

Co-ordination of the Notified Bodies NB-TOYS under the Safety of Toys Directive

NB-TOYS/2014/69

10 June 2014

Recommendation No. 1: Format EC-type examination certificate Rev 3

Agreed by:

NB-Toys group on: 18 April 2013

ADCO group on Toy Safety on: 23 May 2014 Expert group on Toy Safety on: 23 May 2014

This versions includes the comments of Expert group on Toy Safety, 3 May 2013 and 11 October 2013.

Available at:

http://ec.europa.eu/enterprise/sectors/toys/documents/recommendations/index_en.htm

Changes that have been made are:

- Exception to chemical requirements deleted in the answer to question 1 on the minimum information from applicant (p. 3 and 4)
- Annex 1title: List of ... provided to the Notified Body...." Instead of "... provided to the applicant"....
- Annex 1 table: titles of both columns
- Annex 1 list of documentation items d, e, and h are indicated "not applicable"
- Annex 1 change and addition of items f, g and h.
- Editorial corrections

Questions related to: The Toy Safety Directive 2009/48/EC of 18 June 2009 article 20 (EC-type examination certificate).

Note:

This Recommendation No. 1 replaces the following 4 recommendations under the old Toy Safety Directive 88/378/EEC

- NB-TOYS/01/024
- NB-TOYS/01/025
- NB-TOYS/2003/020
- NB-TOYS/2004/01

Questions regarding the EC-type examination certificate:

- 1. What minimum information should appear on an EC-type examination certificate?
- 2. Is it possible for a Notified Body to issue a "partial" EC-type examination certificate that would cover only some of the safety aspects of the toy?

Answer to question 1: Minimum information on an EC-type examination certificate

Name and address of the Notified Body, Notified Body identification number

EC-type examination certificate

Reference:			

Identification and description of the toy including its dimensions:

Colour image of the toy

Manufacturer: (name and address)

Applicant:

The undersigned Notified Body declares, on the basis of the assessment of the tests (the results of which are referenced in the report XXX) and the technical documentation provided by the applicant that the type of the toy complies with the essential safety requirements of Directive 2009/48/EC

List of the tests performed:

Date, place and signature

Notes:

- 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 a toy. And, in any case, every five years (Directive 2009/48/EC, Article 20.4)
- Technical progress or new work could affect the conclusion of this EC-type examination certificate.

This certificate is issued under the following conditions:

- 1. It applies only to the tested model submitted to the tests specified in the report(s) referenced above.
- 2. It does not imply that the notified body has performed any surveillance or control of its manufacture.
- 3. The manufacturer shall ensure that the manufacturing process assures compliance of the products with the approved model subject to this certificate.
- 4. The applicant shall inform the notified body of all modifications made to the approved model which must receive, when necessary, additional approval leading to an addition to the original EC-type-examination certificate.
- 5. As technical progress or new work could affect the conclusion of this EC-type examination, the applicant shall regularly keep himself informed of any modification made to tests carried out on the approved model by the notified body.
- 6. Copies are available upon request by the applicant.

Explanation to answer 1

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 768/2008/EC of the European Parliament and of the Council.

The manufacturer should submit the toy to EC-type examination in cases as specified in article 19.3 of Directive 2009/48/EC.

Requirements for EC-type examination are provided by Directive 2009/48/EC (Article 20).

Directive 2009/48/EC, Article 20.4 specifies that "the EC-type examination certificate shall:

- include a reference to this Directive (2009/48/EC),
- 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."

In Decision 768/2008/EC, Module B(6) of Annex II foresees that "the certificate shall contain:

- the name and address of the manufacturer,
- the conclusions of the examination,
- the conditions (if any) for its validity
- the necessary data for identification of the approved type.
- The certificate may have one or more annexes attached.

The certificate and its annexes shall contain all relevant information to allow the conformity of manufactured products with the examined type to be evaluated and to allow for in-service control."

Note: Directive 2009/48/EC, Article 20.4 specifies that "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." (,)

Annex of the EC-type examination certificate:

List of references to the technical documentation provided to the Notified Body for the EC-type examination carried out on the type of the toy reference (reference of the toy) on (date)

(Directive 2009/48/EC, Annex IV)

The technical documentation shall make it possible to assess the product's conformity with the applicable requirements of the legislative instrument and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the product. The technical documentation shall contain, wherever applicable, at least the following elements:

List of technical documentation to be maintained by the manufacturer	Reference of the documents provided to the Notified Body for EC-type examination
(a) a detailed description of the design and manufacture, including a list of	
components and materials used in the toy	
as well as the safety data sheets on	
chemicals used, to be obtained from the	
chemical suppliers	
(b) the safety assessment(s) carried out in	
accordance with Article 18 of the TSD	
(c) a description of the conformity	
assessment procedure followed	
(d) a copy of the EC declaration of	Not Applicable
conformity	
(e) the addresses of the places of	
manufacture	
the addresses of the places of storage	Not applicable
(f) copies of documents that the	
manufacturer has submitted to a notified	
body, if	
involved	
(g) test reports and description of the	Not applicable
means whereby the manufacturer ensured	
conformity of production with the	
harmonised standards, if the manufacturer	
followed the internal production control	
procedure referred to in Article 19(2) of the	
TSD	
(h) A copy of the EC-type examination	Not applicable
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	

Answer to question 2:

Is it possible for a Notified Body to issue a "partial" EC-type examination certificate that would cover only some of the safety aspects of the toy?

It is not possible to issue "partial" EC type-examination certificates that would cover only some of the safety aspects of the toy.

Explanation to answer 2

EC-type examination is the part of a conformity assessment procedure in which a notified body examines the technical design of a product and verifies and attests that the technical design of the product meets the requirements of the legislative instrument that apply to it (Module B(1) of Decision 768/2008/EC of the European Parliament and of the Council).

Therefore EC type-examination has to cover all the safety aspects of the toy. It is not sufficient that it covers only those safety aspects that are not addressed by the standard or those addressed by a standard but not applied by the manufacturer. It has to also cover safety aspects addressed in the harmonised standards applied by the manufacturer