

## **Safety Update Obligations of Economic Operators Guidance**

### Revised Toy Safety Directive 2009/48/EC

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Record of Amendments						
Version	Date	Amendment	Section/page affected			
1	27.10.09	First published				
2	20.11.09	Importers need to hold EC DoC within EU and be able to make other documentation available	Table 2 line 2 A6(8) Importer obligation text A6(8)			
3	30.11.09	Amendment to business model description in model number 6	Table 1 – model 6 "description"			
4	25.03.10	Amendment to include "own-branding" in "modifications" & EU commission wording in table 2	Table 1 – note 3 insertion of "own-branding" Table 2 – changed "YES" to "Obligated" and "Ensure" to "Verify" to match EU guidance			
5	18.08.10	Corrections to terminology in table 2. (Technical Documentation and role(s) clarification)	Table 2			
6	27.09.11	Extra sentence in Overview Update How to use section for new tables. Update of wording in Table 1 for clarity. Addition of Authorised Representative role in Table 2. Obligations text related to other BTHA guides removed and re-formatted into tables, new AR section.	Overview paragraph 2 How to use this guide (diagrams only) Table 1 Table 2 Authorised Representatives Obligations (new section 9)			



## **Obligations of Economic Operators Guidance**

Revised Toy Safety Directive 2009/48/EC

#### 1. 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 20<sup>th</sup> July 2011.

The revised 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 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.

#### 2. Overview

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

- Manufacturers
- Importers
- Distributors
- Authorised Representatives (formally appointed by manufacturers only)

These roles are adopted by companies 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 roles, as defined in the new 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, companies 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 companies adopt the role of "manufacturer" and 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



#### Step 1 – Determine your role

Table 1 defines nine different business models which reflect the ways toys are typically purchased by UK based companies. 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 company takes responsibility for the product. The box will then indicate your role(s).



### 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 companies can check the original text.



#### 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, where as Importers many 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/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.

	Тур	ical Business Model	Product Cycle			
<b>a</b>	Type	Description	b Design & Production (Bring in to EU)			Storage & 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 <sup>rd</sup> 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 <sup>rd</sup> 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 is 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	3rd 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	Manufacturers 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	

#### **Conditional Notes:**

- 1 An importer or Distributor who modifies the product and by doing so alters it's 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	Manufactuer Ensure toys comply with essential safety requirements		Importer Place only compliant toys on the market		Distributor Take Due Care		Authorised Representative As mandated	
Draw up Technical Documentation	A4(2) A21	Obligated	A6(2)	Ensure its 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 its done		No obligation		No obligation
Draw up EC declaration of conformity	A4(3)	Obligated	A6(8)	Кеер а сору		No obligation	A5 (3)	If mandated
Retain the EC declaration of conformity for 10 years.	A4(3)	Obligated	A6(8)	Кеер а сору		No obligation	A5 (3)	Кеер а сору
Affix conformity marking (CE), batch or model number to toy or packaging	A4(2) A4(5)	Obligated	A6(2)	Ensure its done	A7(2)	Verify its done		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)	Verify its done	A4(6)	If mandated
Ensure the required documents (instructions and safety information) accompany the toy in the correct languages	A4(7)	Obligated	A6(4)	Obligated	A7(2)	Verify its done		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	A5 (3)	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 obliç	gation but Recommended	A6(5)	Obligated	A7(3)	Obligated	No oblig	gation but Recommended if appropriate.
Identify the other Economic Operators in each toy's supply chain.	<b>A</b> 9	Obligated	A9	Obligated	<b>A</b> 9	Obligated		Obligated



### **Manufacturers 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 & Sample Testing
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)	Conformity of Series Production & Sample Testing
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.

### **Importers Obligations**

Where a company imports 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 Manufacture

Obligation

**Related BTHA Guidance Documents / Comments** 

#### (Draw up) Technical Documentation

**Technical Documentation** 

Importers are required to ensure that the Technical Documentation had 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 TSD 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 check 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 enforcement. 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.

