

Toy manufacturers, importers and distributors: your responsibilities

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Applies to:

England, Northern Ireland and Wales

How to produce and label toys for children to comply with safety and warning regulations.

Introduction

As a manufacturer, authorised representative of a manufacturer, importer or distributor of toys intended for children, you must comply with the provisions of the Toys (Safety) Regulations 2011 for toys placed on the market after 19 August 2011. These bring the [European Toy Safety Directive 2009/48/EC](#) into UK law [S.I. 2011 no.1881](#).

This is transposed into UK law by [S.I. 2010 NO. 1881](#).

The main requirements are that toys must:

- satisfy the ‘essential safety requirements’ in the regulations
- be properly marked to ensure traceability
- bear the CE mark
- be accompanied by instructions for use, and warnings where necessary

Technical documentation and a description of the conformity assessment method used for each toy must be available.

There are differing levels of obligation depending on your role as an economic operator (Directive 2009/48/EC) in the supply chain with manufacturers having the most significant obligation.

Roles of economic operators

The Toy Safety Directive 2009/48/EC defines the new obligations of 4 economic operators:

- manufacturers
- importers
- distributors
- authorised representative

The role adopted by an operator depends on how toys are purchased, who designed (or modified) the toy, the ownership of the brand of the toy and the stage in the production cycle at which the operator becomes involved.

The operator roles may be different to a company's normal trading role. For example, a company that physically imports a toy may adopt the role of a manufacturer or distributor depending on their involvement with the product or the business relationship with other operators in the supply chain. It is important to note that the operator role adopted needs to be assessed on a case by case basis.

Detailed guidance on deciding your operator type and associated obligations has been produced by the [British Toy and Hobby Association \(BTHA\)](#). It is for you to make sure that you comply with all applicable obligations.

Manufacturers' obligations

Manufacturers must:

- make sure the toy has been designed and manufactured to comply with the essential safety requirements during its foreseeable and normal period of use
- carry out a safety assessment of the toy
- demonstrate that an applicable conformity assessment procedure has been followed
- draw up the EC declaration of conformity and affix the CE marking
- draw up the technical documentation and keep it for 10 years
- apply information identifying the toy and manufacturer on the toy or packaging
- make sure the toy is accompanied by instructions for safe use and safety information where appropriate
- make sure that continuing production runs of the same toy remain in conformity
- carry out sample testing of marketed toys
- investigate and record any complaint made in relation to the toy and keep a register of complaints, non-compliant toys and recalled toys
- bring non-conforming toys into compliance and tell authorities if there is a safety risk and provide information to authorities on request
- identify the other economic operators in the supply chain

Authorised representatives' obligations

The manufacturer may appoint by written mandate a person established in the EU as an authorised representative to act on their behalf in relation to the above. The mandate must include the requirement to keep the technical documentation and the Declaration of Conformity for 10 years, the obligation to bring non-conforming toys into compliance and tell authorities if there is a safety risk and the requirement to identify the other economic operators in the supply chain. It cannot include drawing up technical documentation. The manufacturer retains responsibility for the performance of its authorised representative.

Importers' obligations

Importers must:

- make sure that the manufacturer has fulfilled their obligations above before placing a toy on the market
- make sure that the importer's name and address is marked on the toy or packaging
- make sure that the compliance of the toy is not affected by the conditions of storage or transport
- carry out sample testing of marketed toys
- investigate and record any complaint made in relation to the toy and keep a register of complaints, non-compliant toys and recalled toys
- bring non-conforming toys into compliance and inform the authorities if there is a safety risk
- keep a copy of the technical documentation for a period of 10 years
- identify the other economic operators in the supply chain

Distributors' obligations

Distributors must:

- verify that the manufacturer has applied information identifying the toy and manufacturer, applied the CE mark and that the toy is accompanied by instructions for safe use and safety information where appropriate
- verify that the importer has applied their name and address on the toy or packaging
- make sure that the compliance of the toy is not affected by the conditions of storage or transport
- bring non-conforming toys into compliance and inform the enforcement authorities, the importer or manufacturer if there is a safety risk and provide information relating to the compliance of the toy to an enforcement authority
- identify the other economic operators in the supply chain

Distributors have no obligations related to technical documentation but must comply with a request for information or documents they know or have regarding the toy's compliance with the safety requirements.

Toys to which the regulations apply

Toys are products designed or intended (whether or not exclusively) for use in play by children under 14 years old.

