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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	
	Article 4	Ensure toys comply with essential safety requirements	Article 6	Place only compliant toys on the market	Article 7	Take due care
Draw up Technical Documentation and carry out the conformity and safety assessments.	A4(2) A21 A18 A19	Obligated	A6(2)	Ensure it is done		No Obligation

A BoM forms a part of the Technical Documentation.

A *Manufacturer* outside of the EU can appoint by a written mandate an *Authorised Representative*. The *Authorised Representative* shall perform all the tasks in the mandate but the drawing up of the technical documentation can NOT form part of this mandate. This remains the responsibility of the *Manufacturer*.

2. Introduction

The revised *Toy Safety Directive* (TSD) (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.

Article 4 of the revised TSD details the *Technical Documentation* required to be kept for each toy placed on the market and this includes 'a list of components and materials used in the toy.....'. Such a listing in manufacturing industry is more commonly known as a *Bill of Materials* (BoM).

This BTHA guidance describes a recommended format for a BoM that should be kept in the technical documentation.

3. Why have a standard BoM format?

The TSD requires that manufacturers keep a detailed description of the design and manufacture of the toy. This description will include technical drawings and a list of the components and materials used in the toy. This list is commonly referred to as the *Bill of Materials* (BoM) and should include purchased parts, sub assemblies and raw materials. As defined in the economic operators guide, this must be produced by the manufacturer:

In simple terms, the prime reason to include a BoM in the Technical Documentation is to fulfil Article 4 and Annex IV(a) of the Toy Safety Directive.

However, other parts of the TSD restrict specific chemicals and require that every toy undergoes a safety assessment, including a chemical safety assessment. Also toys are not immune from other legislation, such as REACH and RoHS which have their own chemical restrictions, these Directives should also be considered. A BoM is a useful tool in evaluating whether the chemical requirements of these Directives are being met. However, in some instances a more detailed BoM can help in this work. For companies that need to go beyond basic compliance two further versions of a BoM are available in a BTHA guide in the member's area of the website.

A BOM shows the *intended* substances of the product and is one of the tools that can help show that restricted chemicals are not a part of the product design. Used with proper manufacturing control procedures, as outlined in the *BTHA Conformity Assessment Guide*, testing costs can be significantly reduced.


All manufacturers use BoMs in one form or another. These are most often used for manufacturing or costing purposes but not to evaluate compliance to product to safety legislation. There is no standard format and many of the versions being used in toy factories make it difficult for small companies to obtain a suitable BoM. Hence many companies, large and small, have concluded that a standardised format it would give uniformity and familiarisation that would allow evaluation of the product to safety legislation.

The following is suggested guide for companies to follow.

4. BoM format

The BTHA suggestion for a BoM is shown below. This format would be suitable for simple products (i.e. products without substances, preparations or formulations). It is considered to be the minimum any toy manufacturer or toy importer should include in the technical documentation with intention of meeting the requirements of Article 4 and Annex IV(a) of the TSD.

It should be noted that a BoM shows the parts, materials or substances that are *intended* to be included in the product.

		Bill of Materials / Bill of Substance		
Product Name:		Item Number:		
Factory Name:		Date:		
		Issue Number:		
Part No	Description	Materials	Method of Compliance (SDS, Test, DoC, TRA)	

The information required is:

Part Number – this is a unique number within the product. There is no predefined format.

Description – description of the part.

Material - a description of the material of the part. Many parts will be composite materials or assemblies of other parts (for instance electronics). The material should be as detailed as possible. For instance, plastics should name the polymer type (e.g. PP, PET etc) and should not just say 'plastic'. Any decoration should be declared (e.g. paint, tampon print etc). This will enable a user to apply simple risk evaluation to determine whether further details or testing is required.

Method of compliance - used by the manufacturer / factory to determine whether the part is in compliance. This could be a Declaration of Conformity (DoC); Toxicology Risk Assessment (TRA); Safety Data Sheet (SDS) or batch Test.

This format allows for a chemical safety assessment using a risk based approach, as described in the *BTHA Chemical Safety Assessment Guide*.

This BTHA format is available as full page template at the end of this guideline. This can be printed out and used to enter BoM information.

Alternatively, an Excel version is available from the BTHA web site.

