



TOY SAFETY IN THE EU

A PRACTICAL GUIDE TO
THE LEGAL OBLIGATIONS
OF MANUFACTURERS,
IMPORTERS AND
DISTRIBUTORS

Part of an education campaign
financed by the European
Commission and carried out by
Toy Industries of Europe (TIE)
between 2012 and 2014 to explain
the requirements of the Toy
Safety Directive 2009/48/EC and
what they mean for businesses in
the European Union.



Disclaimer: This publication is intended as a guide to assist in the understanding and application of the Toy Safety Directive 2009/48/EC, as amended from time to time, and is not intended to replace the contents of the aforementioned directive. For a full version of the directive and its amendments, please refer to the Official Journal of the EU available on the European Commission's website:
http://ec.europa.eu/enterprise/sectors/toys/documents/index_en.htm

INTRODUCTION

Toy safety requirements across Europe are amongst the strictest in the world. The new European Toy Safety Directive 2009/48/EC (TSD) strengthened the rules as laid down in the 1988 Directive with new provisions on enforcement and new safety requirements.

The TSD was published in the Official Journal of the European Union on 30 June 2009 and is applicable to toys placed on the market since 20 July 2011, while the chemical provisions have been in force since 20 July 2013.

This publication is part of an education campaign financed by the European Commission and carried out by Toy Industries of Europe (TIE) between 2012 and 2014 to explain the TSD's requirements and what they mean for businesses in the European Union (EU), be they manufacturers, authorised representatives, importers or distributors of toys. It aims to be a practical guide summarising the obligations of all key players. Because, while manufacturers are responsible for the safety of their products, the importers, distributors, notified bodies and national authorities also have an important role to play in ensuring that toys sold in Europe's shops fulfil all safety requirements.





1.

MANUFACTURER'S OBLIGATIONS



CAN YOU BE CONSIDERED A MANUFACTURER?

A manufacturer is any person or entity that manufactures a toy or has a toy designed or manufactured and markets that toy under their name or trademark.

OF ALL THE DIFFERENT ECONOMIC OPERATORS, THE MANUFACTURER CLEARLY HAS THE GREATEST NUMBER OF OBLIGATIONS:

1

DESIGN AND MANUFACTURE TOYS IN ACCORDANCE WITH THE ESSENTIAL SAFETY REQUIREMENTS.

Manufacturers must ensure that the toys they put on the market have been designed and manufactured in accordance with the so called 'essential safety requirements'. This means that toys, including the substances they contain, must not jeopardise the safety or health of children and other users. Manufacturers have to comply with the rules related to the physical and mechanical, chemical, and electrical properties of toys, as well as flammability, hygiene and radioactivity.

2

DRAW UP THE TECHNICAL DOCUMENTATION AND KEEP IT FOR A MINIMUM OF 10 YEARS. CARRY OUT SAFETY AND CONFORMITY ASSESSMENTS.

Manufacturers need to draw up the technical documentation of the toy, and carry out the applicable safety and conformity assessments.

The technical documentation must contain all relevant details of how the manufacturer has ensured that toys comply with all safety requirements set out in the directive. It should be kept for a minimum of 10 years after the toy has been placed on the market.



IMPORTING OR DISTRIBUTING IN THE EU - KNOW YOUR OBLIGATIONS!

If the manufacturer is outside the EU and you, as the importer or distributor, place the toy on the market under your own name or trademark, you automatically take on the responsibilities of the manufacturer. The same applies if you modify a toy already placed on the market, and by doing so could alter its compliance.

The TSD requires that all technical documentation be written in one of the official languages of the EU. Applicable languages are defined by each Member State, and are listed in a document published on the European Commission's website (see page 8). Upon reasoned request, a national authority can ask for translation of relevant parts of the technical documentation into the language of that Member State.

A **safety assessment** is where the manufacturer identifies potential hazards a toy may present, and assesses potential exposure to those hazards. This is to be carried out before the toy is placed on the market and must cover any chemical, physical, mechanical, electrical, flammability, hygienic and radioactivity hazards (see page 22).

The **conformity assessment** is where the manufacturer establishes that his toy fulfils the applicable safety provisions of the directive. The procedure can be either self or third-party verification (see page 23).



WHAT MUST THE TECHNICAL DOCUMENTATION CONTAIN?

- a detailed description of the design and manufacture, including a list of components and materials used in the toy, and the safety data sheets on chemicals used, to be obtained from chemical suppliers;
- the safety assessment(s) carried out;
- the conformity assessment procedure followed;
- a copy of the EC declaration of conformity;
- the addresses of the places of manufacture and storage;
- copies of documents that the manufacturer has submitted to a notified body, if involved;
- test reports and description of how the manufacturer has ensured conformity of production, if the manufacturer followed the internal production control procedure; and
- a copy of the EC-type examination certificate, a description of how the manufacturer has ensured conformity of production and copies of the documents that the manufacturer submitted to the appropriate notified body, if the manufacturer submitted the toy to EC-type examination.



WHAT DOES ‘REASONED REQUEST’ MEAN?

It means that only the elements of the technical documentation that are necessary for a national authority's investigation should be requested, so as not to constitute a disproportionate burden for the manufacturer. The request may indicate a deadline for the receipt of the requested documents, which must be 30 days, unless a shorter deadline is fixed based on an immediate serious risk.

3

DRAW UP EC DECLARATION OF CONFORMITY AND KEEP IT FOR 10 YEARS.

Before selling a toy, the manufacturer must draw up an EC Declaration of Conformity (DoC), which is a document in which the manufacturer certifies that the toy complies with all safety requirements and assumes, as the manufacturer, responsibility for the toy's compliance (see page 26).

The DoC needs to be kept by the manufacturer, its authorised representative within the EU if any, and the importer if any, for a minimum of 10 years after the toy has been placed on the market. The DoC needs to be translated into all languages of the Member States where the toy is sold. The DoC needs to clearly identify what toy it relates to.



