

BTHA Toy Safety Directive Guidance
2009/48/EC

Obligations of Economic Operators

2



Primary Authority Assurance



Milton Keynes Council (MKC) has assured this BTHA guidance as 'Primary Authority advice'

The level of assurance that this document can give individual members is detailed below:

1 Milton Keynes Primary Authority Partners

British Toy and Hobby Association members who have a coordinated Primary Authority Partnership with Milton Keynes Council.

Milton Keynes Council accepts responsibility for being the principle source of local authority regulatory advice and guidance for these members.

Such members can legally rely on the guidance contained within these documents. Any proposed enforcement action against Primary Authority Partners that is inconsistent with this BTHA Primary Authority assured advice, will be directed against. This means that Milton Keynes Primary Authority may direct an enforcing authority not to take proposed enforcement action (thereby blocking the enforcement action) where such action is inconsistent with Primary Authority advice.

2 Other Primary Authority Partners

British Toy and Hobby Association members who have a Primary Authority Partnership with a Council other than Milton Keynes.

Such members can have this guidance assured as Primary Authority advice within their own Primary Authority Partnership.

MKC can, if required, work with these other Primary Authorities to encourage this advice to be assured within their own partnerships.

Once this Primary Authority advice is issued, such members can legally rely on the guidance contained within these documents. This means that the member's Primary Authority may direct an enforcing authority not to take proposed enforcement action (thereby blocking the enforcement action) where such action is inconsistent with Primary Authority advice.

3 No Primary Authority Partnership

British Toy and Hobby Association members and stakeholders who do not have a Primary Authority Partnership with Milton Keynes or any other Council.

Such members can use the guidance with the knowledge that it is BTHA approved guidance however as the members are not in a Primary Authority Partnership they cannot legally rely on this guidance.

The guidance is intended to explain legal 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.

Further details regarding the BTHA Primary Authority agreements can be obtained from the BTHA.

Contents

1. Introduction
 2. Overview
 3. How to use this guide
 4. Table 1: How to Identify your operator type
 5. Table 2: Determine your obligations
 6. Manufacturer's obligations
 7. Importer's obligations
 8. Distributor's obligations
 9. Authorised Representative's obligations
 10. Identifying your operator type – example 1
 11. Identifying your operator type – example 2
 12. Identifying your operator type – example 3
- Appendix 1 Frequently asked questions

1. Introduction

The Toy Safety Directive (2009/48/EC) (TSD) 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 the implementation of the subject material covered by this guidance document was from 20 July 2011.

The Directive now specifies the roles of Manufacturers, Importers and Distributors, all of which now have related obligations. The traditional definitions and the associated responsibilities of these Economic Operators have fundamentally changed.

This document provides an interpretation of these obligations, as defined in the Directive. 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.

2. Overview

The revised Toy Safety Directive defines the new obligations of four Economic Operators:

- **Manufacturer**
- **Importer**
- **Distributor**
- **Authorised Representative (formally appointed by Manufacturers only)**

2

These roles are adopted by businesses based on criteria laid down in the Directive. The criteria depends, for example, on how toys are purchased, who designed (or modified) the toy, the brand of the toy and the stage in the product cycle at which an operator becomes involved.

The operator role, as defined in the Directive, may be different to what a company would consider to be their “normal trading role”. For example, a company that physically imports a toy may be obliged to adopt the role of a Manufacturer or Distributor depending on such factors as, the business model, if they have made changes to the product etc. Furthermore depending on the mode of supply, businesses may even adopt different operator roles when selling the same toy into different retailers. It is therefore important to note that the role adopted needs to be assessed on a case by case basis. The same product may be sold according to a number of different business models which may in turn alter the responsibilities of the parties involved.

For each operator type there are a series of obligations that they are legally required to meet when supplying or purchasing toys. In general terms the obligations are more onerous when businesses adopt the role of “Manufacturer” and less onerous when adopting the role of “Importer” and even less onerous when adopting the role of “Distributor”. A Manufacturer can appoint by a written mandate, an “Authorised Representative”. The Authorised Representative shall perform all the tasks in the mandate.

3. How to use this guide

A Typical Business Model		B Product Cycle				
Type	Description	Design & Development	Production	Bring into EU	Storage & Transport	Retail
1 EU Production	Product developed, produced and sold entirely within the EU.	Manufacturer				Distributor
2 Developed & Domestic	Product developed and sold within the EU by an EU operator, but produced outside the EU.	Manufacturer				Distributor
3 1 st Party & Domestic (No product alterations)	Unaltered product developed by a supplier, then sold within the EU by an EU operator (see note 1).	Manufacturer		Importer		Distributor
4 1 st Party & Domestic (With product alterations)	Supplier product specifically modified (see note 1) for or by an EU operator and sold within the EU.	Manufacturer				Distributor
5 Direct Import / FOB	Product developed by a non-EU operator sold outside of the EU for direct import by another EU operator.	Manufacturer			Importer	
6 Direct Import / FOB - Manufacturer an EU entity	Product developed by an EU operator sold outside of the EU for direct import by another EU operator (see note 2).	Manufacturer				Distributor
7 1 st Party (Sales Commission) FOB	Product developed by EU or non-EU operator sold outside of the EU by an EU or non-EU sales agent, for direct import by an EU operator.	Manufacturer				Importer
8 Manufacturer's Authorized Representative in EU	Where a Manufacturer mandates an EU entity to be their Authorized Representative.	Manufacturer		Authorized Representative		Distributor
9 Own Brand Product	Product supplied in own brand/label or retailer branded product.	Manufacturer				

Step 1 – Determine your role

Table 1 defines nine different business models which reflect the ways toys are typically purchased by UK based businesses. There is a brief description beside each business model.

