

BTHA Toy Safety Directive Guidance  
2009/48/EC

Introduction to the  
Toy Safety Directive  
and related BTHA  
Guidance documents

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## 1. Introduction

The Toy Safety Directive (2009/48/EC) was adopted by the European Parliament on 18 December 2008 and the final text was formally adopted and published in the Official Journal of the European Union (OJ) on 30 June 2009. The Directive came into force in two stages on 20th July 2011 and for the Chemical requirements on 20th July 2013.

This guide gives an overview of the Directive and shows where BTHA guides are available to help with specific aspects of the Directive.

## 2. Overview

This guide gives an overview of the Directive's structure outlining the chapters, articles, annexes, and appendices.

For every chapter, article, annex, and appendix of the Directive this guide:

- Shows where the BTHA guides cover the subject in full
- Gives guidance where the subject is not contained within the BTHA guides
- Indicates the parts of the Directive that are not of concern for toy companies

A series of guides have been produced by the BTHA to help members and other stakeholders understand their obligations under the Directive. The guides have been made as short and simple as possible to be practical for SME's (Small to Medium Enterprises).

The guides have been developed in association with the BTHA's Technical Committee, which is made up of 24 members from, Avon, Character Group, Disney, Flair, Hasbro, Hornby, HTI, Interplay, Mamas & Papas, Mattel, Paul Lamond, Plum Products, Tomy, Vivid Imaginations, Worlds Apart plus members of the BTHA Toy Safety Advisory Service.

The guides should always be read in conjunction with the Directive. Other EU Commission guides are also available on the Europa website and these should also be read in conjunction with BTHA information. The "blue guide" should also be read in conjunction with this document as it contains more details concerning certain aspects e.g. the free movement of goods.

- Obligations of Economic Operators
- Technical Documentation
- Markings and Warnings
- Conformity of Series Production
- Safety Assessments
- Product Monitoring
- Conformity Assessments

### 3. Structure of the Toy Safety Directive and related BTHA Guides

#### Chapter I – General Provisions

Article	Title	Information or BTHA Guide
1	<b>Subject Matter</b>	States that the purpose of the Directive is the laying down of rules on the safety of toys and on their free movement in the EU.
2	<b>Scope</b>	The Directive applies to products designed or intended, whether or not exclusively, for use in play by children under 14 years of age. Note that Annex 1 includes a list of products that are not considered as toys. In addition to the exclusions in Annex 1 of the Directive, this chapter gives a further list of toys that are not included. There are EU Guidance documents available for grey zone products on the Europa Website.
3	<b>Definitions</b>	This article includes a list of definitions of phrases, words and types of toys referenced throughout the Directive.

#### Chapter II – Obligations Of Economic Operators

4	Obligations of manufacturers.	<b>See Obligations of Economic Operators Guide.</b>
5	Authorised representatives.	
6	Obligations of importers.	
7	Obligations of distributors.	
8	Cases in which obligations of manufacturers apply to importers and distributors.	
9	Identification of economic operators.	

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#### Chapter III – Conformity of Toys Provisions

10	<b>Essential Safety Requirements.</b>	<b>See Safety Assessment guide.</b>
11	<b>Warnings.</b>	<b>See Markings and Warnings guide.</b>
12	<b>Free movement.</b>	The intention of this article to lay down requirements to prevent member states specifying national restrictions that may result in Manufacturers not being able to place toys on the market that are allowed in other member states.
13	<b>Presumption of conformity.</b>	This article means that Toys which are in conformity with relevant harmonised standards shall be presumed to be in conformity with the requirements covered by those standards or parts thereof set out in Article 10 & Annex II.
14	<b>Formal objection to a harmonised standard.</b>	This concerns member states and standards development committees. It is not essential that toy manufacturers be concerned with the detail of this article.
15	<b>EC declaration of conformity.</b>	<b>See Technical Documentation guide.</b>
16	<b>General principles of the CE marking.</b>	<b>See Markings and warnings Guide.</b>
17	<b>Rules and conditions for affixing the CE marking.</b>	

## Chapter IV – Conformity Assessment

18	Safety assessments.	<b>See Safety Assessment guide.</b>
19	Applicable conformity assessment procedures.	<b>See Conformity Assessment guide.</b>
20	EC-type examination.	
21	Technical documentation.	<b>See Technical Documentation guide.</b>

## Chapter V – Notification of Conformity Assessment Bodies

22	Notification.	This concerns Conformity Assessment Bodies. It is not essential that toy manufacturers be concerned with the detail of this chapter.
23	Notifying authorities.	
24	Requirements relating to notifying authorities.	
25	Information obligation of notifying authorities.	
26	Requirements relating to notified bodies.	
27	Presumption of conformity.	
28	Formal objection to a harmonised standard.	
29	Subsidiaries of and subcontracting by notified bodies.	
30	Application for notification.	
31	Notification procedure.	
32	Identification numbers and lists of notified bodies.	
33	Changes to notifications.	
34	Challenge to the competence of notified bodies.	
35	Operational obligations of notified bodies	
36	Information obligation of notified bodies.	
37	Exchange of experience.	
38	Coordination of notified bodies.	