THE EUROPEAN COMMISSION'S WEBSITE CONTAINS A TEMPLATE TO HELP MANUFACTURERS TO DRAFT A DOC:

http://ec.europa.eu/enterprise/sectors/toys/documents/guidance/index_en.htm

4

AFFIX THE CONFORMITY MARKING AND AN IDENTIFICATION NUMBER.



The CE marking is a marking by which the manufacturer indicates that the toy is in conformity with all the applicable requirements set out in EU legislation. The CE marking needs to be affixed to the toy, a label or to the packaging (and it is recommended to be displayed on the website if the toy is sold online) visibly, legibly and indelibly.

In the case of small toys and toys consisting of small parts, the CE marking may alternatively be affixed to a label or an accompanying leaflet. Where toys are sold in counter displays that are part of the original packaging of the toy, the CE marking may be affixed to the counter display. Where the CE marking is not visible from outside the packaging, it must at least be affixed to the packaging.

Manufacturers also must ensure that their toys bear a type or batch or serial or model number or other element allowing identification. If the size or nature of the toy does not allow it, this can be displayed on the packaging or document accompanying the toy.

5

ENSURE CONFORMITY OF SERIES PRODUCTION.

Manufacturers must also ensure that procedures are in place for series production to remain in conformity, and when the design or the characteristics of the toy or the applicable harmonised standards change.

6

DISPLAY NAME AND ADDRESS.

Manufacturers must indicate their name and address on a toy or, if not possible, on the packaging or in an accompanying document. The address indicated should be a physical address and a single point of contact for the manufacturer. A website is additional information, but it is not enough as an address. Normally an address consists of a street and number or post-box, a postal code and a town or city. On packages and products that have several contact addresses, the address of the single contact point must be clearly indicated.

7

ENSURE THAT INSTRUCTIONS AND SAFETY INFORMATION ARE IN THE CORRECT LANGUAGES.

Instructions allow and promote correct use of the toy. These are not necessary if a toy does not need instructions or safety information (for example, a soft filled bear).

Safety information may include text and/or images that accompany or are associated with the toy. The purpose of safety information is to enable

the consumer to use the toy safely thus helping avoid risks to the users or damage to the product. Examples of safety information might include: “cool only in a domestic refrigerator” or “do not place in the freezer compartment”.

The manufacturer must make sure that the toy is accompanied by instructions and safety information in a language or languages easily understood by consumers, as determined by national authorities.

8

AFFIX WARNINGS WHEN APPROPRIATE.

The manufacturer needs to mark the warnings in a visible, legible, comprehensible and accurate manner on the toy, on an affixed label or on the packaging and, if appropriate, on the instructions for use which accompany the toy. Small toys which are sold without packaging must have appropriate warnings affixed to them.

The warnings need to be in a language or languages easily understood by consumers, as determined by each Member State.



THE EUROPEAN COMMISSION'S WEBSITE CONTAINS A LIST OF NATIONAL LANGUAGES TO BE USED IN EACH COUNTRY:

http://ec.europa.eu/enterprise/sectors/toys/documents/guidance/index_en.htm

9

BRING NON-CONFORMING TOYS INTO COMPLIANCE. INFORM AUTHORITIES IF THERE IS A SAFETY RISK. RECALL OR WITHDRAW.

When a manufacturer believes that a toy he sold does not conform to legislation, he must immediately take the necessary corrective measures. These include bringing the toy into conformity, withdrawing it or recalling it, if appropriate. In such cases, it is strongly recommended that businesses cooperate to put together a comprehensive information package to ensure a coordinated response.

Where the toy presents a risk, manufacturers must immediately inform the competent national authorities of the Member States in which the toy is available, giving details of the non-compliance and any corrective measures taken.

10

PROVIDE INFORMATION TO NATIONAL AUTHORITIES UPON REASONED REQUEST.

Manufacturers must, further to a reasoned request from a competent national authority (see page 6), supply all documentation necessary to demonstrate the conformity of the toy. It may be necessary to translate certain parts of the technical documentation into the language of the requesting authority if English (or another language) is not acceptable.

Manufacturers must supply documentation necessary to show conformity in a language that is easily understood by the authority - documents in Chinese, for example, are not acceptable in European countries.

11

SAMPLE TEST TOYS THAT MAY PRESENT A RISK. INVESTIGATE.

When appropriate with regard to the risks the toy may present, manufacturers must carry out sample testing of marketed toys. This does not require that each marketed product be sample tested. As this is also an obligation of importers, cooperation is recommended to prevent duplication.

12

KEEP A REGISTER OF COMPLAINTS ABOUT NON-CONFORMING TOYS AND RECALLS AND INFORM DISTRIBUTORS OF THIS MONITORING.

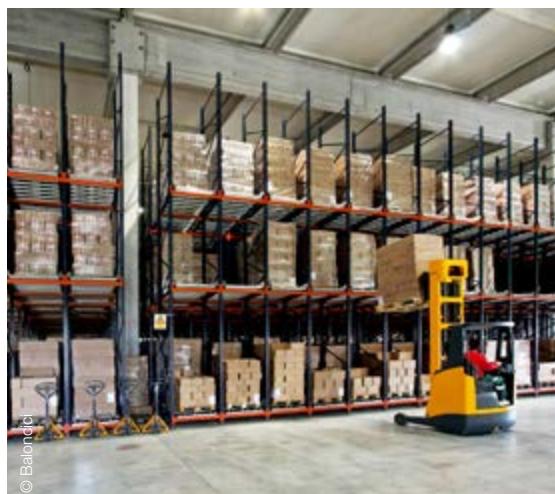
If necessary, manufacturers must keep a register of complaints about non-conforming toys and toy recalls, and keep distributors informed of any such monitoring.

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. Obviously, if the risk is such that a recall is required, other parties in the supply chain should be informed.

13

DO NOT JEOPARDISE COMPLIANCE DURING STORAGE OR TRANSPORT.

Manufacturers should not jeopardise compliance during storage or transport. This is not a specific obligation, but manufacturers should bear in mind that compliance should be maintained while the toy is under their control. Jeopardising compliance would include careless handling or inappropriate storage conditions (e.g. storing wooden or plush toys in damp conditions).