Once the model is determined follow the table across to the right to the earliest point in the “product cycle” that your business takes responsibility for the product. The box will then indicate your role(s).



Obligation	Manufacturer	Importer	Distributor	Authorized Representative
Draw up Technical Documentation	A4 (2) A5 (1) Obligated	A6 (2)	A6 (2)	A6 (2)
Retain Technical Documentation for 10 years	A4 (3)	Obligated	A6 (2)	A6 (2)
Carry out the Conformity & Safety Assessments	A4 (2) A5 (1) A6 (1)	Obligated	A6 (2)	A6 (2)
Draw up EC Declaration of Conformity	A4 (2)	Obligated	A6 (2)	A6 (2)
Retain the EC Declaration of Conformity for 10 years	A4 (3)	Obligated	A6 (2)	A6 (2)
Affix conformity marking (CE), batch or model number to toy or packaging	A4 (2) A4 (3)	Obligated	A6 (2)	A7 (2)
Ensure Conformity of Series Production	A4 (4)	Obligated	No obligation	No obligation
Add name and address onto toy or packaging	A4 (5)	Obligated	A6 (2) A6 (3)	A7 (2)
Ensure the required documents (instructions and safety information) accompany the toy in the correct languages	A4 (7) A1 (2)	Obligated	A6 (4)	A7 (2)
Bring non-conforming toys into compliance (where applicable if there is a safety risk)	A4 (8) A4 (9)	Obligated	A6 (2) A6 (3) A6 (5)	A7 (2) A7 (4) A7 (5)
Recall or withdraw	A4 (10) A4 (11)	Obligated	A6 (5)	A7 (2) A7 (4) A7 (5)
Provide information to authorities on request	A4 (10) A4 (11)	Obligated	A6 (5)	A7 (2) A7 (4) A7 (5)
Sample test marketed toys (taking into account risk)	A4 (14)	Obligated	A6 (5)	Obligated
Keep register of complaints, non-conforming toys and recalls; inform Distributors of this monitoring	A4 (14)	Obligated	A6 (5)	Obligated
Don't jeopardise compliance during storage or transport	No obligation but recommended	A6 (5)	Obligated	A7 (2)
Identify the other Economic Operators in the supply chain	A9	Obligated	A9	Obligated

Step 2 – Determine your obligations

Table 2 lists the obligations for each Economic Operator role based on the requirements of the Directive. Obligations have been grouped together from separate articles of the Directive to simplify the requirements. The article numbers from the Directive are listed so that businesses can check the original text.



Obligation	Related BTHA Guidance Documents / Comments
Draw up Technical Documentation	Technical Documentation
Retain Technical Documentation for 10 years	Technical Documentation
Carry out the Conformity & Safety Assessments	Safety Assessments, Technical Documentation, Conformity Assessment
Draw up EC Declaration of Conformity	Technical Documentation
Retain the EC Declaration of Conformity for 10 years	Technical Documentation
Affix conformity marking (CE), batch or model number to toy or packaging	Markings & Warnings
Ensure Conformity of Series Production	Conformity of Series Production
Add name and address onto toy or packaging	Markings & Warnings
Ensure the required documents (instructions and safety information) are in the correct languages	Markings & Warnings
Bring non-conforming toys into compliance (where applicable if there is a safety risk)	Product Monitoring
Recall or withdraw	Product Monitoring
Provide information to authorities on request	Product Monitoring
Sample test marketed toys (taking into account risk)	Product Monitoring
Keep register of complaints, non-conforming toys and recalls; inform Distributors of this monitoring	Product Monitoring
Don't jeopardise compliance during storage or transport	
<p>This is not a specific obligation for Manufacturers however they should be mindful of this requirement and ensure that compliance is not jeopardised during storage and transit while the toy is under their control. This could include careful handling or appropriate storage conditions (e.g. wooden or plush toys stored in damp conditions). Responsible Manufacturers should design products to cope with expected conditions of transport and storage.</p>	
<p>Identify the other Economic Operators in each toy's supply chain</p> <p>Manufacturers should be able to identify any Economic Operator who has supplied them with a toy and any Economic Operator to whom they have supplied a toy (one up, one down). However, it is advisable to ensure you are aware of and record in the Technical Documentation the complete supply chain for each toy.</p>	

Step 3 – How to meet your obligations

Explanatory text is given for the obligations listed. Reference to other BTHA guidance documents is made where appropriate.

The explanatory text within these sections is intended only to describe where there are differences in the obligations of the Economic Operators. For example, Manufacturers are generally required to carry out all the obligations, whereas Importers may only need to ensure that a particular obligation has been carried out.

4. Table 1: How to identify your operator type

- (a) Select the business model which most closely reflects the circumstances in which the product and/or order is brought to market.
 (b) Identify the earliest point in the product cycle at which you take responsibility for the product. N.B. you may take responsibility for actions even though you might not directly carry them out. Reference the table to determine your operator type for that product.

