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### Record of Amendments

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### 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	
Bring non conforming toys into compliance. Inform authorities if there is a safety risk. Recall or withdraw Provide information to authorities on request	A4(8) A4(9)	Obligated	A6(2) A6(7) A6(9)	Obligated	A7(2) A7(4) A7(5)	Obligated	A5 (3)	Must be mandated
Keep register of complaints, non-conforming toys and recalls. Inform Distributors of this monitoring.	A4(4)	Obligated	A6(6)	Obligated	No obligation but Recommended		If mandated	
Sample test marketed toys (taking into account risk)	A4(4)	Obligated	A6(6)	Obligated	No obligation		If mandated	

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

## **2. 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. From this date, the overall timetable for implementation of the subject covered by this guidance document is July 2011

Among the obligations for economic operators are some related to the monitoring of products after placing them on the market and handling safety issues and co-operating with Authorities.

This document gives an interpretation of these obligations, as defined 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.

## **3. Overview**

The Toy Safety Directive specifies certain obligations for product monitoring after a toy is placed on the market for all Economic Operators. These obligations can be found in the following text extracts from the Directive as follows:

*When deemed appropriate with regard to the risks presented by a toy, manufacturers and Importers shall, to protect the health and safety of consumers, carry out sample testing of marketed toys, investigate, and, if necessary, keep a register of complaints, of non- conforming toys and toy recalls, and shall keep distributors informed of any such monitoring.*

*Manufacturers, Importers and Distributors who consider or have reason to believe that a toy, which they have placed on the market is not in conformity with the relevant Community harmonisation legislation shall immediately take the corrective measures necessary to bring that toy into conformity, to withdraw it or recall*

*it, if appropriate. Furthermore, where the toy presents a risk, Manufacturers, Importers and Distributors shall immediately inform the competent national authorities of the Member States in which they made the toy available to that effect, giving details, in particular, of the non-compliance and of any corrective measures taken.*

*Manufacturers, Importers and Distributors shall, further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the toy in a language easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by toys, which they have placed on the market.*

The actual obligations can be summarised as follows:

1. Investigate and keep a register of complaints, non conforming toys and recalls
2. Sample test marketed toys
3. Inform Distributors of this monitoring
4. Bring non conforming toys into compliance
5. Inform authorities if there is a safety risk
6. Recall or withdrawal of unsafe products
7. Provide information and co-operate with authorities on reasoned request

## 1. Investigate and keep a register of complaints, non conforming toys and recalls

After a toy is placed on the market there may be consumer and customer complaints.

Not all of these will be related to safety however it is generally considered to be good practice to record all complaints received as these can give evidence of safety and good quality as well as the contrary.

Recording of complaints can be on bespoke systems or on simple spreadsheets and can be run by third party companies or by in-house QA personnel.

Suitably qualified staff should review and investigate complaints. There should be a procedure to identify and ensure that any complaints that relate to the safety of a product are prioritised and handled appropriately.

A safety complaint is one that highlights an issue with a product that has the potential to harm a consumer.

Complaints may highlight unforeseen trends of uses, manufacturing errors or design flaws. By monitoring complaints companies can ensure actions can be taken to maintain products safety and quality whilst protecting consumers. Complaint data can lead to product design changes, production changes, inspection or product monitoring changes or even in some cases product withdrawal or recall.

Complaints should be reviewed and be used to improve designs and product Safety Assessments in other products within a range.

This is not an obligation for Distributors (such as retail stores), however it is likely that many consumers will complain to the Distributor in the first instance and therefore it is recommended that Distributors continue to log any complaints received and communicate them to Importers, Manufacturers and Authorised representatives.

## 2. Sample Testing of Marketed Toys

### Guidance on Establishing a Sample Testing Plan

Manufacturers and Importers have an obligation to carry out sample testing of marketed toys when deemed appropriate with regard to the risks of non-compliance or risk to consumers presented.

It is suggested that Economic Operators establish a plan of testing for a range and/or individual lines. This guide is not intended to set clear parameters for this as each company must decide on and set their own plan. The following gives some pointers and a general approach.

### Sample testing plan

The following points should be taken into account when developing a sample testing plan.

- As the Directive places this obligation on both Manufacturers and Importers it is considered best practice if these Economic Operators co-operate to prevent unnecessary duplication and to ensure effective targeted testing.
- Any sample testing carried out by the factory or safety checks during production or inspections should be considered to prevent unnecessary duplication and to ensure effective targeted testing.

- It is important to note that the Directive specifically states that the testing should be appropriate to the risks presented to consumers by a product so it is not considered necessary to test each and every marketed toy.
- Any testing can be targeted based on the risk of non compliance of a product to standard or particular clauses of a standard. Therefore it is not always considered necessary to test to the entire standard.
- It is not considered necessary for manufactures to purchase toys from retail or other distributors in order to carry out sample testing. Samples of marketed toys, including their packaging and instructions for use can be taken from any point in the supply chain, including within the factory.
- Testing must always be conducted on a product selected from actual production.
- Sample testing can be conducted in house or by independent third parties. All testing must be documented and held with the technical documentation.
- Sample testing should complement the work done concerning the obligation to ensure conformity of series production. It should not be used as a substitute for this work (unless only one batch of a product is taken).
- Economic Operators can reduce the risk of placing non-conforming toys on the market by sample testing prior to shipping or distribution.

When establishing a plan, a targeted risk based approach is recommended. Combining knowledge of risk of non-compliance of the product with knowledge of how these risks are being controlled by the factory enables Economic Operators to make sensible judgments on determining the level and frequency of sample testing required to demonstrate conformity of series production.

