

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 V

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 22

Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under Article 20.

Article 23

Notifying authorities

1 Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies for the purposes of this Directive, and for the monitoring of notified bodies, including compliance with Article 29.

2 Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

3 Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 24(1) to (5). In addition, that body shall have arrangements to cover liabilities arising out of its activities.

4 The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article 24

Requirements relating to notifying authorities

1 Notifying authorities shall be established in such a way that no conflict of interest with a conformity assessment body occurs.

2 Notifying authorities shall be organised and operated so as to safeguard the objectivity and impartiality of their activities.

3 Notifying authorities shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

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4 Notifying authorities shall not offer or provide any activities that conformity assessment bodies perform, nor shall they offer or provide consultancy services on a commercial or competitive basis.

5 Notifying authorities shall safeguard the confidentiality of the information they obtain.

6 Notifying authorities shall have a sufficient number of competent personnel at their disposal for the proper performance of their tasks.

Article 25

Information obligation of notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

Article 26

Requirements relating to notified bodies

1 For the purposes of notification under this Directive, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2 Conformity assessment bodies shall be established under national law and shall have legal personality.

3 A conformity assessment body shall be a third-party body independent of the organisation or the toy it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of toys which it assesses, may, on condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4 A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the toys which they assess, nor the authorised representative of any of those parties. This shall not preclude the use of assessed toys that are necessary for the operations of the conformity assessment body or the use of such toys for personal purposes.

A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design or manufacture, the marketing, installation, use or maintenance of those toys, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5 Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6 Conformity assessment bodies shall be capable of carrying out the conformity assessment tasks assigned to them by the provisions of Article 20 and in relation to which they have been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind or category of toy in relation to which it has been notified, a conformity assessment body shall have at its disposal the necessary:

- a personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;
- b descriptions of procedures in accordance with which conformity assessment is carried out ensuring the transparency and ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;
- c procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the technology of the toy in question and the mass or serial nature of the production process.

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7 The personnel responsible for carrying out the conformity assessment activities shall have:

- a sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;
- b satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;
- c appropriate knowledge and understanding of the essential requirements, of the applicable harmonised standards and of the relevant Community harmonisation legislation and of its implementing regulations;
- d the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8 The impartiality of conformity assessment bodies, their top level management and assessment personnel shall be ensured.

The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9 Conformity assessment bodies shall take out liability insurance unless liability is assumed by the Member State in accordance with its national law, or the Member State itself is directly responsible for the conformity assessment.

10 The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Article 20 or any

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provision of national law giving effect to that Article, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11 Conformity assessment bodies shall participate in, or ensure that their assessment personnel are informed of, the relevant standardisation activities and the activities of the notified body coordination group established under Article 38, and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 27

Presumption of conformity

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*, it shall be presumed to comply with the requirements set out in Article 26 insofar as the applicable harmonised standards cover those requirements.

Article 28

Formal objection to a harmonised standard

Where a Member State or the Commission has a formal objection to the harmonised standards referred to in Article 27, Article 14 shall apply.

Article 29

Subsidiaries of and subcontracting by notified bodies

1 Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 26, and shall inform the notifying authority accordingly.

2 Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries, wherever these are established.

3 Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4 Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Article 20.

Article 30

Application for notification

1 A conformity assessment body shall submit an application for notification under this Directive to the notifying authority of the Member State in which it is established.

2 The application referred to in paragraph 1 shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the toy or toys for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 26.

3 Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 26.

Article 31

Notification procedure

1 Notifying authorities may only notify conformity assessment bodies which have satisfied the requirements laid down in Article 26.

2 Notifying authorities shall notify conformity assessment bodies to the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3 The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules, toy or toys concerned and the relevant attestation of competence.

4 Where a notification is not based on an accreditation certificate as referred to in Article 30(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 26.

5 The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of this Directive.

6 The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification.

Article 32

Identification numbers and lists of notified bodies

1 The Commission shall assign an identification number to each notified body.

It shall assign a single identification number even where the same body is notified under several Community acts.

2 The Commission shall make publicly available a list of bodies notified under this Directive, including the identification numbers that have been allocated to them and the activities for which they have been notified.

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The Commission shall ensure that the list is kept up to date.

Article 33

Changes to notifications

1 Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 26, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2 In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available to the responsible notifying and market surveillance authorities, at their request.

Article 34

Challenge to the competence of notified bodies

1 The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2 The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the body concerned.

3 The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4 Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including de-notification if necessary.

Article 35

Operational obligations of notified bodies

1 Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedure provided for in Article 20.

2 Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the technology of the toy in question and the mass or serial nature of the production process.

In so doing, they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the toy with this Directive.

3 Where a notified body finds that the requirements set out in Article 10 and Annex II or in corresponding harmonised standards have not been met by a manufacturer, it shall require that manufacturer to take appropriate corrective measures and shall not issue the EC-type examination certificate as referred to in Article 20(4).

4 Where, in the course of the monitoring of conformity following the issue of a EC-type examination certificate, a notified body finds that a toy is no longer in compliance, it shall require the manufacturer to take appropriate corrective measures, and shall suspend or withdraw the EC-type examination certificate if necessary.

5 Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any EC-type examination certificates, as appropriate.

Article 36

Information obligation of notified bodies

- 1 Notified bodies shall inform the notifying authority of the following:
 - a any refusal, restriction, suspension or withdrawal of an EC-type examination certificate;
 - b any circumstances affecting the scope of and conditions for notification;
 - c any request for information which they have received from market surveillance authorities regarding conformity assessment activities;
 - d on request, conformity assessment activities performed within the scope of their notification, and any other activity performed, including cross-border activities and subcontracting.
- 2 Notified bodies shall provide the other bodies notified under this Directive which carry out similar conformity assessment activities covering the same toys with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 37

Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

Article 38

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Directive are put in place and properly operated in the form of a sectoral group or groups of notified bodies.

Member States shall ensure that the bodies notified by them participate in the work of that group or groups, directly or by means of designated representatives.