14

IDENTIFY THE OTHER ECONOMIC OPERATORS IN EACH TOY'S SUPPLY CHAIN.

The supply chain should be traceable, which means that economic operators have to be able to identify any party who has supplied them with a toy and any party to whom they have supplied a toy. Records must be retained as this information needs to be kept for a minimum of 10 years after the toy was placed on the market.

2. **IMPORTER'S OBLIGATIONS**



CAN YOU BE CONSIDERED AN IMPORTER?

An importer is any person or entity established within the EU who puts a toy from a non-EU country on the EU market.



THE IMPORTER HAS THE OBLIGATION TO:

1

PLACE ONLY COMPLIANT TOYS ON THE EU MARKET.



IMPORTING OR DISTRIBUTING IN THE EU - KNOW YOUR OBLIGATIONS!

The importer should be aware that if the manufacturer is outside the EU and the importer places the toy on the market under his own name or trademark or modifies the toy already placed on the market (and by doing so could alter its compliance), the importer is considered to be the manufacturer, so he assumes all his responsibilities and obligations.

3

KEEP THE EC DECLARATION OF CONFORMITY FOR 10 YEARS AND ENSURE THAT THE MANUFACTURER HAS DRAWN UP THE TECHNICAL DOCUMENTATION. COOPERATE WITH AUTHORITIES.

An importer must keep a copy of the EC Declaration of Conformity (DoC) within the EU, and have it available for the appropriate authorities for 10 years after placing the toy on the market.

The importer must ensure that the manufacturer has drawn up the technical documentation (see page 6 for a full list of the technical documentation requirements). The importer needs to ensure it can be made available to authorities for 10 years after the toy has been sold.

Importers do not need to physically hold the technical documentation themselves (except for the DoC), just to ensure that it will be available. However, if importers are not confident that they will be able to get such documentation within the time limit or that it will not be retained for 10 years by the manufacturer, they should obtain and hold it themselves.

Importers must, further to a reasoned request (see page 6) from a 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.

2

ENSURE THAT THE MANUFACTURER HAS CARRIED OUT THE APPROPRIATE CONFORMITY ASSESSMENT PROCEDURE.

The importer needs to check that the manufacturer has carried out the appropriate conformity assessment and that documentation of this is available on request. A simple check that the manufacturer has systems and procedures in place is sufficient.

These documents must be supplied in a language "easily understood" by national authorities. This means that documents in Chinese are not acceptable in European countries. It may be necessary to translate certain parts of the technical documentation into the language of the requesting authority if English (or another language) is not acceptable.



4

ENSURE THAT THE MANUFACTURER HAS AFFIXED THE CE MARKING, AND AN IDENTIFICATION NUMBER. ENSURE THAT THE TOY IS ACCOMPANIED BY THE REQUIRED DOCUMENTS.

Importers must ensure that the CE marking and an identification number or another element allowing the identification of the toy are present.

Importers also need to ensure that the toy is accompanied by the required documents (safety information, instructions and warnings as detailed on page 8).

Importers do not need to check each product individually, but must ensure that manufacturers have procedures and systems in place to ensure that these are present.

5

ADD IMPORTER'S NAME AND ADDRESS ONTO THE TOY OR PACKAGING AND ENSURE THE MANUFACTURER HAS DONE SO.

Importers need to indicate their name and address on the toy or, if this is not possible, on its packaging or on an accompanying document. These details are required only on the retail packaging in cases where importers would have to open the packaging to put their name and address onto the product.

Importers have to ensure that the manufacturer's name and address are also present on the toy, or on its packaging or on an accompanying document.

If the manufacturer is outside the EU and the importer puts the toy on the market under his own name or trademark or modifies the toy already placed on the market, the importer is considered to be the manufacturer. In this case the only name and address required are the name and address of the importer who is now considered to be the manufacturer.

If the manufacturer is within the EU, and the product is manufactured outside the EU, he is considered to be the entity who puts the toys on the EU market. In this case it is enough to affix only the EU-based manufacturer's name and address.

**Make sure both importer and manufacturer's contact addresses are on the toy.
A website is not enough.
Normally an address consists of a street and number or post-box and number and the postal code and town.**

6

ENSURE THAT THE INSTRUCTIONS AND SAFETY INFORMATION ARE IN THE CORRECT LANGUAGES.

Importers need to ensure that instructions and safety information (see page 8) are in a language or languages easily understood by consumers, as determined by each Member State.

The European Commission's website contains a list of national languages to be used in each country (see page 8).

8

SAMPLE TEST TOYS THAT MAY PRESENT A RISK. INVESTIGATE. KEEP A REGISTER OF COMPLAINTS.

Depending on the risks of a toy, importers have to carry out sample testing of toys, investigate, and if necessary, keep a register of complaints about non-conforming toys and toy recalls.

As this is a sample testing, this does not require that each individual product put on the market be tested. As this is also an obligation of manufacturers, cooperation is recommended to prevent duplication.

7

BRING NON-CONFORMING TOYS INTO COMPLIANCE. RECALL OR WITHDRAW. INFORM AUTHORITIES IF THERE IS A SAFETY RISK.

Importers who consider that a toy is not in conformity with the directive, must immediately take corrective measures. These may include bringing that toy into conformity, withdrawing it or recalling it and informing the authorities, if appropriate.

Where the toy presents a risk, the importer must inform the manufacturer and the market surveillance authorities. It is strongly recommended that the economic operators cooperate to put together a comprehensive information package ensuring a coordinated response.

9

DO NOT JEOPARDISE COMPLIANCE DURING STORAGE OR TRANSPORT.

This could include careless handling or inappropriate storage conditions (e.g. storing wooden or plush toys in damp conditions).

10

IDENTIFY THE OTHER ECONOMIC OPERATORS IN EACH TOY'S SUPPLY CHAIN.

The supply chain needs to be traceable, which means that importers have to 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.

Records must be retained, as this information needs to be available for a period of 10 years after the toy was placed on the market.



CAN YOU BE CONSIDERED A DISTRIBUTOR?

A distributor is any person or entity in the supply chain other than the manufacturer or the importer that makes a toy available on the market.