#### Targeting Effort

It would be sensible to avoid duplication of effort when establishing a plan. For example if certain testing is conducted at the factory or during inspections, this may suggest that this particular aspect could be considered a lower risk for non-compliance. This would allow testing to be targeted elsewhere.

If it can be demonstrated that the factory's own QA systems are robust, the risk of non compliance is reduced. Furthermore, specifying additional controls (see section 5.3) can further reduce the risk of non-compliance. Reducing the risk of non compliance in these two ways can allow Manufacturers and Importers to target sample testing to higher risk areas.

If you do not have sufficient expertise in house to assess the product and factory risks, third party support should be considered.

### 3. Inform Distributors of this monitoring

It is considered sufficient to inform Distributors of the systems that a Manufacturer has in place to do such monitoring. It is not necessary to inform Distributors of each and every complaint or sample test.

Obviously if a non-conforming toy presents a risk which leads to a withdrawal or recall, all other parties in the supply chain should be informed.

It is not a requirement of Distributors to keep a register of complaints, however it is recommended that Distributors inform other Economic Operators in the supply chain of any safety or trends in quality related complaints so that suitable action can be taken.

#### 4. Bring non conforming toys into compliance

Where an Economic Operator has reason to believe that a toy they have placed on the market is not in conformance they must take steps to protect consumers. Such steps must be commensurate with the risk presented.

Before taking action it is suggested that all Economic Operators co-operate, as necessary to ensure the issue is thoroughly investigated and the non-compliance confirmed. This may include product assessments and/or testing, stock checks, risk assessments and an investigation at the manufacturing site.

Importers should stop supplying non-compliant product and consult with the Manufacturer. It is advisable that any resultant actions taken are commensurate with the risk.

The Distributor's responsibility is to stop selling the non-complaint product and immediately consult with the Manufacturer or Importer with regards to bringing the toy back in to compliance. It is advisable that resultant actions taken are commensurate with the risk

#### 5. Inform authorities if there is a safety risk

Although the Directive requires that all Economic Operators inform authorities if there is a safety risk, it is strongly recommended that the Economic Operators co-operate to put together a comprehensive information package ensuring a co-ordinated response.

Before taking action it is suggested that all involved Economic Operators co-operate to ensure the issue is thoroughly investigated and the safety risk established. This may result in product assessments and testing, stock checks, risk assessments and an investigation at the manufacturing site.

Importers should stop supplying product that carries a safety risk and immediately consult with the Manufacturer. It is advisable that any actions taken are commensurate with the risk.

Economic Operators should contact their "Home Authority" trading standards office where they have reason to believe that a toy presents a safety risk. It should be noted that each Economic Operator may have a different Home Authority.

Member state authorities may have an obligation to inform other Member States within the EU using the RAPEX alerts system\*.

\* Further details can be found in "The RAPEX Guidelines" which can be found here:

[http://ec.europa.eu/consumers/safety/rapex/key\\_docs\\_en.htm](http://ec.europa.eu/consumers/safety/rapex/key_docs_en.htm)

\* General information on RAPEX can be found here: [http://ec.europa.eu/consumers/safety/rapex/index\\_en.htm](http://ec.europa.eu/consumers/safety/rapex/index_en.htm)

#### 6. Recall or withdrawal of "unsafe" products

Before taking action it is suggested that all involved Economic Operators co-operate to ensure the issue is thoroughly investigated and the safety risk established. Actions such as product assessments, testing, stock checks, risk assessments and an investigation at the manufacturing site may be required. The number of products sold, the percentage known to be defective and the cause of the incident should all be identified to determine the most appropriate action.

**Product recall** – the suspension of distribution and/or take back of stock from warehouse, store and end consumer which poses a serious and immediate risk of harm to consumers which is likely to occur. A recall includes press, media or store notices to alert customers and to take stock back from consumers.

**Product withdrawal** – the suspension of distribution or take back of stock, which does not pose a serious and immediate risk of harm to consumers or is unlikely to occur. A withdrawal is likely to involve the removal of unsold stock from the supply chain and take back of stock from Distributors.

It is recommended that companies have a Crisis Management Process to identify and handle safety incidents.

Such a process could include procedures such as:

- A defined Crisis Team, with contact details and responsibilities
- Procedures to identify safety issues from a number of sources
- Procedures to trace and quarantine stock within a companies supply chain and customers supply chains
- Procedures to handle returns
- Media and press notice formats
- Internal and external communication process
- Contractual agreements with suppliers
- Processes to identify causes
- Key Third Party contacts
- Helpline procedures
- Product take back and disposal / rework procedures
- A robust risk assessment procedure - one example can be found in “The RAPEX Guidelines” \*

It is recommended that Economic Operators work with their Trading Standards contacts who can provide advice and support in such cases.

Whilst there are various guidance documents related to product incidents, companies may wish to refer to BIP 2217 Business Continuity Management for Small and Medium Sized Enterprises. How to Survive a Major Disaster or Failure.

\* Further details can be found in “The RAPEX Guidelines” which can be found here:

[http://ec.europa.eu/consumers/safety/rapex/key\\_docs\\_en.htm](http://ec.europa.eu/consumers/safety/rapex/key_docs_en.htm)

\* General information on RAPEX can be found here: [http://ec.europa.eu/consumers/safety/rapex/index\\_en.htm](http://ec.europa.eu/consumers/safety/rapex/index_en.htm)

## 7. Provide information and co-operate with authorities on reasoned request

Economic Operators must be able to supply documentation relevant to the nature of the enquiry within 30 days, unless a shorter deadline is justified in the case of serious and immediate risk.

It is not always an obligation to hold such documentation and Distributors are able to request information or refer the Authorities to the relevant party within the EU as required.

Documents must be supplied in a language “easily understood” by the Authority. It may be necessary to translate certain parts of the technical files into the language of the requesting authority if English is not acceptable.