A		Typical Business Model		B				
		Type	Description	Design & Development	Production	Bring into EU	Storage & Transport	Retail
1	EU Production	Product developed, produced and sold entirely within the EU.	Manufacturer	Manufacturer	Distributor			
2	Developed & Domestic	Product developed and sold within the EU by an EU operator, but produced outside the EU.	Manufacturer	Manufacturer	Distributor			
3	3 rd Party & Domestic [No product alternation]	Unaltered product developed by a supplier, then sold within the EU by an EU operator [see note1].	Manufacturer	Importer	Distributor			
4	3 rd Party & Domestic [With product alternation]	Supplier product specifically modified (see note 1) for or by an EU operator and sold within the EU.	Manufacturer	Manufacturer	Distributor			
5	Direct import / FOB	Product developed by a non-EU operator sold outside of the EU for direct import by another EU operator.	Manufacturer	Importer	Importer			
6	Direct import / FOB – Manufacturer an EU entity	Product developed by an EU operator sold outside of the EU for direct import by another EU operator (see note 2).	Manufacturer	Manufacturer	Distributor			
7	3 rd Party (Sale Commission) FOB	Product developed by EU or non-EU operator sold outside of the EU by an EU or non-EU sales agent, for direct import by an EU operator.	Manufacturer	Manufacturer	Importer			
8	Manufacturer's Authorised Representative in EU	Where a Manufacturer mandates an EU entity to be their Authorised Representative.	Manufacturer	Authorised representative	Distributor			
9	Own Brand Product	Product supplied in own brand/label or retailer branded product.	Manufacturer	Manufacturer				

Conditional Notes:

- 1 An Importer or Distributor who modifies the product and by doing so alters its compliance, assumes the responsibilities of the Manufacturer. The addition of legal labels to the retail pack does not constitute modified product. Modifications which may affect compliance are changes in materials, colour, age grading, own branding etc.
- 2 Where an EU entity presents itself as the Manufacturer (by affixing their name, address etc) they are considered to place the product on the market even if they do not physically import the product. In this case there is no Importer.

5. Table 2: Determine your obligations

Obligation	Manufacturer		Importer		Distributor		Authorised Representative	
	Ensure toys comply with essential safety requirements	Place only compliant toys on the market	Take due care	As mandated	As mandated	As mandated	As mandated	
Draw up Technical Documentation	A4 (2) A21	Obligated	A6 (2)	Ensure it's 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	
Carry out the Conformity & Safety Assessments	A4 (2) A18 A19	Obligated	A6 (2)	Ensure it's done	No obligation	No obligation		
Draw up EC Declaration of Conformity	A4 (2)	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	
Affix conformity marking (CE), batch or model number to toy or packaging	A4 (2) A4 (5)	Obligated	A6 (2)	Ensure it's done	A7 (2)	If mandated		
Ensure Conformity of Series Production	A4 (4)	Obligated	No obligation		No obligation	No obligation		
Add name and address onto toy or packaging	A4 (6)	Obligated	A6 (2) A6 (3)	Obligated	A7 (2)	A4 (6)	If mandated	
Ensure the required documents (instructions and safety information) accompany the toy in the correct languages	A4 (7) A11 (2)	Obligated	A6 (4)	Obligated	A7 (2)	If mandated		
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	Must be mandated	
Sample test marketed toys (taking into account risk)	A4 (4)	Obligated	A6 (6)	Obligated	No obligation	If 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		
Don't jeopardise compliance during storage or transport	No obligation but recommended		A6 (5)	Obligated	A7 (3)	Obligated	No obligation but recommended if appropriate.	
Identify the other Economic Operators in the supply chain	A9	Obligated	A9	Obligated	A9	Obligated	Obligated	

6. Manufacturer's obligations

A Manufacturer is a Economic Operator that has a toy designed or manufactured, and markets that toy under his name or trademark. A Manufacturer can be considered an EU based Manufacturer even if the goods are physically produced outside of the EU.

Obligation	Related BTHA Guidance Documents / Comments
Draw up Technical Documentation	Technical Documentation
Retain Technical Documentation for 10 years	Technical Documentation
Carry out the Conformity & Safety Assessments	Safety Assessments, Technical Documentation, Conformity Assessment
Draw up EC Declaration of Conformity	Technical Documentation
Retain the EC Declaration of Conformity for 10 years	Technical Documentation
Affix conformity marking (CE), batch or model number to toy or packaging	Markings & Warnings
Ensure Conformity of Series Production	Conformity of Series Production
Add name and address onto toy or packaging	Markings & Warnings
Ensure the required documents (instructions and safety information) are in the correct languages	Markings & Warnings
Bring non-conforming toys into compliance Inform authorities if there is a safety risk Recall or withdraw Provide information to authorities on request	Product Monitoring
Sample test marketed toys (taking into account risk)	Product Monitoring
Keep register of complaints, non-conforming toys and recalls; inform Distributors of this monitoring	Product Monitoring

Don't jeopardise compliance during storage or transport

This is not a specific obligation for Manufacturers however they should be mindful of this requirement and ensure that compliance is not jeopardised during storage and transit while the toy is under their control. This could include careless handling or inappropriate storage conditions (e.g. wooden or plush toys stored in damp conditions). Responsible Manufacturers should design products to cope with expected conditions of transport and storage.

Identify the other Economic Operators in each toy's supply chain

Manufacturers should be able to identify any Economic Operator who has supplied them with a toy and any Economic Operator to whom they have supplied a toy (one up, one down). However, it is advisable to ensure you are aware of and record in the Technical Documentation the complete supply chain for each toy.

