

Directive 2009/48/EC of the European Parliament and of the Council
of 18 June 2009 on the safety of toys (Text with EEA relevance)

CHAPTER IV

CONFORMITY ASSESSMENT

Article 18

Safety assessments

Manufacturers shall, before placing a toy on the market, carry out an analysis of the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards that the toy may present, as well as an assessment of the potential exposure to such hazards.

Article 19

Applicable conformity assessment procedures

1 Before placing a toy on the market, manufacturers shall use the conformity assessment procedures referred to in paragraphs 2 and 3 to demonstrate that the toy complies with the requirements set out in Article 10 and Annex II.

2 If the manufacturer has applied harmonised standards, the reference number of which has been published in the *Official Journal of the European Union*, covering all relevant safety requirements for the toy, it shall use the internal production control procedure set out in Module A of Annex II to Decision No 768/2008/EC.

3 In the following cases, the toy shall be submitted to EC-type examination, as referred to in Article 20, together with the conformity to type procedure set out in Module C of Annex II to Decision No 768/2008/EC:

- a where harmonised standards, the reference number of which has been published in the *Official Journal of the European Union*, covering all relevant safety requirements for the toy, do not exist;
- b where the harmonised standards referred to in point (a) exist but the manufacturer has not applied them or has applied them only in part;
- c where one or more of the harmonised standards referred to in point (a) has been published with a restriction;
- d when the manufacturer considers that the nature, design, construction or purpose of the toy necessitate third party verification.

Article 20

EC-type examination

1 An application for EC-type examination, performance of that examination and issue of the EC-type examination certificate shall be carried out in accordance with the procedures set out in Module B of Annex II to Decision No 768/2008/EC.

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EC-type examination shall be carried out in the manner specified in the second indent of point 2 of that Module.

In addition to those provisions, the requirements laid down in paragraphs 2 to 5 of this Article shall apply.

2 The application for an EC-type examination shall include a description of the toy and an indication of the place of manufacture, including the address.

3 When a conformity assessment body notified under Article 22 (hereinafter referred to as a ‘notified body’) carries out the EC-type examination, it shall evaluate, if necessary together with the manufacturer, the analysis of the hazards that the toy may present carried out by the manufacturer in accordance with Article 18.

4 The EC-type examination certificate shall include a reference to this Directive, a colour image, a clear description of the toy, including its dimensions, and a list of the tests performed, together with a reference to the relevant test report.

The EC-type examination certificate shall be reviewed whenever necessary, in particular in case of a change to the manufacturing process, the raw materials or the components of the toy, and, in any case, every five years.

The EC-type examination certificate shall be withdrawn if the toy fails to comply with the requirements set out in Article 10 and Annex II.

Member States shall ensure that their notified bodies do not grant an EC-type examination certificate for a toy in respect of which a certificate has been refused or withdrawn.

5 The technical documentation and correspondence relating to the EC-type examination procedures shall be drawn up in an official language of the Member State in which the notified body is established or in a language acceptable to that body.

Article 21

Technical documentation

1 The technical documentation referred to in Article 4(2) shall contain all relevant data or details of the means used by the manufacturer to ensure that toys comply with the requirements set out in Article 10 and Annex II. It shall, in particular, contain the documents listed in Annex IV.

2 The technical documentation shall be drawn up in one of the official languages of the Community, subject to the requirement set out in Article 20(5).

3 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.

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.

4 If the manufacturer does not comply with the requirements of paragraphs 1, 2 and 3, the market surveillance authority may require it to have a test performed by a notified body at

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its own expense within a specified period in order to verify compliance with the harmonised standards and essential safety requirements.