

Conformity Assessments Revised Toy Safety Directive 2009/48/EC

Contents

1. Obligations of Economic Operators
2. Introduction
3. Overview
4. How to use this guide
5. The Conformity Assessment
6. The Modules
7. Self Verification (Module A)
8. Third Party Verification (Modules B&C)

Record of Amendments			
Version	Date	Amendment	Section/page affected
1	01.06.12		

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.

1. Obligations of Economic Operators

Obligation	Manufacturer		Importer		Distributor	Authorised Representative
Carry out the conformity assessment	A4(2) A19	Obligated	A6(2)	Ensure its done	No obligation	No obligation

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.

Article 4 of the revised Toy Safety Directive specifies the following obligation for Manufacturers for Conformity Assessments:

Manufacturers shall carry out or have carried out the applicable conformity assessment procedure in accordance with Article 19.

This document gives an interpretation of this obligation. It is based on the current understanding of the Directive and may be subject to change as more information is published by the EU Commission and UK Enforcement Authorities.

3. Overview

A Conformity Assessment is defined as the process of demonstrating whether or not specified requirements relating to a product, process, service, system, person or body have been fulfilled. The Conformity Assessment described by the Toy Safety Directive is required in order to demonstrate that the toy complies with:

- The Essential Safety Requirements specified in Article 10 and
- The Particular Safety Requirements specified in Annex II.

A Conformity Assessment is mandatory for every toy and must be carried out before the toy is placed on the market.

It must be noted that the requirement to carry out a Conformity Assessment and the Safety Assessment are separate obligations. The Safety Assessment is intended to identify any potential hazards that a toy may present and any exposure to those hazards. A Conformity Assessment is intended to provide demonstrable evidence that the toy is in conformity with the legal requirements of the Toys Safety Directive.

Where companies have any doubt about their ability to conduct a Conformity Assessment third party expert help may be needed.

4. How to Use This Guide

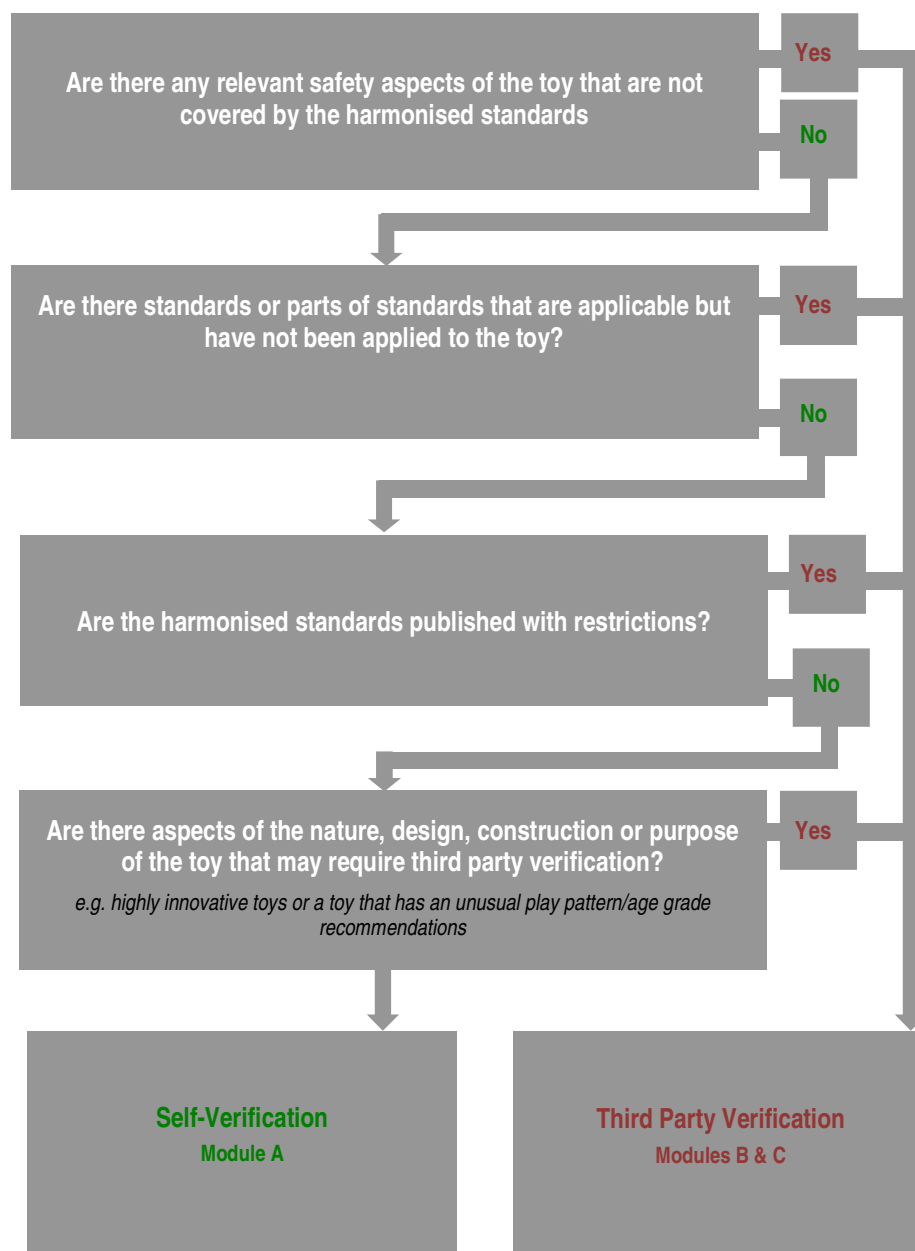
There are two ways of carrying out a conformity assessment. Table 1 can be used to decide which method of carrying out the Conformity Assessment is required for the toy in question.