3.

DISTRIBUTOR'S OBLIGATIONS



THE DISTRIBUTOR HAS THE OBLIGATION TO:

1

**ACT WITH DUE CARE
IN RELATION TO
THE APPROPRIATE
REQUIREMENTS.**



IMPORTING OR DISTRIBUTING IN THE EU - KNOW YOUR OBLIGATIONS!

The distributor should be aware that if the manufacturer is outside the EU and the distributor places the toy on the market under his own name or trademark or modifies the toy already placed on the market (and by doing so could alter its compliance), the distributor is considered to be the manufacturer, so he assumes all his responsibilities and obligations.

2

ENSURE CONFORMITY MARKINGS ARE PRESENT.

Distributors have to ensure that the required conformity marking (for the TSD, this is the CE marking) is present. They do not need to check each product individually, only to have confidence that manufacturers have procedures and systems in place to ensure compliance.



3

**VERIFY THAT THE NAME
AND ADDRESS AND
IDENTIFICATION NUMBER
ARE PRESENT.**

Distributors have to verify that the address of the importer and/or the manufacturer is present. Distributors must also ensure that the manufacturer has affixed an identification number or code on the toy, on the packaging or on an accompanying document.

4

**ENSURE THAT SAFETY
INFORMATION,
INSTRUCTIONS AND
WARNINGS ARE PRESENT, IN
THE CORRECT LANGUAGES.**

Before distributing a toy, distributors have to verify that the toy is accompanied by the required documents (safety information, instructions and warnings).

Distributors should verify the presence of the required warnings, but they do not need the technical documentation. For example, a distributor should only check whether a phrase such as "Warning. Not suitable for children under 36 months. Small parts" is on a toy intended for children over 36 months that contains small parts and therefore could present a choking hazard for a younger child.

Where a doubt exists, for products falling in the “grey area” for example, the distributor can always ask the importer or manufacturer for an explanation as to the absence of any conformity marking. Annex I of the directive presents a list of products that are not considered as toys but that could be subject to confusion. The European Commission has also published guidance documents to help businesses distinguish toys from non-toys (visit the website referred to in page 8).

Instructions and safety information need to be in a language or languages easily understood by consumers, as determined by the Member State concerned.

The European Commission’s website contains a list of national languages to be used in each country (see page 8).



THE DISTRIBUTOR IS NOT REQUIRED TO HOLD THE TECHNICAL DOCUMENTATION.

The obligation to act with due care and verify the presence of the required documents must be interpreted with this in mind. The distributor must check the coherence between the toy and the documents received with it, by checking for example the safety information, the warnings, the CE marking and the names and addresses of the manufacturer / importer.

5

HAVE NON-CONFORMING TOYS BROUGHT INTO COMPLIANCE. INFORM AUTHORITIES IF THERE IS A SAFETY RISK. RECALL OR WITHDRAW.

Distributors who consider that a toy is not in conformity with the directive, must immediately take corrective measures. These may include bringing that toy into conformity, withdrawing it or recalling it and informing the authorities, if appropriate.

Where the toy presents a risk, the distributor needs to inform the manufacturer or the importer, as well as the market surveillance authorities.

It is strongly recommended that businesses cooperate to put together a comprehensive information package ensuring a coordinated response.

6

PROVIDE INFORMATION TO AUTHORITIES UPON REASONED REQUEST.

Distributors must, further to a reasoned request (see page 6) from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the toy.

7

INFORM ECONOMIC OPERATORS OF SAFETY RELATED COMPLAINTS.

While distributors are not required to keep a register of complaints, it is recommended that distributors inform other economic operators in the supply chain of any safety related complaints.

8

DO NOT JEOPARDISE COMPLIANCE DURING STORAGE OR TRANSPORT.

This could include careless handling or inappropriate storage conditions (e.g. storing wooden or plush toys in damp conditions).

9

IDENTIFY THE OTHER ECONOMIC OPERATORS IN EACH TOY'S SUPPLY CHAIN.

The supply chain needs to be traceable meaning that economic operators have to be able to identify any party who has supplied them with a toy and any party to whom they have supplied a toy.

Records must be retained, as this information needs to be available for a period of 10 years after the toy was placed on the market, but it is advisable that this period starts once the toy was last supplied.



CAN YOU BE CONSIDERED AN AUTHORISED REPRESENTATIVE?

An authorised representative is any person or entity established in the EU that has received a written mandate from a manufacturer detailing the tasks to be carried out on the manufacturer's behalf.

4

AUTHORISED REPRESENTATIVE'S OBLIGATIONS



OBLIGATIONS OF THE AUTHORISED REPRESENTATIVE:

While the manufacturer's obligation is to ensure that toys have been designed and manufactured in accordance with the safety requirements of the directive, as well as the drawing up of technical documentation, this is not part of the authorised representative's mandate.

An authorised representative has to perform the tasks specified in the mandate received from the manufacturer. The mandate needs to allow the authorised representative to do at least the following:

1

Keep the EC declaration of conformity and the technical documentation at the disposal of national surveillance authorities for a period of 10 years after the toy has been placed on the market.

2

Further to a reasoned request from national authorities, provide that authority with all the information and documentation necessary to demonstrate the conformity of a toy.

3

Cooperate with national authorities, at their request, on any action taken to eliminate the risks posed by toys covered by the mandate.



5

**FOCUS ON SOME
IMPORTANT ISSUES**

SAFETY ASSESSMENT.

The **safety assessment** requires the manufacturer to identify the potential hazards that a toy may present, and to assess potential exposure to those hazards before the toy is put on the market. This is a mandatory assessment according to the directive.



SPOTLIGHT ON THE SAFETY ASSESSMENT

The safety assessment is the responsibility of the manufacturer and must be carried out before the toy is put on the EU market. It must cover the various chemical, physical, mechanical, electrical, flammability, hygienic and radioactivity hazards that the toy may present.

