

<b>Product Responsibility Best Practices</b>	<b>SUBJECT</b>	<b>LAST UPDATE</b>
	Technical Files For Toys (European Union)	July 2018
	<b>APPLIES TO</b> <ul style="list-style-type: none"> <li>• Suppliers</li> <li>• Distributors</li> </ul>	<b>FOCUS ON</b> <p>How to develop a comprehensive collection of all paperwork associated with a robust compliance program.</p>
	<b>QUICK LINKS</b> <ul style="list-style-type: none"> <li>• PPAI Corporate Responsibility: <a href="http://ppai.org/corporate-responsibility">ppai.org/corporate-responsibility</a></li> <li>• CPSC: <a href="http://www.cpsc.gov">www.cpsc.gov</a></li> </ul>	<b>Intended for intermediate compliance programs</b>

*Italic grey text indicates a hyperlink listed in the Online Resources section of this document.*

## Regulations

Many regulations require various forms of document retention. Here we will focus on the technical file required by the *European New Toy Safety Directive (TSD)*. Toys and children's products are one of the many categories that require technical file documentation in both the United States and the European Union (EU).

A technical file is a comprehensive collection of information and documents that details nearly everything about your product. Documentation should include details about the design, manufacture, and operation of a product, as well as compliance documentation.

The EU has broad technical file requirements and mandates that technical files be created and maintained for a wide variety of products which require *CE marking*. "The letters 'CE' appear on many products traded on the extended Single Market in the European Economic Area (EEA). They signify that products sold in the EEA have been assessed to meet specific CE marking directives. Not all products must have CE marking. It is compulsory only for most of the products covered by the New Approach Directives. It is forbidden to affix CE marking to other products.

## Requirements For European Technical File

The European TSD requires manufacturers to provide documentation that demonstrates that toys comply with design, manufacture, and operational requirements. This technical file must be kept up to date and reflect any changes to the toy, as well as changes in legislation or standards. This includes any material change, such as a new paint color. The history of the product must also be retained.

The EU technical documentation has to be drawn up in one of the official languages of the European Community. When market surveillance authority of a Member State requires the technical

documentation, it may pose a 30-day deadline for the receipt of the information, but this deadline may be reduced in the case that the product poses a serious risk. Manufacturers must keep the technical documentation for a period of ten (10) years after the toy was last placed on the market.

### Contents of the EU Technical File

The contents of the technical file are specific:

#### 1. Detailed description of the design and manufacture:

- This information can be found within a product specification and is likely to include a description of the features, functions, age grade, performance requirements, packaging, instructions and a color image of the toy.
- Should identify the procedures and steps in the production process (ex: melting or cutting).

#### 2. List of components and materials used in the toy:

- Typically contained within the Bill of Materials (BOM) and Bill of Substance (BOS), which identifies all materials used in manufacturing the item. The BOM lists raw materials, purchased parts and sub-assemblies. The BOS contains more detailed information about each material used, such as the colorants and additives.

Safety Data Sheets (SDS) for all chemicals, chemical preparations or mixtures used in the toy must be included.

#### 3. Safety or risk assessments done on the product:

- Conducted to ensure that all hazards are identified (chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity) and adequately controlled by reference to the harmonized toy safety standards or other suitable means.

**4. Conformity assessment procedure:**

- a. The procedure followed should be identified and described.

**5. EC Declaration of Conformity (DoC):**

- a. The DoC is similar to the U.S. Children's Product Certificate (CPC).
- b. The content for this is defined within the directive. It must include a color image of the toy and be completed and signed by the manufacturer.

**6. Addresses of the manufacturing, storage and distribution location(s) :**

- a. Addresses where the product has been manufactured and stored, including locations outside of the EU.

**7. Test reports:**

- a. In order to demonstrate that the product has been tested to the relevant harmonized standards, a list of the harmonized standards that were applied should be held with the copies of the reports.