7. Importer's obligations

Where a business imports a product from outside of the EU but where the Manufacturer, or the Manufacturer's Authorised Representative is based in the EU the importing company is considered to be the Distributor. There is no Importer role in this scenario (Manufacturer location does not necessarily mean where the goods are physically manufactured). If an Importer makes changes to a product that may affect the product's compliance, the Importer is considered to be the Manufacturer and must take on the obligations of the Manufacturer.

Obligation	Related BTHA Guidance Documents / Comments
(Draw up) Technical Documentation	Technical Documentation

Importers are required to ensure that the Technical Documentation has been drawn up by the Manufacturer. It is considered sufficient that an Importer check that the Manufacturer has systems and procedures in place to do this rather than requesting evidence on a product by product basis (see below).

It is possible for Importers to gain assurance that the Technical Documentation has been drawn up by a Manufacturer by requesting a Declaration of Conformity. However it is important for Importers to have taken steps to assure themselves that the Manufacturer is producing the required documentation and will be able to supply it on request.

(Retain) Technical Documentation for 10 years	Technical Documentation
--	---

Importers are required to ensure that this documentation can be made available to authorities for 10 years after last placing the toy on the market. It is important to note that the requirement is not to obtain and retain such documentation themselves (except for EC Declaration of Conformity – see below), but to ensure that it will be available.

As stated above Importers must have taken steps to assure themselves that the Manufacturer has produced the required documentation. In addition to this Importers need to ensure that this documentation is being retained by the Manufacturer for the required 10 years and that the Manufacturer will be able to supply it on request.

If Importers cannot gain this level of confidence, they should consider holding the Technical Documentation themselves. Also Importers should be mindful of the requirement to be able to supply this documentation for 10 years after the product has last been placed on the market and may want to retain the documentation for this reason, e.g. if there may be a risk that the Manufacturer may close. Importers should be aware that they will be in breach of the Toy Safety Directive requirements if they are unable to supply the technical information on request.

NB: It should be noted that there will be a time limit given to supply such documents, therefore if Importers are not confident that they will be able to obtain it within the required time limit or that it will not be retained for 10 years by the Manufacturer, they should obtain and hold it themselves.

(Carry out the) Conformity & Safety Assessments	Safety Assessments, Technical Documentation, Conformity Assessment
--	--

As per the Technical Documentation requirements above it is for the Importer to ensure that the appropriate Conformity Assessment and Safety Assessments have been carried out by the Manufacturer. It is considered sufficient that an Importer checks that the Manufacturer has systems and procedures in place to do this rather than requesting evidence on a product by product basis.

NB: It should be noted that there will be a time limit given to supply such documents to the enforcement authorities. If Importers are not confident that they will be able to get such documentation within the time limit from a Manufacturer or that it will not be retained for 10 years by the Manufacturer, they should obtain and hold it themselves.

(Draw up) EC Declaration of Conformity	Technical Documentation
---	---

Importers are required to keep a copy of the Manufacturers Declaration of Conformity for a period of 10 years after last placing the product on the market.

Importer's obligations (continued)

Retain the EC Declaration of Conformity for 10 years

Technical Documentation

Importers must retain the Declaration of Conformity so that it can be made available to the enforcement authorities for 10 years after last placing the toy on the market.

(Affix) conformity marking (CE), batch or model number to toy or packaging

Markings & Warnings

Importers need only to ensure that type or batch or serial or model number is present. It is not considered necessary for Importers to check each product individually but only to ensure that Manufacturers have procedures and systems in place to ensure that the required marking is present.

Add name and address onto toy or packaging

Markings & Warnings

Importers should add their identification and address to the toy or its packaging. Importers should ensure that the Manufacturers identification and address is also present.

If the Manufacturer is based within the EU, but the toy itself is manufactured outside the EU, the Manufacturer is considered to be the entity that places the toys on the EU market – even if another Economic Operator physically imports the toy. In this case there is no Importer and it is sufficient to apply only the Manufacturer's identification and address.

Ensure the required documents (instructions and safety information) are in the correct languages

Markings & Warnings

It is considered sufficient that an Importer checks that the Manufacturer has systems and procedures in place to do this rather than requesting evidence on a product by product basis. Importers need to ensure the toys they supply have the required documentation in the appropriate language for each Member State.

Bring non-conforming toys into compliance Inform authorities if there is a safety risk Recall or withdraw Provide information to authorities on request

Product Monitoring

This is an obligation of all Economic Operators. It is expected that all Economic Operators work together on this obligation to ensure a consistent, agreed and coordinated approach.

Sample test marketed toys (taking into account risk)

Product Monitoring

As this is also an obligation of Manufacturers, co-operation is recommended to prevent unnecessary duplication.

Keep register of complaints, non-conforming toys and recalls; inform Distributors of this monitoring

Product Monitoring

It is recommended that any such monitoring is shared with the Manufacturer of the product so that they are able to respond and take necessary actions.

Don't jeopardise compliance during storage or transport

Importers should ensure that compliance is not jeopardised during storage and transit while the toy is under their control. This may include careless handling or inappropriate storage conditions (e.g. wooden or plush toys stored in damp conditions).

Identify the other Economic Operators in each toy's supply chain

Importers should be able to identify any Economic Operator who has supplied them with a toy and any Economic Operator to whom they have supplied a toy (one up, one down). However, it is advisable to ensure you are aware of and record in the Technical Documentation the complete supply chain for each toy.

8. Distributor's obligations

Where a business imports a product from outside of the EU when the Manufacturer or the Manufacturer's Authorised Representative is based within the EU the importing company is considered to be the Distributor. There is no Importer role in this scenario.