Many of the safety requirements related to these hazards are embodied in the **harmonised toy safety standards**; however, the manufacturer remains obliged to assess any features in the toy that could present a potential hazard that would not be sufficiently covered by these standards. The outcome of a safety assessment will help determine which conformity assessment procedure is required, and any appropriate risk minimization steps and/or testing.

The safety assessment must be kept by the manufacturer as part of the technical documentation for 10 years after the toy has been placed on the market.



HARMONISED TOY SAFETY STANDARDS

A harmonised standard is a European standard that provides solutions for compliance with the essential safety requirements of EU legislation. For example, there is a harmonised standard setting test methods to measure migration of certain chemical elements from toys. The European Commission tasks European Standards Organisations with developing these standards. Compliance with harmonised standards provides presumption of conformity with the corresponding legal requirements. In order to convey this presumption of conformity, the references of harmonised standards must be published in the Official Journal of the European Union.

CONFORMITY ASSESSMENT PROCEDURE.

Conformity assessment is the procedure by which a manufacturer establishes that his toy fulfils the essential safety requirements of the directive. Details as to who must undertake the procedure and how it is done are provided in the TSD. Conformity assessment can be carried out by one of two methods, depending upon the nature of the toy:

1

Self-verification

Self-verification is used in cases where harmonised standards cover all relevant safety aspects of a toy. In this case, the manufacturer must apply the existing harmonised standards and ensure that the toy conforms to them. The manufacturer must also put in place an internal production procedure which does not require the involvement of a notified body.

2

Third-party verification

Third-party verification, often referred to as "EC-type examination", is required in cases where:

- harmonised standards do not exist;
- harmonised standards have not or only partly been applied by a manufacturer;
- one or more harmonised standards have been published with a restriction; or
- the manufacturer considers that the nature, design, construction or purpose of the toy requires third-party verification.



In such cases a manufacturer submits a sample of the toy to a notified body for examination. The notified body examines the technical design of the toy and verifies and attests that the technical design of the toy meets the requirements of the TSD by issuing an EC-type examination certificate.



DIFFERENCES BETWEEN SAFETY ASSESSMENT AND CONFORMITY ASSESSMENT

The objective of the safety assessment is to identify the potential hazards of a toy, as well as to assess the potential exposure to those hazards. The aim of the conformity assessment procedure, on the other hand, is to provide demonstrable evidence that the toy is in conformity with the essential safety requirements under the TSD. In general, the safety assessment is drawn up before submitting the toy to the appropriate conformity assessment procedure (although it may be completed at a later stage) and must be completed before the toy is placed on the market.

WARNINGS.

General rules

Where appropriate, warnings which specify user limitations need to accompany the toy for safer use. In addition to the mandatory requirements set out in the TSD, the harmonised standards also specify warnings that should accompany certain categories of toys. Within its territory, a Member State may stipulate that the warnings need to be written in a language or languages easily understood by consumers.

The manufacturer needs to mark the warnings in a clearly visible, easily legible and understandable and accurate manner.

Location of warnings

Warnings must be marked on the toy, an affixed label or the packaging, as defined by the TSD and harmonised standards, and could also be required to be included in the instructions. It is important to note that in cases where the toy is sold without packaging, the warning needs to be affixed on the toy itself. Affixing warnings on a counter display box is not sufficient to meet the requirements of the TSD. Warnings which determine the purchase decision, such as minimum and maximum user age indications and the specific warnings described in the directive, must appear on the consumer packaging or be otherwise clearly visible to the consumer before the purchase, even in cases where the purchase is made online.

Specific warnings

User limitations must contain at least the minimum or maximum age of the user. If appropriate, they must also contain the abilities or characteristics required by a user to be able to use the toy safely (e.g. ability to sit unaided, maximum and minimum weight of the user, need to use the toy under supervision). In order to indicate that a toy is not suitable for children under 36 months for safety reasons, manufacturers may choose between a warning phrase or pictogram (or both):



Not suitable for children under 36 months.

In both cases the phrase and/or the pictogram must be preceded by the word "Warning" or "Warnings" as appropriate.

The age warning alone is not sufficient. It needs to be accompanied by a brief indication of the specific hazard calling for this precaution, which may appear in the instructions for use. The hazard is the potential source of harm. Harm means physical injury or any other damage to health, including long term health effect.

Examples of acceptable warnings, together with brief indications of the specific hazard and, in the second example, a clear description of the harm, are:

- "Warning. Not suitable for children under 36 months. Small parts"
- "Warning. Not suitable for children under 36 months. Long cord. Strangulation hazard"

TRACEABILITY.

Every manufacturer must ensure that their toy can be identified. This can be done by using a type, batch, serial/ model number or other element allowing the toy to be identified. The toy must also bear the manufacturer's name, registered trade name/mark and address.

A single contact point address for the manufacturer must also be provided. If the size or nature of the toy does not allow it to the identification element and the manufacturer's information, the manufacturer must place the required information on the packaging or in a document accompanying the toy. It is important to note that the single address at which the manufacturer can be contacted must be a street address or post box (a website will not be considered as a point of contact address).



If an importer puts a toy on the market, his name, registered trade name/mark, and address must also all be on the toy or, where that is not possible, on its packaging or in a document accompanying the toy.

Manufacturers are free to choose what to use on a toy to allow its identification as long as its traceability is ensured.

DECLARATION OF CONFORMITY.

Before selling a toy, the manufacturer must draw up an EC declaration of conformity (DoC). By doing so, the manufacturer certifies and assumes responsibility for the compliance of the toy with the essential requirements of the TSD (see page 5).

The manufacturer or the authorised representative established within the EU must keep the DoC for 10 years after the toy is put on the market.

The DoC needs to be translated into the languages required by the Member States in whose market the toy is placed or made available. The DoC states that the fulfilment of the TSD safety requirements has been demonstrated.

It is worth noting that an importer must also keep a copy of the manufacturer's DoC for a period of 10 years after the toy has been placed on the market.

The DoC needs to clearly identify what toy it relates to. More than one toy can be referenced in the same DoC provided the above requirements are fulfilled and the toys comply with the same EU harmonised legislation and the same standards, but there is a requirement to continuously update the DoC should changes be necessary.



