2009/48/EC Toy Directive FAQS ON THE TECHNICAL DOCUMENTATION

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Did you know?

According to the European Toy Safety Directive 2009/48/EC, the technical documentation should contain all relevant data or details of the means used by the manufacturer to ensure that toys comply with the safety mandatory requirements.

Our recommendations and insights are with regards to a variety of questions that we received from international toy companies.

Please note that additional technical documentation can be required also by other directives (e.g. RoHS, EMA, LVD, RED), in this document we are only focusing on the requirements of the European Toy Directive 2009/48/EC.

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1 – Who must draw up the technical documentation and on what basis?

The manufacturer is the economic operator that shall draw up the technical documentation, as this is the operator who knows the design, production, composition of the toy.

The other economic operators (authorised representatives, importers, distributors) are obliged to make this information available. The responsibility for the collation of the technical documentation by the manufacturer does not imply that the manufacturer has to draw up each individual document required.

Since the technical documentation is a compilation of documents, it may contain documents that are prepared and issued by others (e.g. test reports provided by labs, safety data sheets provided by chemical suppliers)

2 – Who is the "manufacturer" according to the directive?

Manufacturer means any natural or legal person who manufactures a toy or has a toy designed or manufactured, and markets that toy under his name or trademark. The definition contains two cumulative conditions: the person has to manufacture (or has a toy manufactured) and to market the toy under his own name or trademark. So, if the toy is marketed under another person's name or trademark, that person will be considered as the manufacturer.

The manufacturer does not need to be located in the European Union.

3 – Does the importer have to possess the technical documentation?

No, however according to the EU Toy Safety Directive, the importer should ensure that the manufacturer has drawn up the technical documentation and should, for a period of 10 years after the toy has been placed on the market, ensure that the technical documentation can be made available to market surveillance authorities, upon request.

4 – What does the technical documentation consist of?

The technical documentation shall contain, in particular, so far as relevant for assessment:

- Detailed description of the design and manufacture
- Safety Assessment(s)
- Conformity assessment procedure followed
- EC declaration of conformity
- Addresses of the places of manufacture and storage
- Test reports and description of the means whereby the manufacturerensured conformity of production with the harmonized standards
- Copies of documents that the manufacturer has submitted to a notified body
- Copy of the EC-type examination certificate, a description of the means whereby the manufacturer ensured conformity of the production with the product type as described in the EC-type examination certificate, and copies of the documents that the manufacturer submitted to the notified body, if the manufacturer submitted the toy to EC-type examination and followed the conformity to type procedure.



5 – In which languages do I have to translate the technical documentation?

The technical documentation shall be drawn up in one of the official languages of the EU.

Following a reasoned request from the market surveillance authority of a Member State, the manufacturer shall provide a translation of the relevant parts of the technical documentation into the language of that Member State.

6 – How long do I need to keep the technical documentation?

Manufacturer and Authorized representatives shall keep the technical documentation for a period of 10 years after the toy has been placed on the market. Importers shall ensure that the technical documentation can be made available to market surveillance authorities, upon request, for a period of 10 years after the toy has been placed on the market.

7 – To whom do I have to make the technical documentation available?

If the market surveillance authorities have a doubt as to the conformity of toys with the safety requirements, they may request communication of the manufacturer's technical documentation or a translation of relevant parts. The request for communication of the technical documentation or a translation of relevant parts should indicate the nature of the doubt about the conformity of the toy concerned and the parts or aspects of the toy that are subject to investigation.

The manufacturer is obliged to provide the documentation and cannot argue that it contains confidential information. When a market surveillance authority requests the technical documentation or a translation of parts thereof from a manufacturer, it may fix a deadline for receipt of such file or translation, which shall be 30 days, unless a shorter deadline is justified in the case of serious and immediate risk.

8 – If on the packaging of a toy we only find the detail of the "imported from", who is identified as a manufacturer?

It is not an explicit obligation of the EU Toy Safety Directive on whether the addresses shall be preceded by the words "Manufactured by", "Imported by", "Represented by" or "Distributed by" but an implicit one, based on the aim of the Legislator to identify each economic operator and his role, when you have more than one address on the toy.

In cases where such information is not present or is not accurate, market surveillance authorities will determine the role of each economic operator. It is then up to the economic operator to prove then he has a different role.

Sources:

http://ec.europa.eu/DocsRoom/documents/17190/attac hments/1/translations

http://ec.europa.eu/DocsRoom/documents/16183/attac hments/1/translations



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