Obligation	Related BTHA Guidance Documents / Comments
(Affix) conformity marking (CE), batch or model number to toy or packaging	Markings & Warnings
Distributors are required to verify that the required conformity markings are present. It is not considered necessary for Distributors to check each product individually but only to have confidence that Manufacturers have the procedures and systems in place to ensure that the required markings are applied.	
(Add) name and address onto toy or packaging	Markings & Warnings
Distributors should verify that the applicable Manufacturer's and Importer's identifications and addresses are present. It is not considered necessary for Distributors to check each product individually but only to verify that Manufacturers and Importers have procedures and systems in place to ensure that the required details have been applied correctly.	
Ensure the required documents (instructions and safety information) are in the correct languages	Markings & Warnings
It is considered sufficient that Distributors check that the Manufacturer or Importer (if applicable) has the systems and procedures in place to do this rather than requesting evidence on a product by product basis. Distributors need to verify that the toys they supply have the required documentation in the appropriate language for each Member State.	
Bring non-conforming toys into compliance Inform authorities if there is a safety risk Recall or withdraw Provide information to authorities on request	Product Monitoring
This is an obligation of all Economic Operators. It is expected that all Economic Operators work together on this obligation to ensure a consistent, agreed and coordinated approach. With regards to the provision of information, because the Distributor has no obligations in relation to Technical Documentation, it is expected that Distributors will provide the authorities with the Manufacturer or Importer details. Authorities will then be able to request the required documentation directly from the relevant Manufacturer or Importer.	
Keep register of complaints, non-conforming toys and recalls; inform Distributors of this monitoring	Product Monitoring
Although this is not an obligation of Distributors it is recommended that Distributors keep a register of complaints and ensure that Manufacturers or Importers (if applicable) are made aware of them as appropriate.	
Don't jeopardise compliance during storage or transport	
Distributors should ensure that compliance is not jeopardised during storage and transit while the toy is under their control. This could include careless handling or inappropriate storage conditions (e.g. wooden or plush toys stored in damp conditions). Responsible Manufacturers should design products to cope with expected conditions of transport and storage.	
Identify the other Economic Operators in each toy's supply chain	
Distributors should be able to identify any Economic Operator who has supplied them with a toy and any Economic Operator to whom they have supplied a toy (one up, one down). However, it is advisable to ensure you are aware of and record in the Technical Documentation the complete supply chain for each toy.	

9. Authorised Representative's obligations

The Manufacturer's obligations may be fulfilled by his/her Authorised Representative, on his/her behalf and under his/her responsibility. Details of the Authorised Representative's role must be specified in a written mandate. Some aspects must be mandated and are specified in the Directive.

Obligation	Related BTHA Guidance Documents / Comments
Draw up Technical Documentation	Technical Documentation
The drawing up of the Technical Documentation cannot be mandated. The Authorised Representative can assist where appropriate; however, it is important to note that the Manufacturer remains wholly responsible for the Technical Documentation.	
Retain Technical Documentation for 10 years	Technical Documentation
Keeping and retaining the EC Declaration of Conformity must form part of the mandate and therefore will be an obligation of the Authorised Representative.	
Carry out the Conformity & Safety Assessments	Safety Assessments, Technical Documentation, Conformity Assessments
Authorised Representatives have no obligation to carry the Conformity and Safety Assessments, however they may carry out parts of the Conformity Assessment (decision 768/2008 Module A and C).	
Draw up EC Declaration of Conformity	Technical Documentation
The Authorised Representative should draw up the EC Declaration of Conformity if it is part of the mandate. The Authorised Representative's name and address can be on the Declaration of Conformity (768/2008/EC Page 17 Section 5).	
Retain the EC Declaration of Conformity for 10 years	Technical Documentation
The Authorised Representative should keep the EC Declaration of Conformity and retain for 10 years after the product was last placed on the market.	
Affix conformity marking (CE), batch or model number to toy or packaging	Markings & Warnings
The Authorised Representative can affix the conformity marking if it is part of the mandate.	
Add name and address onto toy or packaging	Markings & Warnings
Manufacturers are obligated to show a single point at which they can be contacted. This contact point can be the name and address of the Authorised Representative if this forms part of the mandate.	
Ensure the required documents (instructions and safety information) accompany the toy in the correct languages	Markings & Warnings
The Authorised Representative should ensure that the required documents accompany the toy in the correct languages if it is part of the mandate. Authorised Representatives need to ensure the toys they supply have the required documentation in the appropriate language for each Member State where they are involved in supplying a product.	

Authorised Representative's obligations (continued)

Bring non-conforming toys into compliance
Inform authorities if there is a safety risk
Recall or withdraw
Provide information to authorities on request

Product Monitoring

This must be part of the mandate. This is an obligation of all Economic Operators. It is expected that all Economic Operators work together on this obligation to ensure a consistent, agreed and coordinated approach.

Sample test marketed toys (taking into account risk)

Product Monitoring

The Authorised Representative must sample test marketed toys if this is part of the mandate.

Keep register of complaints, non-conforming toys and recalls; inform Distributors of this monitoring

Product Monitoring

The Authorised Representative must keep a register of complaints, non-conforming toys and recalls if this is part of the mandate.