WHAT MUST A DoC INCLUDE?

- the (unique) identification number of the toy;
- the name and address of the manufacturer or his authorised representative;
- the statement that “This declaration of conformity is issued under the sole responsibility of the manufacturer”;
- the object of the declaration (including a colour image of the toy);
- conformity of the above object with relevant EU harmonisation legislation;
- the references to the relevant harmonised standards used or references to the specifications in relation to which conformity is declared;
- (where applicable) the statement that “the notified body... (name, number)... performed... (description of intervention performed)... and issued the certificate”;
- additional information;
- date, place, name, function and signature.

SUMMARY OF ALL OBLIGATIONS



SUMMARY OF ALL OBLIGATIONS.

MANUFACTURER	IMPORTER	DISTRIBUTOR	REPRESENTATIVE
Design and manufacture in accordance with essential safety requirements	Only place compliant toys on the market	Act with due care	
Draw up technical documentation	Ensure the technical documentation has been drawn up and the conformity and safety assessments have been carried out	No obligation	No obligation
Assess the conformity of the toy and carry out safety assessment			
Keep the technical documentation for ten years after placing on the market	No obligation		Keep the technical documentation for ten years after placing on the market
Upon reasoned request from an authority, make available the technical documentation to that authority		Upon reasoned request from an authority, ensure the technical documentation can be made available to that authority	
Draw up the EC declaration of conformity	No obligation		Draw up the EC declaration of conformity
Keep a declaration of conformity and have it available for the authority for ten years after placing on the market		Make it available upon reasoned request from an authority	Keep a declaration of conformity and have it available for the authority for ten years after placing on the market
Affix CE marking and identification: type, batch, serial or model number	Ensure the CE marking, the type, batch, serial or model number are affixed	Verify the CE marking, the type, batch, serial or model number are affixed	Affix CE marking and identification: type, batch, serial or model number
Ensure conformity of series production		No obligation	
Add name and address		Verify the name and address is present	Add name and address only if manufacturer is outside EU
Ensure the required documents accompany the toy in the correct languages			
Bring non-conforming toys into compliance. Inform authorities if there is a safety risk. Recall or withdraw. Provide information to the authorities on request		Ensure non-conforming toys are brought into compliance	Depends on the written mandate
Sample test marketed toys (taking into account risk)		No obligation	
Keep register of complaints, non-conforming toys and recalls. Inform distributors of this monitoring			
Ensure that conditions of storage and transport do not impact the toy's compliance with the requirements (not an obligation for manufacturers, but they should bear that in mind)			
Identify the other economic operators in each toy's supply chain			

FREQUENTLY ASKED QUESTIONS (FAQS).

1

How can you determine whether a product is a toy or not? How can you distinguish a promotional product from a toy?

The definition of a toy in the Toy Safety Directive (TSD) must always be the basis for deciding whether a product is a toy or not. Annex I gives examples of products that are not considered as toys but could be confused with toys, but the list is naturally not exhaustive. However, if a particular product is not mentioned in the list, it does not mean that it is automatically a toy. To be considered as a toy for the purpose of the directive, the playing value has to be introduced in an intended way by the manufacturer. The declaration by the manufacturer of the intended use is a criterion to be considered since it figures in the wording itself, but the reasonable expected use is considered to prevail over the declaration of intended use by the manufacturer. If the manufacturer labels the product as not being a toy, he has to be able to support this claim. [Guidance document No 4](#) gives further indicative criteria that need to be considered for the classification of a product as a toy. Furthermore, several [guidance documents](#) have been drafted for the classification of specific products.

2

What happens if an economic operator does not provide the required information to authorities?

If the required information is not available and/or provided, the market surveillance authority may require the toy to be tested by a notified body at the manufacturer's own expense within a specified period in order to verify compliance with the harmonised standards and essential safety requirements. If non-compliance persists, the authority will take all appropriate measures to restrict or prohibit the toy being made available on the market, or will ensure that it is recalled or withdrawn from the market. Furthermore, if toy manufacturers, importers, and distributors do not fulfil the safety requirements of the directive, Member States can also impose penalties.

3

What should an economic operator do if he thinks a toy is not in conformity?

In this case, the TSD stipulates that 'economic operators 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 should immediately take the corrective measures necessary to bring that toy into conformity, to withdraw it or recall it, if appropriate'. It also requires that 'when deemed appropriate with regard to the risks presented by a toy, economic operators should, 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'.

4

How can a manufacturer determine the age of the children its toys are intended for? Who controls the manufacturer's decision?

The European Committee for Standardisation (CEN) report CR 14379 Classification of toys gives guidelines for matching toy characteristics to children's ages. Although functions and characteristics and examples are listed in this report, some toys can give rise to discussion and [Guidance document No11](#) (Toys intended for children above and under 36 months) details the classification for children above and under 3 years of age. There is also the United States' Consumer Product Safety Commission ([CPSC's Age Determination Guidelines](#)) issued in 2002, the international ISO/TR 8124-8: 2014 on Age determination guidelines and other European Commission [guidance documents](#). The market surveillance authorities use the same guidelines to ensure conformity.

5

If an economic operator changes a toy, can they be considered a manufacturer?

An importer or distributor who modifies a product, and by doing so alters its compliance, assumes the obligations and responsibilities of the manufacturer and is responsible for the conformity of the product. He does not have to provide details to authorities unless requested but must ensure that he has up-to-date technical documentation which includes the changes made to the toy and the compliance of the new version of the toy.

6

What information do manufacturers need to provide in the technical documentation to show conformity of the toy?

The technical documentation file should consist of the following elements, which prove that the toy is in conformity with the TSD and has undergone all the necessary assessments.

Related clauses	Suggested Content
Annex IV (a)	Description of the design and manufacture; List of components and materials; Safety data sheets
Annex IV (b), Art 18	Safety assessments
Annex IV (c) Art 4 (2) Art 6 (2) Art 19	Conformity assessment procedure
Annex III & IV (d), Art 15	EC Declaration of Conformity (DoC)
Annex IV (e)	Address of manufacture and storage
Annex IV (f)	Documents submitted to a Notified Body
Annex IV (g) Art 4 (4), Art 19 (2)	Test reports, conformity of series production details
Annex IV (h)	EC type examination details

The European Commission's website provides a [template of a Declaration of Conformity \(DoC\)](#) in all official European languages. Annex IV of the TSD lists all documents required for the technical documentation.

