

Technical Documentation Revised Toy Safety Directive 2009/48/EC

Contents

1. Obligations of Economic Operators
2. Introduction
3. Overview
4. How to use this guide
5. Table 1: Technical Documentation
6. Guidance on Contents
7. Appendix 1 – Economic Operator Obligations

Record of Amendments			
Version	Date	Amendment	Section/page affected
1	08.03.10	First published	
2	21.06.10	Minor grammar and typing revision	
3	12.12.11	Redraft to reflect Obligations guide V6 content and format	

LEGAL NOTICE

This document contains guidance only.

It is intended to explain obligations and how to fulfil them. However readers are reminded that the text of the original regulation, directive or standard is the only authentic legal reference and that the information in this document does not constitute legal advice.

The British Toy and Hobby Association does not accept any liability with regard to the contents of this document.

Technical Documentation

Revised Toy Safety Directive 2009/48/EC

1. Obligations of Economic Operators

Obligation	Manufacturer		Importer		Distributor	Authorised	
Draw up Technical Documentation	A4(2) A21	Obligated	A6(2)	Ensure its done	No obligation	A5 (2)	Cannot be mandated
Retain Technical Documentation for 10 years	A4(3)	Obligated	A6(8)	Ensure it can be made available	No obligation	A5 (3)	Must be mandated
Draw up EC declaration of conformity	A4(3)	Obligated	A6(8)	Keep a copy	No obligation	A5 (3)	If mandated
Retain the EC declaration of conformity for 10 years.	A4(3)	Obligated	A6(8)	Keep a copy	No obligation	A5 (3)	Keep a copy

See separate BTHA guidance on the Obligations of Economic Operators which should be read first.

2. Introduction

The revised 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. From this date, the overall timetable for implementation of the subject covered by this guidance document is July 2011.

The revised Directive specifies requirements for Technical Documentation and Declarations of Conformity.

This document provides an interpretation of the type of documents that need to be present to meet the requirements in the revised Directive. It is based on the current understanding of the revised Directive and may be subject to change as more information is published by the EU Commission and UK Enforcement Authorities.

Please note that there are separate obligations surrounding which Economic Operator (company) produces and retains the Technical Documentation, physically holds it or needs to be able to make it available in a set time to enforcement authorities. Different obligations exist specifically for Declarations of Conformity.

3. Overview

The revised Toy Safety Directive defines the requirements for what is required to be held in the Technical Documentation in Annex IV.

The Technical Documentation shall be in English or one of the official languages of the Community.

It is the responsibility of the Manufacturer to produce, hold and make available the Technical Documentation.

Economic Operators should be prepared to supply a market surveillance authority the relevant parts of the Technical Documentation, translated if necessary on request.

This must be provided within 30 days unless a shorter deadline is justified because there is a serious and immediate risk.

Failure to comply with these points means that the market surveillance authority may require the Economic Operator to have further examinations performed by a notified body at his own expense within a specified period. Where non-conformance persists a member state can take appropriate measures to restrict or prohibit the toy being made available on the market and can demand the recall or withdrawal of the toy.

The Technical Documentation will be unique to an individual toy, however much of the content may be repeated across a range of similar toys. Generic files are therefore permitted as long as the differences between toys and the documents unique to individual toys are held.

Technical Documentation does not have to consist of single files in hard copy. Information can be stored in any format and in various locations within a company e.g. Artwork files may all be held together.

It is important to ensure that the Technical Documentation is kept up to date so that it reflects any changes to the toy, legislation or standards. It is essential that the history of the product is retained.

This guidance has provided an interpretation as to what is legally required to be found in the "Technical Documentation". It is inevitable that more information other than that listed above may be generated as a result of activity related to the toy's safety, performance and other quality control and quality assurance activity. It would be advisable that this additional information also be retained in the Technical Documentation.

The Directive states that documentation (this includes the Technical Documentation) should be kept for 10 years after first placing the toy on the market. The BTHA consider it is advisable to keep the records for 10 years after the last toy has been supplied so that they will be available in the event of an enforcement challenge.

4. How to use this guide

The Technical documentation required to be held is given in Annex IV of the Directive and is summarised in table 1 section 5 of this document.

Against each entry in the table the suggested contents of the Technical Documentation are given on the subsequent pages.

