



FACTSHEET

The 2009 Toy Safety Directive

Provisions on Conformity and Safety Assessment

October 2009

This document is one of a series of factsheets, aimed at providing a general overview of the changes introduced by the new Toy Safety Directive (2009 TSD) as adopted in 2009. The objective of the TIE/EC factsheets is to provide guidance to toy manufacturers across the EU regarding the implementation of the 2009 TSD. A particular focus is put on the obligation of manufacturers.

The 2009 TSD will strengthen the rules as laid down in the 1988 TSD. As a result, this new legislation will require adaptations in the manufacturing chain, as well as new procedures along the supply chain.

The 2009 TSD was published in the *Official Journal of the European Union* on 30 June 2009 and entered into force on 20 July 2009. The general provisions of the 2009 TSD will be applicable to toys placed on the market as of 20 July 2011, while the chemical provisions will be applicable to toys placed on the market as of 20 July 2013 (additional 2-year transition period for chemical properties). In practice, this means that **the toys compliant with the 1988 TSD will be allowed to be placed on the market until 19 July 2011 or 19 July 2013 in the case of certain chemical provisions.**

Conformity assessment procedure

Each toy to be placed on the market is submitted to a conformity assessment procedure. Details as to who must undertake the procedure and how it is done are provided in the 2009 TSD. A brief overview is set out below.

Objective of conformity assessment

The objective of the conformity assessment procedure is to demonstrate to the manufacturer and the public authorities that a toy placed on the market complies with the legal requirements of the 2009 TSD.

Definition of conformity assessment

Conformity assessment is the procedure by which a manufacturer establishes that his toy fulfills the applicable safety provisions of the directive. The manufacturer is required to apply one of two possible procedures depending upon the nature of the toy:

1. Self verification

Self verification is used in cases where harmonized standards cover all relevant safety aspects of a toy. In such instances, the manufacturer must apply the existing harmonized standards and ensure that the toy is in conformity therewith. The manufacturer must also put in place an internal production procedure in accordance with Module A of Annex II to Decision No. 768/2008/EC. Module A does not require the involvement of a notified body.

2. Third party verification

Conformity to type or Module B is often referred to as “EC-type examination”. EC-type examination and certification is required in cases where:

- harmonized standards do not exist;
- harmonized standards have not or only partly been applied by a manufacturer;
- one or more harmonized 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 model of the toy to a notified body for EC-type examination. Under Module B, the notified body examines the technical design of a toy and verifies and attests that the technical design of the toy meets the requirements of the 2009 TSD by issuing an EC-type examination certificate. It is important to note that Module B covers the design phase only, whereas Module C covers the production phase and follows Module B.

Under Module C, the manufacturer ensures the conformity of the toys with the type described in the EC-type examination certificate and with the relevant requirements of the legislative instrument that apply. This conformity is evaluated against an approved EC-type examination certificate issued under Module B. Unlike Module B, Module C does not require the involvement of a notified body.

Difference 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 conformity assessment procedure, on the other hand, is to provide demonstrable evidence that the toy is in conformity with the legal requirements under the 2009 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.

Safety assessment procedure

Definition of safety assessment

A safety assessment requires the manufacturer to identify the potential hazards that the toy may present, and to assess the potential exposure to those hazards. This procedure is mandatory under the 2009 TSD and must be performed before the toy is placed on the market.

Scope of the safety assessment

The safety assessment is the responsibility of the manufacturer and must be carried out before the toy is placed on the Community market. It must cover the various chemical, physical, mechanical, electrical, flammability, hygienic and radioactivity hazards that the toy may present. A list of the various requirements that a manufacturer must assess in relation to these hazards is provided in Annex II of the 2009 TSD.

Many of these requirements are embodied in the harmonized toy safety standards; however, the manufacturer remains obliged to assess whether there are any gaps in the standard and/or features in the toy that could present a potential hazard. The outcome of a safety assessment will 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 in the technical documentation for ten (10) years after the toy has been placed on the market.

Sources of information

The final text of the 2009 TSD is available [here](#) and as a backgrounder the text of the 1988 TSD is available [here](#).

The two documents can also be found at the following URLs:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ%3AL%3A2009%3A170%3A0001%3A0037%3AEN%3APDF>
<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1988L0378:20090112:EN:PDF>

Important notice:

This factsheet reflects our understanding of the 2009 TSD text as published in the *Official Journal of the European Union* on 30 June 2009 and is intended merely to highlight in a general manner certain provisions of that text. TIE does not make any warranties about the completeness of the information herein and assumes no responsibility for any use of or reliance on this factsheet.

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