7

Is an importer who is obliged to attach instructions in the local language then considered to be the manufacturer?

The addition of labels to the retail pack does not constitute a modified product and thus the importer would not be considered a manufacturer. The importer is considered the manufacturer if they modify the toy in a way that affects compliance, e.g. changes in materials, colour, age grading, etc., or if it places a toy on the market under its name or trademark.

8

What type of economic operator is an importer that sells a batch of products to a distributor in the Far East?

According to the TSD, an importer means any natural or legal person established within the EU who places a toy from a third country on the EU market. As this action does not concern placing on the EU market, it is not subject to EU legislation.

9

Is a grandmother that buys a toy abroad and brings it into the EU an importer?

An importer (a person responsible for placing on the market), in the meaning of the New Approach Directives and as defined in the TSD, is any natural or legal person established in the European Union who places a product from a third country on the EU market. Therefore, a private individual would only be considered an importer if they were to place the product bought abroad on the EU market.

10

What are the obligations for importers of second hand toys?

There is no text in the TSD that specifically covers second hand toys. The TSD covers toys placed on the EU market since 20 July 2011. If the second hand toy was placed on the EU market before that date, it is not covered by the TSD. However, if the toy comes from outside the EU and is introduced onto the EU market for the first time, then the TSD is applicable. Importers of second hand toys have the same obligations as importers of other toys, there is no differentiation regarding the requirements for newly produced or used toys – both must have the relevant documentation and the necessary markings.

11

How can we ensure that Chinese players in the supply chain meet the requirements? What are the responsibilities for the importer in the case of noncompliance?

Both the general explanatory guidance document and the guidance document on technical documentation are available in [Chinese](#) in the European Commission's website, which should help Chinese economic operators to meet the requirements. An importer who considers or has reason to believe that a toy which they have placed on the market is not in conformity with the relevant EU legislation should 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, the importer should immediately inform the competent national authorities of the Member States in which they made the toy available. They must give details, in particular, of the noncompliance and of any corrective measures taken. The European Commission and Toy Industries of Europe also carry out many educational campaigns on the Toy Safety Directive in China to ensure that local economic operators are aware of and comply with the requirements.

12

If a company manufacturing a product abroad goes out of business, is the importer liable? What happens if the importer is formally requested to provide technical documentation but had no records because its supplier no longer existed?

The importer has a number of obligations and is therefore liable if he is not able to meet, inter alia, the following requirements.

The importer must ensure that the manufacturer has the technical documentation and that it can be made available upon request, for ten years after the last toy has been placed on the market. The importer can do this by getting a declaration from the manufacturer saying that he has the technical documentation. If the importer previously visited the manufacturer, this will be in its records and can be used to prove their relationship to the enforcement body and to possibly disclaim any liability. If the technical documentation cannot be provided, it would be considered by the authorities as a formal non-compliance.

The importer must, 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 must 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.

13

Does an importer or distributor assume the responsibility for the translation of instructions?

According to the TSD, the importer should ensure that the toy is accompanied by instructions and safety information in a language or languages easily understood by consumers, as determined by the Member State concerned. Therefore, an importer or distributor does assume responsibility for the translation of instructions.

14

Is a distributor expected to make sure that the commercialised products bear the CE marking or warning pictograms?

The distributor should act with due care and have a basic knowledge of the applicable legal requirements. He should know, for instance, which products must bear the CE marking, what information has to accompany the product, and what the language requirements for users' instructions or other accompanying documents are. A distributor may not supply products that he knows or should have assumed, on the basis of available information and professional knowledge, do not comply with the legislation. A distributor should cooperate in actions taken to avoid or minimise the risk of non-compliant toys reaching the market.

15

How should the distributor ensure that the required documentation is available?

The distributor is not required to have the DoC or the technical documentation but must be able to, following a reasoned request from a competent authority, provide that authority with all the information and documentation necessary to demonstrate conformity of the toy. The distributor must also be able to identify the manufacturer, his authorised representative (if any), the importer or the person who has provided him with the product in order to assist the surveillance authority in its efforts to receive the DoC and the necessary parts of the technical documentation.

16

Regarding the obligations of the distributor and specifically Article 7, paragraph 2 of the TSD, what are the ‘required documents’?

When making a toy available on the market, the distributor must ensure that the toy bears the appropriate conformity marking(s) and is accompanied by the required documents, instructions and safety information in the appropriate language. ‘Required documents’ refers to all documents that must accompany the toy itself. According to the TSD, these documents are the safety information, instructions and the warnings. The distributor must also ensure that the manufacturer and/or importer have complied with their own obligations, in other words the distributor must verify the presence of the name, brand name and the address at which the manufacturer and/or importer can be contacted on the toy or its packaging and that the batch number, serial number or other elements have been affixed on the toy by the manufacturer to allow identification.

17

What is the distributor supposed to do if the manufacturer does not affix his address? Should the distributor affix his address?

The distributor is not obliged to affix his address but is obliged to check that the manufacturer’s address is affixed. If the distributor notices that a manufacturer has not affixed his address, he should inform the manufacturer that he has placed on the market a product that does not conform to the requirements of the TSD.

18

Can distributors ask for the technical documentation?

The TSD does not oblige manufacturers to provide the technical documentation to any other operator. Only Member States’ authorities have the right to request the technical documentation. Upon reasoned request from an authority, the distributor is obliged to provide this information and therefore must ask the manufacturer or its authorised representative within the EU, or the importer to provide the technical documentation to the authorities.

19

Is the technical file related to a product or to the batch?

The technical file is related to a product and as a company has internal production control, this should be part of the technical documentation. For example, if a company tests every batch of paint for lead, then those test reports could be included in the technical documentation.

20

Is it correct that only part of the technical documentation is required when doubts exist about non-compliance of a toy?

