
STATUTORY INSTRUMENTS

2011 No. 1881

The Toys (Safety) Regulations 2011

PART 4

Functions of UK Notified Bodies

Duty to perform EC-type examinations

42.—(1) A UK notified body to whom an application for EC-type examination is made in accordance with regulation 14 must carry out the functions specified in Module B (EC-type examination) in relation to that application.

(2) But a UK notified body is not obliged to carry out such functions where—

- (a) the documents submitted to it in relation to the carrying out of the functions are not in English or another language acceptable to the body;
- (b) the manufacturer has not submitted with its application the fee which the body requires (in accordance with regulation 50);
- (c) the body reasonably believes that, having regard to the number of outstanding applications made to it in relation to its designation, it will be unable to carry out the required work within 6 months of receiving the application; or
- (d) the terms of the body's designation do not entitle the body to carry out the functions of notified bodies specified in Module B in relation to the application.

Performance of EC-type examinations

43.—(1) A UK notified body performing an EC-type examination in relation to a toy must—

- (a) perform that examination in accordance with the provisions of Module B;
- (b) evaluate (if necessary together with the manufacturer) the analysis carried out by the manufacturer in accordance with regulation 12 (safety assessment); and
- (c) while respecting the need for the requirements that are imposed by these Regulations in relation to the toy to be complied with, perform the examination—
 - (i) in a proportionate manner, avoiding unnecessary burdens for economic operators; and
 - (ii) taking due account of—
 - (aa) the size of the relevant economic operator;
 - (bb) the sector in which the economic operator operates;
 - (cc) the structure of the economic operator;
 - (dd) the degree of complexity of the technology of the toy; and
 - (ee) the mass or serial nature of the production process for the toy.

(2) Point 2 of Module B shall be treated as requiring EC-type examination to be performed in the manner specified in the second indent of point 2 (combination of product type and design type).

Issue and content of EC-type examination certificate, and refusal and appeal against refusal to issue certificate

44.—(1) A UK notified body who has performed an EC-type examination in relation to a toy must comply with the provisions of Module B relating to the issue of (or refusal to issue) an EC-type examination certificate.

(2) An EC-type examination certificate must include—

- (a) a reference to the Directive;
- (b) a colour image of the toy;
- (c) a clear description of the toy, including its dimensions;
- (d) a list of the tests performed during the EC-type examination of the toy; and
- (e) a reference to the test report for each listed test.

(3) A UK notified body must refuse to issue an EC-type examination certificate if—

- (a) in the body's opinion the toy will not comply with the essential safety requirements during its foreseeable and normal period of use;
- (b) the body is aware that an EC-type examination certificate that was previously issued in relation to the toy has been withdrawn by any notified body; or
- (c) the body is aware that a notified body has previously refused to issue an EC-type examination certificate in relation to the toy.

(4) But sub-paragraphs (b) and (c) of paragraph (3) do not preclude a UK notified body from issuing an EC-type examination certificate if, following the withdrawal of, or refusal to issue, an EC-type examination certificate, the manufacturer has taken corrective measures in relation to the toy which have the effect that the toy will comply with the essential safety requirements during its foreseeable and normal period of use.

(5) If a UK notified body has refused to issue an EC-type examination certificate under paragraph (3)(a), the body must inform the manufacturer of the corrective measures which in the body's view the manufacturer needs to take in relation to the toy.

(6) A UK notified body must make provision for a manufacturer to appeal against a refusal by the body to issue an EC-type examination certificate in relation to a toy.

Action (after issue of EC-type examination certificate) where a toy fails to comply with essential safety requirements

45.—(1) This regulation applies where—

- (a) an EC-type examination certificate has been issued in relation to a toy; and
- (b) a UK notified body finds that the toy will not comply with the essential safety requirements during its foreseeable and normal period of use—
 - (i) following the review by the body of the certificate on its submission to the body for review by the manufacturer; or
 - (ii) in the course of any other monitoring by the body of whether the toy will comply with the essential safety requirements during its foreseeable and normal period of use.

(2) The UK notified body must—

- (a) consider—

- (i) what corrective measures the manufacturer needs to take in relation to the toy in the light of the body's findings; and
 - (ii) whether it is necessary to suspend or withdraw the EC-type examination certificate;
 - (b) send the manufacturer a notice in writing—
 - (i) setting out the conclusions the body has provisionally reached under sub-paragraph (a);
 - (ii) setting out the reasons for those conclusions; and
 - (iii) inviting the manufacturer to respond to the conclusions within such reasonable period as is specified in the notice;
 - (c) make a decision on the matters specified in sub-paragraph (2)(a), taking into account any response received from the manufacturer within the period specified in the notice; and
 - (d) inform the manufacturer of the decision and the reasons for it.
- (3) The UK notified body must restrict, suspend or withdraw, as appropriate, the EC-type examination certificate issued in relation to the toy, where the manufacturer has been informed in accordance with paragraph (2)(d) of the corrective measures that the manufacturer needs to take in relation to the toy and where—
- (a) the EC-type examination certificate issued in relation to the toy has not already been withdrawn under paragraph (2)(c); and either
 - (b) the manufacturer fails within such period as is reasonable in the circumstances to take those measures; or
 - (c) the manufacturer takes those measures, but the UK notified body forms the view that those measures have not in fact had the effect that the toy will comply with the essential safety requirements during its foreseeable and normal period of use.
- (4) Before restricting, suspending or withdrawing an EC-type examination certificate under paragraph (3) the UK notified body must—
- (a) consider which of those actions it is appropriate to take in the circumstances; and
 - (b) send the manufacturer a notice in writing—
 - (i) setting out the conclusions the body has provisionally reached under sub-paragraph (a);
 - (ii) setting out the reasons for those conclusions; and
 - (iii) inviting the manufacturer to respond to the conclusions within such reasonable period as is specified in the notice;
 - (c) make a decision on the matter specified in sub-paragraph (a), taking into account any response received from the manufacturer within the period specified in the notice; and
 - (d) inform the manufacturer of the decision and the reasons for it.