Don't jeopardise compliance during storage or transport

This is not a specific obligation for Authorised Representatives. However, if they have storage and distribution responsibilities they should be mindful of this requirement and ensure that compliance is not jeopardised whilst the toy is under their control. This could include careless handling or inappropriate storage conditions (e.g. wooden or plush toys stored in damp conditions). Responsible Manufacturers should design products to cope with expected conditions of transport and storage.

Identify the other Economic Operators in each toy's supply chain

Authorised Representatives must be able to identify the Manufacturer. Where they have a distribution function, independent of the Manufacturer they should be able to identify any Economic Operator to whom they have supplied a toy. However, it is advisable to ensure you are aware of and record in the Technical Documentation the complete supply chain for each toy.

10. Identifying your operator type – example 1 FOB / direct import (Manufacturer based outside the EU)

In the case of a retailer who buys a complete container of product and imports it into Europe from a Manufacturer based outside the EU.

(a) Identify the business model – **DIRECT IMPORT.**

(b) Identify the earliest point in the product cycle at which the Operator becomes responsible for the product..... **BRING IN TO EU.**

This retailer therefore adopts the responsibilities of the **IMPORTER.**

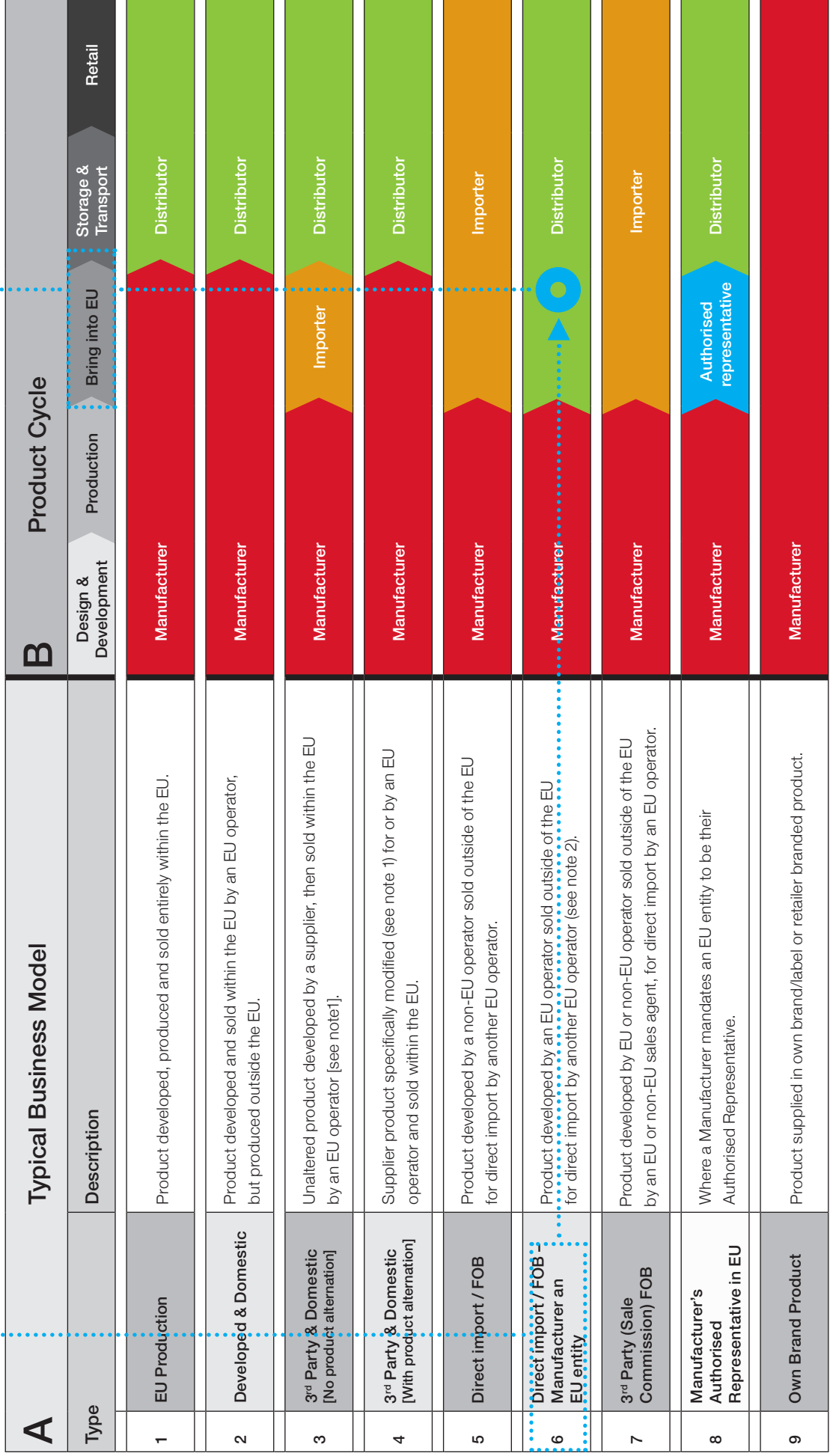
A		B				
Typical Business Model		Product Cycle				
Type	Description	Design & Development	Production	Bring into EU	Storage & Transport	Retail
1	EU Production	Product developed, produced and sold entirely within the EU.	Manufacturer		Distributor	
2	Developed & Domestic	Product developed and sold within the EU by an EU operator, but produced outside the EU.	Manufacturer		Distributor	
3	3 rd Party & Domestic [No product alternation]	Unaltered product developed by a supplier, then sold within the EU by an EU operator [see note 1].	Manufacturer	Importer	Distributor	
4	3 rd Party & Domestic [With product alternation]	Supplier product specifically modified (see note 1) for or by an EU operator and sold within the EU.	Manufacturer		Distributor	
5	Direct import / FOB	Product developed by a non-EU operator sold outside of the EU for direct import by another EU operator.	Manufacturer		Importer	
6	Direct import / FOB – Manufacturer an EU entity	Product developed by an EU operator sold outside of the EU for direct import by another EU operator (see note 2).	Manufacturer		Distributor	
7	3 rd Party (Sale Commission) FOB	Product developed by EU or non-EU operator sold outside of the EU by an EU or non-EU sales agent, for direct import by an EU operator.	Manufacturer		Importer	
8	Manufacturer's Authorised Representative in EU	Where a Manufacturer mandates an EU entity to be their Authorised Representative.	Manufacturer	Authorised representative	Distributor	
9	Own Brand Product	Product supplied in own brand/label or retailer branded product.	Manufacturer			