There are certain types of product that fulfil the definition of toys but are excluded from the scope of the regulations and these are:

- playground equipment intended for public use
- automatic playing machines, whether coin operated or not, intended for public use
- toy vehicles equipped with combustion engines
- toy steam engines
- slings and catapults

Annex 1 of the Toy Safety Directive 2009/48/EC sets out a list of products that do not fulfil the definition of a toy but could be confused with a toy. This is a non-exhaustive list. If a particular product is not mentioned in the list, it does not mean that it is automatically a toy.

We recommend that you look at the [guidance documents](#) to help decide whether or not a product is a toy.

List of products that are not considered as toys

The following is a list of products that are not considered as toys within the meaning of this directive - Article 2(1).

- decorative objects for festivities and celebrations
- products for collectors, provided that the product or its packaging bears a visible and legible indication that it is intended for collectors of 14 years of age and above - examples of this category are: (a) detailed and faithful scale models (b) kits for the assembly of detailed scale models (c) folk dolls and decorative dolls and other similar articles (d) historical replicas of toys (e) reproductions of real firearms
- sports equipment, including roller skates, inline skates, and skateboards intended for children with a body mass of more than 20 kg
- bicycles with a maximum saddle height of more than 435 mm, measured as the vertical distance from the ground to the top of the seat surface, with the seat in a horizontal position and with the seat pillar set to the minimum insertion mark
- scooters and other means of transport designed for sport or which are intended to be used for travel on public roads or public pathways
- electrically driven vehicles which are intended to be used for travel on public roads, public pathways, or the pavement
- aquatic equipment intended to be used in deep water, and swimming learning devices for children, such as swim seats and swimming aids
- puzzles with more than 500 pieces
- guns and pistols using compressed gas, with the exception of water guns and water pistols, and bows for archery over 120 cm long
- fireworks, including percussion caps which are not specifically designed for toys
- products and games using sharp-pointed missiles, such as sets of darts with metallic points
- 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
- products intended for use for educational purposes in schools and other pedagogical contexts under the surveillance of an adult instructor, such as science equipment
- 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
- interactive software, intended for leisure and entertainment, such as computer games, and their storage media, such as CDs
- babies' soothers
- child-appealing luminaires
- electrical transformers for toys
- fashion accessories for children which are not for use in play

Essential safety requirements for toys

Toys must not adversely affect the safety or health of users or third parties when used as intended or in a foreseeable way, bearing in mind the behaviour of children. Take the ability of the user or supervisor into account particularly for toys intended for children under 36 months. This provision does not apply to toys that are manifestly unsuitable for children under 36 months, but equally if the toy is likely to appeal primarily to children under 36 months, it is not permitted to claim otherwise. For further advice see [guidance document number 11 on the application of the Directive on the Safety of Toys \(88/378/EEC\)](#).

The particular safety requirements are set out in Annex II to the directive and cover hazards relating to physical/mechanical properties, flammability, electrical properties, hygiene requirements, radioactivity and chemical properties.

After 20 July 2013 there are additional essential safety requirements relating to chemical properties and these include:

- changed migration limits for a wider range of elements and toy materials
- restrictions and labelling requirements for allergenic fragrances
- restrictions on the presence of chemicals classified as carcinogenic, mutagenic or reprotoxic (CMR)
- restrictions on certain other toys for children under 36 months or intended to be placed in the mouth (Appendix C of the directive)
- compliance with the Cosmetic Safety Directive for Dolls' make-up

The full provisions of Annex II, part 3 apply.

Since then there have been the following amendments to Annex II, part 3:

[Cadmium levels](#)

[Barium levels](#)

[Restrictions on TCEP, TCPP and TDCP in Appendix C of Annex II](#)

[Levels of Bisphenol A](#)

There is also an entry in [Annex A of Appendix II in respect of nickel](#).

Safety assessment

A manufacturer is required to carry out a safety assessment before placing a toy on the market.

The safety assessment is an analysis of the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards that the toy may present, as well as an assessment of the potential exposure to such hazards.

[Guidance on safety assessment](#) is on the Europa website and from the [British Toy and Hobby Association](#).

Use of standards

Toys which conform to the relevant harmonised standards which have been published in the Official Journal of the European Union are presumed to conform to the essential safety requirements.

There is a range of EN standards such as the EN71 series that cover the essential safety requirements in Annex II of the directive.

The [BTHA legislation guide for toys](#) gives examples of the typical standards often applied to toys.

Type examination

In the following circumstances an EC type examination by a notified body will be necessary:

- where the design or characteristics of the toy result in the hazards presented not being covered by standards
- where no standards exist
- where standards are published with a restriction
- where the manufacturer has not followed the standards completely or only in part

The notified body will perform the tests and examinations necessary to decide whether or not the toy satisfies the essential safety requirements and if it does the body will issue an EC type-examination certificate.