Provision of information by UK notified bodies to other notified bodies

46. A UK notified body must provide other notified bodies 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.

Instructions to UK notified bodies in relation to EC-type examination certificates

47.—(1) An enforcement authority may request a UK notified body to provide to it, within such period as the body may specify, information relating to—

- (a) an EC-type examination certificate which that body has issued or withdrawn in relation to a toy; or
 - (b) a refusal by that body to issue an EC-type examination certificate in relation to a toy.
- (2) The information which may be requested under paragraph (1) includes test reports and the technical documentation which relate to the toy.
- (3) The UK notified body must comply with the request.
- (4) If an enforcement authority forms the opinion that a toy will not comply with the essential safety requirements during its foreseeable and normal period of use, it must, where appropriate, require a UK notified body who issued an EC-type examination certificate in relation to the toy to withdraw it.
- (5) An enforcement authority must, where it considers it to be necessary, require a UK notified body to review an EC-type examination certificate issued by that body in relation to a toy.
- (6) The following are examples of when an enforcement authority may consider it to be necessary to impose a requirement under paragraph (5)—
- (a) where any change has been made to the following without the certificate having been reviewed by a notified body—
 - (i) the manufacturing process for the toy;
 - (ii) any raw material used in the toy; or
 - (iii) any component of the toy;
 - (b) where 5 years have elapsed since the certificate was issued without it having being reviewed by a notified body;
 - (c) where 5 years have elapsed since the certificate was last reviewed by a notified body without it having being reviewed again by a notified body.
- (7) The UK notified body must comply with a requirement imposed under paragraph (5).

Participation by UK notified bodies in sectoral groups of notified bodies

48.—(1) A UK notified body must participate in the work of each relevant sectoral group of notified bodies put in place by the European Commission in accordance with Article 38 of the Directive (coordination of notified bodies).

(2) A UK notified body may participate by means of a representative designated by it to participate on its behalf.

Subcontracting by a UK notified body

49.—(1) A UK notified body may subcontract a specific task or activity connected with conformity assessment or have recourse to a subsidiary to carry out a task or activity if—

- (a) the body is satisfied that the subcontractor or subsidiary meets the requirements laid down in paragraphs 2 to 11 of Article 26 of the Directive (requirements relating to notified bodies); and
- (b) the economic operator for whom the task or activity is to be carried out has consented to the task or activity being performed by that person.

(2) A UK notified body which subcontracts a specific task or activity connected with conformity assessment or has recourse to a subsidiary to carry out a task or activity—

- (a) must inform the Secretary of State that the body is satisfied that the subcontractor or subsidiary meets the requirements laid down in paragraphs 2 to 11 of Article 26 of the Directive; and

- (b) remains responsible for the proper performance of the task or activity (irrespective of where the subcontractor or subsidiary is established).
- (3) The Secretary of State may request a UK notified body to provide to the Secretary of State, within a specified period, any relevant documents concerning the assessment of the qualifications of the subcontractor or subsidiary and the tasks or activities carried out by the subcontractor or subsidiary.
- (4) The UK notified body must comply with the request.

Charging of fees by UK notified body

50.—(1) A UK notified body may charge such fees in connection with, or incidental to, the carrying out of its functions under regulations 42 to 45 as it may determine

- (2) But any such fee shall not exceed the sum of—
 - (a) the costs incurred or to be incurred by the body in performing the relevant functions; and
 - (b) an amount on account of profit which is reasonable in the circumstances having regard to—
 - (i) the character and extent of the work done or to be done by the body for the manufacturer, and
 - (ii) the commercial rate normally charged on account of profit for that work or similar work.

(3) A UK notified body may require the payment of fees or a reasonable estimate of fees in advance of carrying out the work for the manufacturer.

Provision of information by UK notified bodies to the Secretary of State

51.—(1) A UK notified body must notify the Secretary of State of—

- (a) any refusal by the body to issue an EC-type examination certificate in relation to a toy;
- (b) any restriction, suspension or withdrawal by the body of an EC-type examination certificate issued in relation to a toy;
- (c) any circumstances affecting the scope of the body's designation or any conditions to which its designation is subject; and
- (d) any request which the body has received from an enforcement body for information about conformity assessment activities.

(2) The Secretary of State may request a UK notified body to provide to the Secretary of State, within such period as the Secretary of State may specify—

- (a) information about any conformity assessment activity carried out by the body within the scope of the body's designation;
- (b) information about any other activity carried out by the body, including cross-border activities and sub-contracting; and
- (c) information relevant to determining the body's compliance with any of the requirements laid down in paragraphs (2) to (11) of Article 26 of the Directive (requirements relating to notified bodies), any provision of these Regulations or any condition to which the body's designation is subject.

(3) The UK notified body must comply with the request.