5. The Conformity Assessment

Article 10 of the Directive outlines the Essential Safety Requirements with which a toy must comply. Further to this, Annex II lists Particular Safety Requirements for certain toys. Both these sections of the TSD detail requirements for the mechanical and physical properties as well as requirements for flammability, chemical, electrical, hygiene and radioactive aspects of a toy.

The Conformity Assessment must show documented and demonstrable evidence that the toy conforms with all of these requirements. The Manufacturer can demonstrate this conformity by (a) self-assessment or by (b) third party assessment (not to be confused with simple third party testing). Table 1 can be used to determine which method is required.

Table 1. Conformity Assessment method determination



6. The Modules

The procedures that Manufacturers must use to demonstrate conformity are defined in “Modules” These are described in Decision No 768/2008/EC. The Toy Safety Directive makes reference to Modules A, B and C.

7. Self-Verification (Module A)

Manufacturers must put in place an “*internal production procedure*” in accordance with Module A of Annex II to Decision No. 768/2008/EC. Module A does not require the involvement of a Notified Body.

Module A describes the following obligations.

Conformity to Harmonised Standards

Manufacturers must ensure that their toy complies with:

- The Essential Safety Requirements shown in Article 10 and
- The Particular Safety Requirements in Annex II of the Toy Safety Directive.

One way of achieving this is to demonstrate compliance with the relevant Harmonised Safety Standards.

The assessment/verification can either be carried out by the Manufacturer himself or by a third party (a test laboratory for example)(or a combination of the two).

It is often assumed that a third party testing organisation must be used to assess a toy against the harmonised standards. This is not the case. If conformity to any of the requirements of the harmonised standards can be demonstrated easily, perhaps without the use of specialised equipment then a Manufacturer is at liberty to carry out the assessment for himself. Sometimes a combination of third party and in-house testing may be the most prudent approach. Unfortunately some toy safety standards are open to interpretation. In-house tests and assessments should only be carried out by those with a full knowledge and understanding of the standards. Third party testing organisations specifically accredited for toy safety tests should be aware of the proper interpretations and latest developments and can usually be relied upon with confidence.

Some Manufacturers or customers prefer the reassurance of a third party, independent test certificate within a toy technical file. However it is important to note that the Toy Safety Directive does not require this.

Technical Documentation

Documents demonstrating conformity should be produced and held in the Technical File for a toy together with the Declaration of Conformity. See separate BTHA guide concerning Technical Documentation.

Application of CE Mark

Once the Manufacturer has demonstrated conformity, he must apply the CE Mark as required by the relevant Directives.

Manufacturing (Conformity of Series Production)

Manufacturers must have documented procedures to ensure that on-going production continues to conform with the requirements of the Directive.

See separate BTHA Guide concerning Conformity of Series Production.

8. Third Party Verification (Module B & Module C)

Module B

EC-type examination *of the design* is covered by Module B of Annex II to Decision No. 768/2008/EC. EC-type examination cannot be carried out by the Manufacturer. It must be carried out by a Notified Body. Notified Bodies are specially qualified testing organisations within the EU who are assessed and appointed by the authorities to do this work.

More details on notified bodies can be found here:

<http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=country.main>

A Manufacturer can submit the toy or a model of the toy, together with supporting technical documentation, to a Notified Body for the EC-type examination. The Notified Body assesses the toy and verifies that the design meets the essential safety requirements and other relevant safety requirements of the Toys Safety Directive. If the toy is in conformity the Notified body will issue an EC-type examination certificate. The notified body is certifying that the toy complies with the Toys Safety Directive itself – unlike simple third party testing in which usually the laboratory certifies against the requirements of the harmonised standards. For this reason EC-type examination is necessarily more involved (and therefore costly) and closely controlled. If, for example, the model of the toy fails to comply with the requirements of the Directive, the Notified Body is required to report that fact to others in the enforcement chain.

Module C

If a toy has undergone and EC-type examination, the Manufacturer must also comply with Module C. Module C requires that the Manufacturer ensure that the manufactured toys are in conformity with that model that has been EC-type examined.

Manufacturers must also ensure manufactured toys are in conformity with the requirements of the Toys Safety Directive.

Unlike Module B above, Module C can be done by the Manufacturer and does not require the involvement of a notified body. It should be noted however that a notified body may specify production control requirements that must be followed.

Application of CE Mark

Once a Manufacturer has demonstrated conformity, he must apply the CE Mark as required by the relevant Directives.

Technical Documentation

Documentation demonstrating conformity should be produced and held in the Technical Documentation together with the Declaration of Conformity. See separate BTHA guide concerning Technical Documentation.