11. Identifying your operator type – example 2 FOB / direct import (where the Manufacturer or Authorised Representative is based in the EU)

In the case of an EU Operator who buys product from an EU based Manufacturer (product not necessarily manufactured in the EU) and imports it themselves (FOB).

- (a) Identify the business model – direct import FOB (Manufacturer is EU entity).
- (b) Identify the earliest point in the product cycle at which the Operator becomes responsible for the product.... BRING IN TO EU.

This Operator therefore adopts the responsibilities of the **DISTRIBUTOR**.



12. Identifying your operator type – example 3, third party & domestic with product alteration

In the case of an EU Operator who buys product developed by a third party and makes any alterations (including packaging and / or product) before or after importation.

- (a) Identify the business model – third party & domestic (with alteration).
- (b) Identify the earliest point in the product cycle at which the Operator becomes responsible for the product..... BRING IN TO EU.

➡ This Operator therefore adopts the responsibilities of the **MANUFACTURER**.

A		B				
Typical Business Model		Product Cycle				
Type	Description	Design & Development	Production	Bring into EU	Storage & Transport	Retail
1	EU Production	Product developed, produced and sold entirely within the EU.	Manufacturer			Distributor
2	Developed & Domestic	Product developed and sold within the EU by an EU operator, but produced outside the EU.	Manufacturer			Distributor
3	3 rd Party & Domestic [No product alteration]	Unaltered product developed by a supplier, then sold within the EU by an EU operator [see note 1].	Manufacturer	Importer		Distributor
4	3 rd Party & Domestic [With product alteration]	Supplier product specifically modified (see note 1) for or by an EU operator and sold within the EU.	Manufacturer	Importer		Distributor
5	Direct import / FOB	Product developed by a non-EU operator sold outside of the EU for direct import by another EU operator.	Manufacturer		Importer	Importer
6	Direct import / FOB – Manufacturer an EU entity	Product developed by an EU operator sold outside of the EU for direct import by another EU operator (see note 2).	Manufacturer			Distributor
7	3 rd Party (Sale Commission) FOB	Product developed by EU or non-EU operator sold outside of the EU by an EU or non-EU sales agent, for direct import by an EU operator.	Manufacturer		Importer	Importer
8	Manufacturer's Authorised Representative in EU	Where a Manufacturer mandates an EU entity to be their Authorised Representative.	Manufacturer	Authorised representative		Distributor
9	Own Brand Product	Product supplied in own brand/label or retailer branded product.	Manufacturer			

Appendix 1 – Frequently asked questions

1. Is it considered adequate to gain assurance that documentation e.g. technical files and risk assessments are available using a signed letter declaration system? Is getting a letter from my suppliers committing to send Technical Documentation on request enough?

In some cases yes, where you are dealing with a competent Manufacturer who is able to demonstrate the existence and availability of this documentation.

It would not be considered adequate if you have not taken steps to assure yourself that the Manufacturer is actually correctly producing and retaining the required documentation and will actually be able to supply it. If you do not have this confidence you should consider holding the Technical Documentation yourself. You should be mindful of the risk of not being able to get access to the required Technical Documentation if a Manufacturer should close.

Importers and Manufacturers will be in breach of the Toy Safety Directive requirements if the required documentation is not available or is not complete.

Expert help may be required should a business not have expertise in house.

2. What should I do if a Manufacturer or factory closes or goes out of business and they are holding the Technical Documentation?

Manufacturers and Importers still have the obligation to ensure that it is available. If you have any doubts it would be prudent to obtain and hold the Technical Documentation yourself.

3. The Guidance document states that documentation should be retained for 10 years after last placing the toy on the market but the Directive states that such records should only be kept for 10 years after first placing the toy on the market. Why is there a difference?

The BTHA consider it prudent to keep the records for 10 years after last placing the toy on the market so that they will be available in the event of a challenge. It may be the case that the toy is sold for more than 10 years, if that is the case, documents are only kept for the 10 years after first placing on the market, it could be challenged that you are marketing a toy without a technical file.

4. There are two business models for FOB, one with the Manufacturer as an EU entity and one with the Manufacturer outside the EU. The Directive does not appear to make this distinction?

The Draft Commission Guidance Document on traceability, instructions, warnings and CE marking. (CEN/TC 52 N 1340) October 2009 states:

If the Manufacturer is within the Community (a company located in the Community presents itself as being the Manufacturer by allowing to having put on their trademark, address,...) although the products are manufactured outside the Community, they are considered to be the Manufacturer, who places the toys on the EU market – even if they do not import in reality – it can be done by another company on their behalf. In this case there is no Importer in the meaning of the Importer's definition and it is sufficient to put only the Manufacturer's address.