If the market surveillance authorities have doubts regarding the conformity of a toy, they may request the manufacturer’s technical documentation or a translation of relevant parts. The authority should indicate the nature of the doubt and the parts or aspects of the toy that are subject to investigation. Only the elements of the technical documentation that are necessary for the investigation should be requested, so as not to constitute a disproportionate burden for the manufacturer. The request should indicate the deadline for the receipt of the requested documents, which shall be 30 days. A shorter deadline can be fixed if the national authority justifies the urgency based on an immediate serious risk. These provisions have a dual purpose: on the one hand, to provide the relevant elements of the technical documentation enables a manufacturer to explain the measures he has taken to deal with the risks associated with the toy in order to comply with the TSD requirements. On the other hand, the examination of these documents helps the market surveillance authorities to complete their investigation and either dispel or confirm their doubts about the conformity of the toy concerned.

21

Can the importer/distributor translate the technical files?

According to the TSD, it is the manufacturer who should provide a translation of the relevant parts of the technical documentation into a Member State's language following a reasoned request from the market surveillance authority of that Member State.

22

Who is obliged to have the Declaration of Conformity?

When a toy is placed on the market, the manufacturer must draw up a DoC. By doing so, the manufacturer certifies and assumes responsibility for the compliance of the toy with the essential requirements of the TSD. The manufacturer, his authorised representative established within the EU (if applicable) and the importer must keep the DoC for ten years after the toy is put on the market. The distributor, upon reasoned request, must be able to provide the DoC to the competent authorities.

23

Is there an obligation to sign the Declaration of Conformity?

A manufacturer must sign the DoC as this affirms that the toy conforms to the TSD, which must be assured before the toy is placed on the market.

24

Can an importer draw up the Declaration of Conformity?

The manufacturer is obliged to draw up the DoC. However, if the manufacturer has, by written mandate, appointed an authorised representative, the authorised representative may draw up the DoC. If the importer has been nominated as the manufacturer's authorised representative, then, under these circumstances, the importer would be able to draw up the DoC.

25

How fast would an authority expect to have the Declaration of Conformity delivered by a distributor?

The DoC must be made available for the market surveillance authority immediately upon reasoned request. The technical documentation must be made available to the surveillance authority within 30 days, unless a shorter deadline is justified in the case of serious and immediate risk.

26

What is a 'harmonised standard'?

Harmonised standards are European standards, adopted by European standards organisations and prepared in accordance with the General Guidelines agreed between the European Commission and the European standards organisations following a mandate issued by the Commission after consultation with the Member States. References to these standards can be published in the Official Journal of the European Union. See:

http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/toys/index_en.htm

27

If the chemical standards are not available, what should a manufacturer do?

The chapter on chemical safety assessment in the [guidance document on the technical documentation](#) explains how to proceed when no standards are available or when such standards do not cover the chemical hazards in question.

28

How can it be ensured that a toy is only notified on RAPEX if it presents a serious risk?

RAPEX is the EU alert system for rapidly exchanging information between Member States and the Commission on measures taken to prevent or restrict the marketing or use of products posing a serious risk to the health and safety of consumers. It works according to the detailed procedures laid down in the Annex to the General Product Safety Directive 2001/95 (GPSD).

As soon as a serious and immediate risk is detected, the national authority must consult, insofar as possible and appropriate, the producer or distributor of the product concerned. The authority should try to obtain the maximum amount of information on the products and the nature of the danger, without compromising the need for rapidity. The Member State should inform the Commission when it adopts, or decides to adopt, emergency measures to prevent, restrict or impose specific conditions on the possible marketing or use of consumer products presenting a serious and immediate risk.

A further condition for invoking RAPEX is that the effects of the risk can go beyond the territory of the Member State concerned. Member States are not required, as is the case under the safeguard clause procedure according to the New Approach Directives, to provide evidence to justify the national measure. The Commission verifies that the information complies with the provisions of the GPSD and circulates it to the other Member States.

29

Who is responsible for market surveillance?

Market surveillance is the responsibility of national authorities. This, in particular, guarantees the impartiality of market surveillance operations. Each Member State can decide on its own market surveillance infrastructure. For example, there is no limitation on the allocation of responsibilities between authorities on a functional or geographical basis as long as surveillance is efficient and covers the whole territory.

30

What happens to counterfeit toys that are seized?

According to Article 8 of the General Product Safety Directive (GPSD), market surveillance authorities can order, coordinate or organise the recall and destruction of dangerous products. However, the actions taken by the market surveillance authorities must be proportional to the seriousness of the risk and take into account the precautionary principle. Regulation 765/2008 only foresees recalls of products presenting a 'serious risk' (Article 20) and enables authorities to destroy such products.

31

Where can information about laboratories performing EC-type examination be found?

The European Commission's [website](#) lists all notified bodies for the Toy Safety Directive.

32

Do the warning labels have to be in the language of the country?

Manufacturers should ensure that the toy is accompanied by warnings, instructions and safety information in a language or languages easily understood by consumers, as determined by the Member State concerned (national law indicates the language required for each Member State).

33

What steps have been taken to harmonise EU and US requirements?

New toy safety legislation has recently been introduced in both the EU and US. These two new pieces of legislation necessitated an update of the respective standards. EU standards are predominantly based on the TSD while the US standards have to be approved by the Consumer Product Safety Commission (CPSC). However, the European Commission and the CPSC as well as the respective standardisation bodies are discussing cooperation.

ABBREVIATIONS:

- CE:** Conformité Européenne (European conformity)
CEN: European Committee for Standardisation
CMRs: substances that are carcinogenic, mutagenic or toxic for reproduction
CPSC: United States' Consumer Product Safety Commission
DoC: Declaration of Conformity
EU: European Union
GPSD: General Product Safety Directive
RAPEX: System for the rapid exchange of information
TSD: Toy Safety Directive

MORE INFORMATION:

European Commission – DG Enterprise and Industry
<http://ec.europa.eu/enterprise/sectors/toys>

Toy Industries of Europe (TIE)
<http://www.tietoy.org>