You can see [a list of UK notified bodies](#) on the Europa website.

EC declaration of conformity and CE marking

Where the toy has been shown to conform to the essential safety requirements the manufacturer must draw up an EC declaration of conformity to follow the structure set out in Annex III of the directive.

The manufacturer must affix the CE marking to the toy, to an affixed label or to the packaging. The mark must be visible at the point of sale, be easily legible and in an indelible form.

CE marking is a visible declaration by a manufacturer that the toy satisfies all the provisions of the Toys (Safety) Regulations 2011. It does not mean that the toy cannot be examined by an enforcement authority if they have reasonable grounds for suspecting an infringement of the regulations.

The CE marking is not a European safety mark or quality symbol intended for consumers. It indicates to enforcement authorities that the toy is intended for sale in the European Economic Area (EEA).

If a toy falls within other new approach directives, then, unless provided otherwise, it must comply with the requirements of that legislation as well. The CE marking will confirm that the product conforms to other new approach directives where they apply.

Technical documentation

The directive requires that a comprehensive technical file is maintained for each toy that includes:

- a detailed description of the design and manufacture including a list of components and materials
- the safety assessments
- a description of the conformity assessment procedure used
- a copy of the EC declaration of conformity
- the addresses of the places of manufacture and storage
- copies of any documents submitted to a notified body (where applicable)
- test reports or documentation demonstrating compliance to harmonised standards
- a copy of the EC type examination certificate (where applicable)
- safety assessment
- a colour image of the toy

Further guidance on safety assessment is available from:

- [British Toy and Hobby Association](#)
- [Europa website](#)

Instructions, markings and warnings

The toy must be accompanied by instructions and relevant safety information. These may also contain details such as use instructions or information regarding ways in which hazards may be further reduced, such as the requirement for adult supervision or by the use of additional personal protective equipment.

Traceability markings must be applied to the toy or packaging or instructions. These must include a model number type or batch number, the identification and address of the manufacturer and any importer.

Where applicable the toy or packaging must bear specific warnings and indications of precautions to be taken when using the toy. These are usually specified in safety standards.

Charities and toy sales, second-hand toys

Many charities are subject to the regulations because they run trading companies or bodies that are similar to businesses that are:

- money generating
- have a degree of continuity
- keep regular business hours

People organizing events such as jumble sales and car boot sales - which are held at infrequent and irregular intervals - are unlikely to be considered as acting in the course of business. However, traders invited to sell toys there would not be exempt from the requirements of the regulations.

Individuals producing toys on an occasional basis to give to charities to sell are also likely to be exempt.

Second-hand toys should be sold in a safe condition, and the General Product Safety Regulations will apply to them.

Enforcement

Trading standards departments of local authorities in England, Scotland and Wales, and environmental health departments of district councils in Northern Ireland, are responsible for day-to-day enforcement of the regulations.

Enforcement action may be taken in cases of formal non-compliance such as inappropriate CE marking or in cases where the enforcement authority has reason to believe that the toy presents a risk to the safety and health of persons.

The enforcement authority may issue a compliance notice in the case of a formal non-compliance or where this notice is not complied with or a safety risk exists the operator may be required to withdraw the toys from the market or undertake a recall.

Where the required technical documentation cannot be produced, enforcement authorities have the power to require toys to be tested at the supplier's own expense.

It is an offence for a manufacturer, authorised representative or importer to supply toys:

- which do not satisfy the essential safety requirements
- which do not carry the CE mark or apply it incorrectly
- which do not carry the required safety warnings or addresses
- for which the relevant information does not exist within the EU

It is an offence for a distributor to supply toys which:

- would put at risk the safety or health of users or third parties when used as intended or in a foreseeable way, bearing in mind the normal behaviour of children
- do not have the CE marking or the name and address details of the person who first placed them on the EC market

Penalties

Offences may result in fines of up to £5,000, or a maximum prison term of 6 months, or both. Where a supplier does not comply with a request to have toys tested within a reasonable time the penalties are a term of imprisonment for up to 3 months or a fine of up to £5,000.

Safeguard procedure

If your product fails to meet safety requirements, it will either be removed from the market or prevented from being sold in the first place.

If this happens to your product within the UK, the European Commission will be notified of any action taken against your product when the non-compliance relates to safety and the toy carries the CE marking. If the Commission is satisfied that the action is justified, it will send details of the case to other member states so that they can consider taking similar action.

Further information

- [European Commission: Enterprise and Industry](#)
- [British Toy and Hobby Association](#)