Conformity of Series Production
Revised Toy Safety Directive 2009/48/EC

Contents
1 Obligations of Economic Operators
2 Introduction
3 Overview
4 How to use this guide
5 Ensuring Conformity
   Changes to the Toy Safety Directive and Harmonised Standards
   Changes in the Toy’s characteristics or design
6 Steps to Ensure Conformity of Series Production
Appendix A – Principles of Ensuring On-going Compliance

Record of Amendments

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Amendment</th>
<th>Section/page affected</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>20.10.10</td>
<td>First published</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>18.4.12</td>
<td>Removal of Sample testing. Addition of the Authorised Representative obligation. General Updating and simplification</td>
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LEGAL NOTICE
This document contains guidance only. It is intended to explain obligations and how to fulfill 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

<table>
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<tr>
<th>Obligation</th>
<th>Manufacturer</th>
<th>Importer</th>
<th>Distributor</th>
<th>Authorised Representative</th>
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<td>Ensure conformity of series production</td>
<td>A4(4)</td>
<td>No obligation</td>
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<td>Sample test marketed toys (taking into account risk)</td>
<td>A4(4)</td>
<td>A6(6)</td>
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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 Toy Safety Directive specifies the following obligation for Manufacturers:

*Manufacturers shall ensure that procedures are in place for series production to remain in conformity. Changes in toy design or characteristics and changes in the harmonised standards by reference to which conformity of a toy is declared shall be adequately taken into account.*

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

Manufacturers are obliged to ensure that the design and manufacture of any toy they place on the market must be in accordance with the requirements of the Toy Safety Directive. Additionally they must have procedures in place that ensures that they remain in conformity when there are changes to the relevant harmonised standards or if the product specification changes. This guide gives an overview of the steps that are required to ensure products and the related technical documentation remain in conformity.

Conformity of series production is an obligation of the Manufacturer *as defined by the Directive*. It should be noted that the Manufacturer is not necessarily the factory itself (see Obligations of Economic Operators guidance).

4. How to use this Guide

This guidance works on the premise that the starting point is a compliant toy.

Table 1 has been developed to enable Economic Operators to determine the steps needed to ensure the product remains in conformity and that the requirements of the Toys Safety Directive remain satisfied.

The table highlights the actions required to be taken in the event of changes to the toy or to the harmonised safety standards to ensure continued compliance with the requirements of the Toy Safety Directive.
5 Ensuring Conformity

Manufacturers should ensure toys are in conformity and there are procedures in place with the supplier and in the factory to achieve this. This document assumes that there are on-going compliance systems in place. Examples can be found in Appendix A – Principles of ensuring on-going compliance.

In addition to ensuring ongoing conformity when there are no changes, Manufacturers are obliged by the Directive to have procedures to ensure production remains in conformity when there are:-

- Changes to the Toy Safety Directive and harmonised standards
- Changes to the toy’s characteristics or design

Changes to the Toy Safety Directive and Harmonised Standards

Legislation can change at any time as new hazards are identified and toy technology develops. Manufacturers are obliged to ensure that products remain in compliance with any applicable legislation.


Other sources of information include:
- BTHA (via membership updates)
- BSI online (free access to standards and updates are available to BTHA full members)
- Notified bodies/test laboratories

Changes in the Toy’s Characteristics or Design

Examples of such changes would include changes in size, shape, materials, colour, age grading, packaging, play patterns etc. Changes can be made by any Economic Operator; however the Manufacturer remains responsible for ensuring compliance. It is essential that agreements exist whereby all parties, (including the factory) are required to obtain approval from the Manufacturer for any product changes before they are made.

Factories with a good quality management system should have processes already in place regarding change control. E.g. Engineering change notes (for permanent changes) or concession notifications (for temporary changes).

6 Steps to Ensure Conformity of Series Production

Table 1 shows the steps that are required in the event of changes to harmonised standards or product characteristics or design.

It also shows the possible link between changes to harmonised standards and the need to change the product design and characteristics that may be necessary to comply with these changed standards. Lastly it shows the other aspects that need to be considered to ensure the toy and the Technical Documentation conforms to the requirements of the Directive.
Table 1: Steps to Ensure Conformity of Series Production

Change to harmonised standards

Change to characteristics or design

Conformity Assessment
Are product changes required to make it conform?
A change requires that the toy be assessed to ensure that it is still in conformity.

