Manufacturer

- **Has an obligation**

Authorised Representative

- **If specified in the written mandate**

Importer

- **No obligation**

Distributor

- **No obligation**

Keep the DoC and make it available

*Manufacturer (and his Authorised Representative)
Importer*

- **Upon reasoned request, 10 years after the toy has been placed on the market**

Distributor

- **Upon reasoned request**

Affix CE mark and identification elements

Manufacturer (and his Authorised Representative)

- **Has an obligation**

Importer

- **Ensures it was done**

Distributor

- **Verify it was done**

Affix name and address

Manufacturer

- Has an obligation

Authorised Representative

- Only his address if the manufacturer is outside the EU

Importer

- Has an obligation

Distributor

- Verify it was done

Take all appropriate measures in relation to non compliant toys and cooperate with market surveillance authorities

Manufacturer

Importer

Distributor

- **Have an obligation**

Authorised Representative

- **If specified in the written mandate**

Identify the other Economic Operators

*Each economic operator must identify any other economic operator to whom he supplied a toy or who supplied him with a toy
10 years after the toy has been supplied to him*

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MORE INFORMATION

http://ec.europa.eu/enterprise/sectors/toys/index_en.htm

Questions?