5. Table 1

Directive clauses	Directive Extract
Annex IV (a)	A detailed description of the design and manufacture, including a list of components and materials used in the toy as well as the safety data sheets on chemicals used, to be obtained from the chemical suppliers.
Annex IV (b), A 18	The safety assessment(s) carried out in accordance with Article 18.
Annex IV (c) A3 (11) (16) A4 (2) A6 (2) A19	A description of the conformity assessment procedure followed.
Annex III & IV (d), A15	A copy of the EC declaration of conformity
Annex IV (e)	The addresses of the places of manufacture and storage
Annex IV (f)	Copies of documents that the manufacturer has submitted to a notified body
Annex IV (g) A4 (4) A19 (2)	Test reports and description of the means whereby the manufacturer ensured conformity of production with the harmonised standards, if the manufacturer followed the internal production control procedure referred to in Article 19(2)
Annex 4 (h)	A copy of the EC type-examination certificate, a description of the means whereby the manufacturer ensures conformity of the production with the product-type as described in the EC type-examination certificate and copies of the documents that the manufacturer has submitted to the notified body, if the manufacturer has followed the EC type-examination and type conformity –declaration referred to in Articles19 (3)
Annex 4 (i)	Colour image of the toy.

Description of the design and manufacture of the toy

The Directive requires a detailed description of the design of the toy. No particular format or specific content is defined in the Directive; however it is likely that this is to be found in a product specification. A product specification is likely to include:

- Description of the features and functions
- Age Grade (both safety and recommended)
- Performance and functional requirements
- Packaging specification, pack and instruction artwork and/or text
- Conformity markings and location of markings
- Colour image of the toy (photographs, drawings etc)

The Directive requires a detailed description of the manufacture of the toy. No particular format or specific content is defined in the Directive. Some Manufacturers may already have production documentation which defines the manufacturing process and which may be acceptable. For example, ISO9001 certified factories should have the description of the manufacture documented as part of this certification.

List of components and materials

Bill of Materials

Safety data sheets

It is recommended that safety data sheets are kept as part of the Technical Documentation for all chemical preparations or mixtures that are used in the toy. Typically this would include components such as liquids, inks, paints, slimes, glues and adhesives and putties etc.

Safety data sheets are only legally required if one of the following conditions are met:

- The preparation or mixture is classified under the Classification Labelling of Packaging Regulation (CLP) (1272/2008/EC), or
- the preparation or mixture contains an individual component classified under CLP in an amount more than 0.1%; or
- it contains PBT, vPvB or SVHC substances.

The format of safety data sheets should be in compliance with the REACH Regulations (1907/2006/EC) and the new GHS classification system - Classification, Labelling and Packaging Regulations (1272/2008/EC).

Safety Assessments

Safety and Conformity Assessments

Conformity Assessment Procedure

Safety and Conformity Assessments

EC Declaration of Conformity

An EC Declaration of Conformity is required for all toys placed on the market. This is a document prepared by the Manufacturer to declare that the toy meets the requirements of the Toy Safety Directive. The text of the Declaration is defined in the Directive (see below) and must be followed, although it can form part of an existing document.

1. No ... (unique identification of the toy(s))
 2. Name and address of the manufacturer or his authorised representative:
 3. This declaration of conformity is issued under the sole responsibility of the manufacturer:
 4. Object of the declaration (identification of toy allowing traceability). It shall include a colour image of sufficient clarity to enable the identification of the toy.
 5. The object of the declaration described in point 4 is in conformity with the relevant Community harmonisation legislation:
 6. References to the relevant harmonised standards used, or references to the specifications in relation to which conformity is declared:
 7. Where applicable: the notified body ... (name, number) ... performed ... (description of intervention) ... and issued the certificate:
 8. Additional information:
- Signed for and on behalf of: Place and date of issue) (Name, function) (Signature)

The DoC can be found in the various languages of the EU on the Europa website

Technical Documentation Contents	Related BTHA Guidance Document / Comments
----------------------------------	---

Addresses of manufacture and storage

Addresses where the product has been manufactured and stored should be recorded. It is the address of the factory that has made the product which must be recorded, not the address of a Hong Kong Agent, export company or distributor.

Documents submitted to a Notified Body

Copies of documents that a Manufacturer has submitted to a notified body when carrying out an EC type approval are required to be retained when relevant. It is considered good practice to keep copies of all documents relating to the safety of toys including those used to request any third party testing

Test reports & Copy of EC type approval certificates

Test reports, declarations of conformity or other documentation received as part of the approval process should also be kept in the Technical Documentation.

Conformity of series production

Conformity of Series Production and Sample Testing

A copy of the EC type-examination certificate

Carrying out an EC Type approval means that the following additional information should be retained in the Technical Documentation:

- EC Type certificate,
- Copies of the documents that the manufacturer has submitted to the notified body (see section 9)
- Any specific requirements concerning the conformity of series production.

Colour image of the toy

This is required in the EC Declaration of Conformity and may also form part of the description of the design of the toy (see section 1) and therefore will not always need to be a separate document. A colour image can include a range of toys.