

TOY SAFETY



Ensuring children benefit from
the highest level of protection



European Commission
Enterprise and Industry




There are around **80 million children** under 14 in the EU, and about **2 000 companies** employing over **100 000 people** directly in the toys and games sector, most are small and medium-sized enterprises (SMEs).

Toys and games are vital tools for child development. Whilst manufacturers are responsible for the safety of their products, importers, notified bodies and national authorities all have a role to play in ensuring toys sold in Europe's shops fulfil all safety requirements.

Ensuring safety requirements and standards keep up with the latest toy trends is vital, especially as new materials and manufacturing processes are constantly being developed.

The internal market for toys has positively contributed to the development of the sector and to consumer protection, by harmonising the safety characteristics of toys across the EU. The new **Toy Safety Directive** (TSD) strengthens provisions on enforcement and new safety requirements, ensuring children continue to benefit from the highest levels of protection.



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.

The background features a collage of images. On the left, there are wooden alphabet blocks with letters 'D', 'Y', and 'S' visible. On the right, there is a blurred image of a white toy car. The text is overlaid on a white and yellow geometric background.

THE SCOPE OF THE 2009 TOY SAFETY DIRECTIVE

The scope of the 2009 Toy Safety Directive is covered by Article 2. It provides a definition for toys and therefore determines whether a product falls under the scope of the Directive:

“Any product or material designed or intended whether or not exclusively for use in play by children under 14 years of age”.

Compared to the 1988 TSD, the only new element is the wording ‘whether or not exclusively’, which has been added to indicate that the product does not have to be exclusively intended for playing purposes in order to be considered as a toy. Accordingly, products with double functions are considered as toys (e.g. key-ring with a teddy bear attached to it).

The 2009 TSD recognizes the existence of a “grey zone” for the classification of products as toys. Annex I of the 2009 TSD presents a non-exhaustive list of examples that are not considered as toys but that could be subject to confusion.

Further, the 2009 TSD (Article 2(2)) lists a limited number of products that comply with the definition of toys but are nonetheless excluded from the scope of the 2009 TSD.

It is worth noting that the new definition of toys was meant to be aligned with what are believed to be the current practices of toy manufacturers.

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

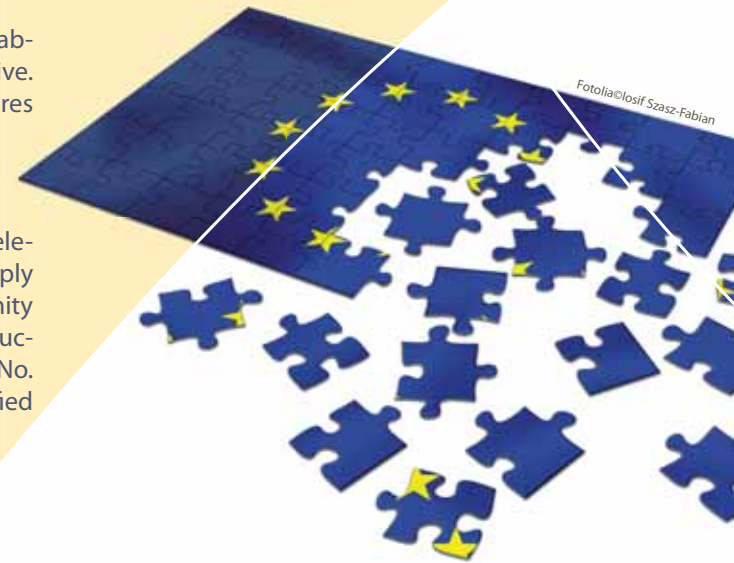
The objective of the conformity assessment procedure is to demonstrate to the manufacturer and the public authorities that a toy placed on the market complies with the legal requirements of the 2009 TSD.

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.



WARNINGS

General rules

General warnings which specify user limitations should be provided with the toy where appropriate for safe use. In addition, Part B of Annex V of the 2009 TSD provides that specific warnings for certain categories of toys should be provided. In addition to the mandatory requirements set out in the 2009 TSD, the harmonized standards also specify warnings that should accompany certain categories of toys. Within its territory, a Member State may stipulate that the warnings shall be written in a language or languages easily understood by consumers, as determined by the Member State.

Location of the warnings

The manufacturer shall mark the warnings in a clearly visible, easily legible and understandable and accurate manner. Warnings must be marked on the toy, an affixed label or the packaging. If appropriate, warnings should also 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 2009 TSD. Warnings which determine the purchase decision, such as minimum and maximum user age indications and the specific warnings described in Part B of Annex V of the 2009 TSD, 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 shall 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). Economic operators may choose between a warning phrase or pictogram (or both):



Warning – Not suitable for children under 36 months

In any case, the wording and/or the pictogram must be preceded by the word “Warning” or “warnings” as appropriate. The specific warning “Not suitable for children under 3 years” and pictogram described in Part B of Annex V of the 2009 TSD in relation to children under 3 years cannot be used for toys intended for children under 3 years. More generally, specific warnings provided for certain categories of toys must not conflict with the intended use of the toy, as determined by virtue of its function, dimension and characteristics. If necessary, the European Commission may propose wording for the specific warnings of certain categories of toys.

TRACEABILITY

What the 2009 TSD says: **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.** 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 bear 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 places a toy on the market, the importer's name, registered trade name/mark, and single contact address point must also all be on the toy or, where that is not possible, on its packaging or in a document accompanying the toy.

Possible options for manufacturers

Manufacturers have the freedom to choose the element they wish to use on a toy to allow its identification, as long as traceability is in fact ensured.



DECLARATION OF CONFORMITY

When a toy is placed on the market, 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 2009 TSD.

The manufacturer or the authorized representative established within the EU must keep the DoC for ten (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 should state that the fulfillment of the 2009 TSD safety requirements has been demonstrated, and should at a minimum include (for the layout, please see Annex III of the 2009 TSD):

- *the (unique) identification number of the toy;*
- *the name and address of the manufacturer or his authorized 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);*
- *the references to the relevant harmonized 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, such as the date, place, signature of manufacturer, and function of signatory.*



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

More than one toy could be referenced by the DoC provided the above requirements are fulfilled but there is a requirement to continuously update the DoC should changes be necessary.



SOURCES OF INFORMATION:

<http://ec.europa.eu/enterprise/toys>

HOW TO CONTACT US:

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Directorate-General for Enterprise and Industry

WE MEAN BUSINESS

This brochure reflects our understanding of the 2009 TSD text 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.

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