5. What are the obligations of Operators who change products already placed on the market?

Examples of Operators who may do this are “jobbers”, retailers etc.

(a) If an Operator takes stock from within the EU for distribution in the EU and does not change the product in a way that may affect compliance then they are classed as and adopt the obligations of a Distributor.

Note: If a product is modified or changed in any kind of way that might affect compliance then the operator is classed as and takes on the obligations of a Manufacturer.

Obscuring a brand name and address is not considered to alter a product's compliance but changing the age grade will probably do so.

(b) If an Operator takes stock from outside the EU without alteration they are considered to be the Importer and adopt the obligations of the Importer.

(c) If the Operator takes stock from outside the EU and changes it in a way that affects compliance (e.g. changing the age grade etc.), they are then considered to be the Manufacturer.

Jobbers are advised that they should assess their actions on a case by case basis as there is a risk that their actions may change their operator type and therefore their obligations.

6. What should I do if I don't have the expertise or capability to carry out my new obligations?

Some Economic Operators in the supply chain (including the factory) may already have much of the required information and it is not necessary to duplicate this where it exists and is correct. It is permissible to use external expertise to help you assess and carry out your obligations, however the responsibility for the obligations remains yours.

7. Where an Importer or Distributor modifies the product what changes are considered to affect compliance (table 1 conditional note 1)? Also see questions 9, 10, 11.

It is advised that each situation requires review on a case-by-case basis. If in doubt independent expert advice should be sought. The following are examples only:

- **Change in age grading**

In most cases this will affect compliance especially in the younger age groupings. Recommended age grade changes in the older age ranges may not necessarily affect compliance, e.g a grade change from age 11 to 12.

- **Packaging changes**

Could affect compliance if instructions, graphics, dimensions and prominence of warnings are changed. Protection of the product within a pack must not be affected.

- **Composing assortments out of existing toys**

Could affect compliance if age ranges are not compatible. Products are likely to be packed differently therefore protection of the product must not be affected.

- **New colour ways**

Could affect chemical compliance.

- **Translation, modification and addition of warnings and instructions**

Could affect compliance if not done correctly.

8. Some Distributors of products add their name and address to products for customer service contacts.

Does adding this detail change their obligations (e.g. do they become the Importer or the Manufacturer)?

No. Where the Importer or Manufacturer is already established in the EU and where this is an additional customer service option only, the obligations remain with the original Economic Operator. Formal agreement of this may be desirable.

9. Where an Economic Operator requests changes to a product and the Manufacturer assesses the changes and confirms that compliance has not been affected (e.g. Safety and Compliance Assessments etc.), does the original Manufacturer retain the Manufacturer obligations?

Yes. Formal agreement of this may be desirable.

10. During the process of ensuring all compliance requirements have been met, an Importer may point out additional standards that may apply to the toy or that are unique in a particular market of sale. In these instances does this requirement make the Importer liable for the obligations of a Manufacturer?

No, this should be considered as part of the Importer's obligation to "ensure that it is done". Businesses may want to review the wording of such requests to ensure this is understood. It should be noted that this Guidance only relates to the requirements of the Toy Safety Directive based on the definitions contained within it. Other, non-harmonised, legal instruments may have different applicability and definitions.

11. An Importer may, through customer complaints or experience, suggest that changes are carried out on a product in order to improve its quality, durability or appearance. Would this make them liable for the obligations of a Manufacturer?

No. In our opinion this sort of feedback should always be monitored by Manufacturers and they should always consider improving their products. This should be considered as part of the obligations of Importers with regards to complaints monitoring etc. Companies may want to review the wording of such requests to ensure this is understood.

12. If a business buys a promotional toy which bears their company logo, are they liable for the obligations of a Manufacturer?

If the product and any packaging only bears the company's logo then this is considered to be own-brand product (see table 1 row 9). This does give them the obligations of the Manufacturer.

Brand logos appearing on products do not necessarily mean that the brand owner is the Manufacturer. If the product is clearly marked with the Manufacturer's name and address (different to the brand owner) then it is reasonable to assume that responsibility still stays with the Manufacturer. All obligations are required to be carried out and it would be advisable for both parties in this instance to ensure that the roles and responsibilities are clarified as the buyer may still have other obligations (i.e. as an Importer).

13. What is the difference between "verify" and "ensure"?

These terms are intentional and are related to the fact that the responsibilities and obligations of Distributors and Importers are not equal. The Importer has to "place only compliant toys on the market", whereas the Distributor has to "take due care".

Ensure means to make certain that the obligation had been fulfilled.

Verify means to check that the correct information exists.

14. I supply promotional items to museums, theme parks and similar customers. The products are supplied in the customer's own packaging design and therefore they would normally take on responsibility as the Manufacturer. However these companies rely on us to meet all the obligations under the Directive and have no skills to meet the obligations required of Manufacturers. Can I meet the obligations of the Manufacturer on their behalf?

Yes, it would seem inappropriate for such institutions or companies to try and meet the TSD obligations. We would suggest that the packaging and/or product is marked, as required by the Directive, with your address as the Manufacturer (it is suggested you use the words "manufactured by") and that this agreement is confirmed in writing with your customer. This is in the spirit of the Directive in our opinion, there is a clear EU company that enforcement can contact and that company has met the obligations of a Manufacturer.