**8. Internal production control procedure:**

- a. Description of the means whereby the manufacturer ensured conformity of production with the harmonized standards by following the internal production control procedure referred to in TSD 2009/48/EC Article 19(2). This can often be addressed by inclusion of the quality assurance (QA) program details and QA reports.

**9. EC type-examination certificate (if applicable)**

- a. On occasion, an EC Type Exam is needed. This type of evaluation is performed only by notified bodies within the EU, and may occur if a standard does not fully cover the potential hazards of a product or if the product does not fully meet a standard but does not present a hazard. If performed, the EC Type examination certification must be included in the technical file.

**Declaration of Conformity (DoC)**

A Declaration of Conformity (DoC) is a document that may be required to accompany a product when distributing it in Europe. It must be issued by the manufacturer. In order for it to be valid, the DoC must include a color image of the product which is of sufficient clarity to enable the identification of a toy. Also, a signature of the person issuing the certificate is required.

Europe's DoC requires certain things that the United States does not:

1. Unique identification number of the toy
2. Name and address of the manufacturer or his authorized representative
3. A statement that the DoC is issued under the sole responsibility of the manufacturer
4. Object of the declaration (identification of toy allowing traceability) that includes a color image of sufficient clarity to enable the identification of the toy
- a. The object of the declaration is in conformity with the relevant community harmonization legislation
5. References to the relevant harmonized standards used or references to the specifications in relation to which conformity is declared
6. Where applicable, the DoC should include the notified body (name, number) that performed the EC type-examination and issued the certificate
7. Additional information including the signature and title of the individual who created the DoC as well as the place and date the document was created

Similar technical files are also required for the following EU Directives which may be applied to toy and electrical products which utilize electricity to fulfil at least one function.

- Directive 2011/65/EU Restriction of the use of certain Hazardous Substances in electrical and electronic equipment (RoHS)
- Directive 2014/30/EU Electromagnetic compatibility

**Summary**

When taking into account the documentation requirements of various countries, one could have a single file that includes all of these appropriate documents. Please keep in mind that testing requirements are not harmonized resulting in many unique requirements for various countries, such as the U.S. Undue Influence requirement, and Europe's Safety Assessment and Safety Data Sheets. And while not mandatory for all items, the information included here is an important part of any compliance program. The manufacturer or supplier must know their product—what it is made of, how and where it was manufactured, compliance information and more

**Online Resources:**

**PPAI Product Responsibility:** <http://ppai.org/corporate-responsibility/product-responsibility/>

**European New Toy Safety Directive:** [http://ec.europa.eu/growth/sectors/toys/safety/index\\_en.htm](http://ec.europa.eu/growth/sectors/toys/safety/index_en.htm)

**European Declaration of Conformity:** [http://www.export.gov/cemark/eg\\_main\\_017272.asp](http://www.export.gov/cemark/eg_main_017272.asp)

**Technical File Procedures:** [http://www.export.gov/cemark/eg\\_main\\_017275.asp](http://www.export.gov/cemark/eg_main_017275.asp)

**Conformance CE Marking and Product Safety:** <http://www.conformance.co.uk/index.php>

**CE Marking:** [http://ec.europa.eu/growth/single-market/ce-marking/index\\_en.htm](http://ec.europa.eu/growth/single-market/ce-marking/index_en.htm)

**Declaration of Conformity (DoC):** [http://export.gov/cemark/eg\\_main\\_017272.asp](http://export.gov/cemark/eg_main_017272.asp)

**EU Technical Documentation:** [https://ec.europa.eu/growth/single-market/ce-marking/manufacturers\\_en](https://ec.europa.eu/growth/single-market/ce-marking/manufacturers_en)

**Recalls:** [www.recalls.gov](http://www.recalls.gov)

**REACH:** [http://ec.europa.eu/environment/chemicals/reach/reach\\_en.htm](http://ec.europa.eu/environment/chemicals/reach/reach_en.htm)

**The 'Blue Guide' on the implementation of EU product rules 2016:** <http://ec.europa.eu/DocsRoom/documents/12661>

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