Safety Assessment
Are there new hazards identified that require product modification?
A change requires that the Safety Assessment be reviewed.

Series Production Procedures
Quality Management Systems may need to be reviewed to determine if they are still effective following any changes to toys characteristics or design or harmonised standards.

REC Type Approval Requirements
Any changes may affect the validity of the EC type examination certificate. Manufactures must ensure that any production control requirements specified under the conditions of the EC type approval are adhered to.

Sample testing or marketed toys plan
Any changes requires that the sample testing plan is reviewed bearing in mind any modifications to production controls, product design, standard changes etc.

Technical Documentation
It is the responsibility of the Manufacturer to ensure the Technical Documentation is kept up to date to reflect changes in toy characteristics or design, or changes to legislation or standards.
Appendix A – Principles of Ensuring On-going Compliance

There are many ways to control conformity of production. Individual companies will use different systems based on their business model. For instance some companies may invest time in factory controls whilst others may place more of their resources on product testing. In reality, most companies use a combination of such tools.

The principles of manufacturing a consistently compliant product can be summarised in the table below. The feedback aspect is most important.

| Compliant product | Consistent manufacture of compliant product | Ensure the system is working |

The Compliant Product

Before a toy is manufactured, Manufacturers must have taken steps to ensure that the specification of the toy is compliant with the requirements of the Toy Safety Directive and other relevant Directives.

The technical documentation requirement of the Toy Safety Directive requires Manufacturers to have a detailed description of the design and manufacture of the toy including a list of components and materials used in the toy. Both of these items can help specify a product accurately.

Further information on product specifications and related documents can be found in the BTHA guidance on Technical Documentation. Further BTHA guidance on Bills of Materials is available.

Consistent Manufacture of the Compliant Product

Once a compliant specification and Bill of Materials has been confirmed, it would be prudent to ensure that there is a formal agreement or contract with the factory or supplier referencing the relevant materials and specification.

A good quality management at the factory system should ensure that any product is consistently produced to the agreed specification. A quality management system will typically include processes for:-

- Control of raw materials, incoming components and sub-assemblies
- Supplier approval
- Control of product specification and change control
- Control of operations and critical control point management
- Product inspection and sample testing
- Traceability
- Corrective and preventive action
- Training
- Continual improvement - review of process improvements and procedures.

Manufacturers should assess the factories used to manufacture their products to ensure that procedures are in place to adequately control the manufacture of the product to a consistent specification. Such assessments are usually in the form of audits.

Companies can assess such systems themselves, commission auditing by third parties or choose to rely on independent certification schemes such as ISO9001, BRC Global Standard etc. In addition, companies can rely on audits carried out other reputable companies or organisations.
Written reports and or certificates should normally be supplied in the case of third party audits and records and documentation should be available in all cases. It is vital, before relying on them, that any formal quality assurance procedures include those which address compliance with legal requirements.

In some cases a supplier may represent a group of factories and may have their own robust factory approval and monitoring systems in place. It would be advisable to assess such systems to determine if they are acceptable, but this does not remove the need to obtain additional information on the individual factory manufacturing the product.

If you do not have sufficient expertise in house to assess the suitability of a factory or supplier, third party support should be considered.

**Ensuring the System is Working**

It is not enough to assume products will remain in compliance. Additional controls should be used to assure Manufacturers that the systems used are effective and that the toy remains in compliance throughout its production cycle.

There are various tools that can be used, for example:-

**Inspections**

Product inspections, both during production and pre-shipment and on finished production are recommended. Inspection formats, criteria, acceptable quality levels (AQL’s) etc., should be tailored to the product type and inspection stage in question. Inspections will only cover that specified in the check list and may not cover all legal requirements. Indeed, some requirements can not be assessed by simple inspection and require the involvement of more detailed testing.

The inspection will only be valid for the batch concerned.

Inspections can be carried out by factory personnel, representatives of customers or by independent inspection companies, dependant on risk.

Reports of inspections should be available and approved.

**Approved samples**

Samples can be retained for reference and comparison with ongoing production and for use in inspections.

**Sample testing of marketed toys**

Manufacturers and Importers have an obligation to sample test marketed toys.

See separate BTHA guidance on Product Monitoring.

**Production controls**

Purchasing and Production controls and procedures should be continually assessed to ensure that they remain effective.