#### Importer Obligations continued...

#### Retain the EC declaration of conformity for 10 years. Technical Documentation

Importers must retain Declaration of Conformity so that it can be made available to 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 only to ensure that Manufacturers have procedures and systems in place to ensure that this 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 within the EU, although the products are manufactured outside the EU, they are considered to be the entity who 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 address.

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

#### Markings & Warnings

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. 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

#### Product Monitoring

Provide information to authorities on request

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) Conformity of Series Production & Sample Testing

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.

### **Distributors Obligations**

Where a company imports product from outside of the EU 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.

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 only to have confidence that Manufacturers have procedures and systems in place to ensure that these 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 only to verify that Manufacturers and Importers have procedures and systems in place to ensure that this is done 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 has systems and procedures in place to do this rather than requesting evidence on a product by product basis. Distributors 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.

With regards to provision of information, because the Distributor has no obligations with regards 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 are made aware of these 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.

### **Authorised Representative Obligations**

The manufacturer's obligations may be fulfilled by his Authorised Representative, on his behalf and under his 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 Technical documentation should be 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 assessment)

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 should 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.

# 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 product.

#### **Authorised Representatives 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) Conformity of Series Production & Sample Testing

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.

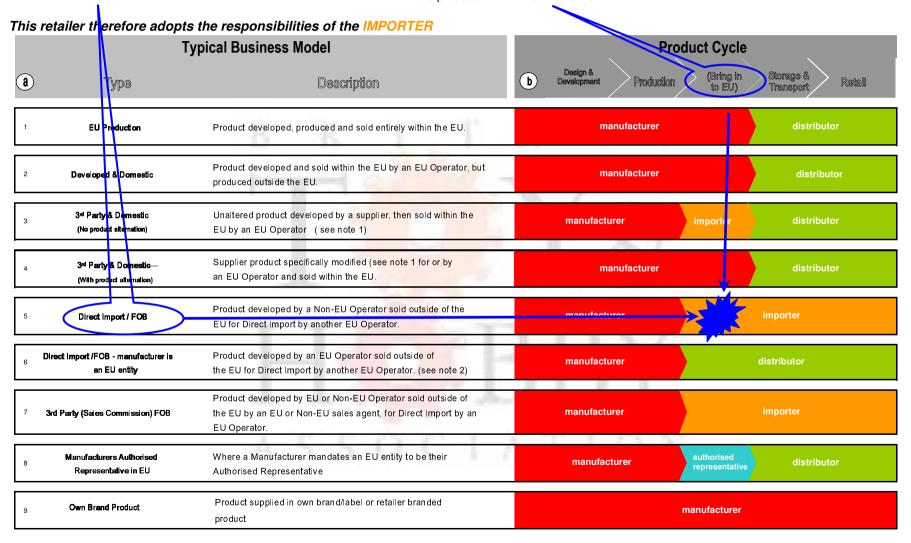


#### 10. Identifying your Operator Type - Example 1 FOB / Direct Import (Manufacturer based outside the EU)

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





# 11. Identifying your Operator Type - Example 2 Direct Import FOB (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

		//				
	Т	ypical <mark>B</mark> usiness Model	Product Cycle			
<b>a</b>	Туре	Description	b Design & Production (Bring in to EU)	Storage & 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	3rd 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 <sup>rd</sup> 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 / FØB	Product developed by a Non-EU Operator sold outside of the EU for Direct Import by another EU Operator.	manufacturer	importer		
	Direct import /FOB - manufacturer is 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	3rd 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	Manufacturers 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			



#### 12. Identifying your Operator Type - Example 3 3rd Party & Domestic with product alteration

In the case of an EU Operator who buys product developed by a 3rd party and makes any alterations (including packaging and / or product) before or after importation.

- (a) Identify the business model 3rd 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