## Chapter VI – Obligations and Powers Of Member States

39	Precautionary principle.	Enables rapid response in the face of a possible danger to human, animal or plant health, or to protect the environment. In particular, where scientific data does not permit a complete evaluation of the risk, recourse to this principle may, for example, be used to stop distribution or order withdrawal from the market of products likely to be hazardous.
40	General obligation to organise market.	It is not essential that toy manufacturers be concerned with the detail of these articles.
41	Instructions to the notified body.	
42	Procedure for dealing with toys presenting a risk at national level.	<b>See Product Monitoring Guide.</b>
43	Community safeguard procedure.	This article allows the Commission to determine if any national measures related to actions taken against a toy by a member state is justified or not. It should do this in consultation with the Member States and the relevant economic operator or operator. It describes the actions that are available to the Commission once the decision is made.

43	Community safeguard procedure <i>Cont.</i>	If the non-compliance of the toy is attributed to shortcomings in the harmonised standards the Commission shall inform the relevant European standardisation body and shall bring the matter before the Committee set up by Article 5 of Directive 98/34/EC. That Committee shall consult the relevant European standardisation body or bodies and deliver its opinion without delay. This can trigger a new standard or standard amendment.
44	Exchange of information – Community RAPEX System.	This article concerns the correct use of Rapid Information Exchange System (RAPEX ) when a member state takes notifying measures with a toy.
45	Formal non-compliance.	<p>This states that not having a CE mark on the product or packaging, the incorrect placement of the CE mark, not having the correct declaration of conformity or not holding complete technical documentation is a non-compliance with the Directive. This is the case even if the product and documentation is otherwise compliant.</p> <p>In this case the Member state can take appropriate measures to restrict or prohibit the toy being made available on the market, or shall ensure that it is recalled or withdrawn from the market.</p> <p>Also see <b>See Product Monitoring and Markings and Warnings Guide.</b></p>

## Chapter VII – Committee Procedures

46	Amendments and implementing measures.	<p>These articles show the parts of the Directive that can be amended.</p> <p><b>Annex I</b> List of products that, in particular, are not considered as toys within the meaning of this Directive.</p> <p><b>Points 11 and 13 of Part III of Annex II;</b> Fragrances, EN71 Part 3 limits.</p> <p><b>Annex V</b> Warnings.</p>
47	Committee procedure.	<p><b>Appendix C</b> The Commission may adopt specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth.</p> <p>The Commission shall amend Appendix C to Annex II to this Directive accordingly.</p> <p><b>Appendix A</b> The Commission may decide upon the use in toys of substances or mixtures that are classified as carcinogenic, mutagenic or toxic for reproduction and may amend Appendix A to Annex II.</p>

## Chapter VIII – Specific Administrative Provisions

48	Reporting.	Member States are obliged to send the Commission a report on the application of the TSD every 5 years from 2009. After this the Commission publishes a summary of the national reports.
49	Transparency & confidentiality.	Information relating to risks to consumer health and safety posed by products shall in general be available to the public. In particular information on product identification, the nature of the risk and the measures taken.
50	Motivation of measures.	<b>See Product Monitoring Guide.</b>
51	Penalties.	Parts 1 and 2 of the Toys (Safety) Regulations 2011 are enforceable under the Consumer Protection Act 1987. Section 12 of the Act contains offences for breaching safety regulations and other enforcement provisions. A person supplying toys which are subject to the Directive, but which do not meet their requirements, could be liable on summary conviction to imprisonment for a term not exceeding six months or to a fine not exceeding level 5 on the standard scale or to both.

## Chapter VIII – Specific Administrative Provisions

52	Application of Directives 85/374/EEC & 2001/95/EC.	This Directive is without prejudice to Directive 85/374/EEC. Directive 2001/95/EC shall apply to toys in accordance with Article 1(2). Directive 2001/95/EC on general product safety shall apply to toys in so far as there are no specific provisions with the same objective in the Toy Safety Directive. Where a product is already subject to the Toy Safety Directive, the general product safety regulations will apply where requirements go further than the Toy Safety Directive in terms of the specific aspects of safety covered, the extent of the obligations on producers and distributors, and the powers available to enforcement officers.
53	Transitional periods.	The overall timetable for implementation of the Directive is 20th July 2011 and 20th July 2013 for chemicals.
54	Transposition.	This outlines the time by which member states must transpose the Directive into their national legislation.
55	Repeal.	This concerns the removal of the previous Toy Safety Directive.
56	Entry into force.	This Directive shall enter into force on the 20th day following its publication in the <i>Official Journal of the European Union</i> .
57	Addressees.	This shows that the Directive is addressed to the member states of the EU.

## Annexes

I	List of products that, in particular, are not considered as toys within the meaning of this Directive.	The Directive applies to products designed or intended, whether or not exclusively, for use in play by children under 14 years of age.
II	Particular Safety Requirements.	<b>See Safety Assessment Guide.</b>

## Appendices to Annex II

A	List of CMR substances and their permitted uses.
B	Classification of substances and mixtures.
C	Specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth adopted in accordance with Article 46(2).

## Annexes

III	EC Declaration of Conformity.	<b>See Technical Documentation guide.</b>
IV	Technical Documentation.	
V	Warnings.	<b>See Markings and warnings Guide.</b>