

SCHEDULE 15

Amendment of the Toys (Safety) Regulations 2011

Substitution of Part 3

28. For Part 3, substitute—

“PART 3

Approval of Conformity Assessment Bodies

Approved bodies

40A.—(1) An approved body is a conformity assessment body which—

- (a) has been approved by the Secretary of State pursuant to the procedure set out in regulation 41 (approval of conformity assessment bodies);
- (b) immediately before exit day was a UK notified body in respect of which the Secretary of State has taken no action under regulation 41(4) as it had effect immediately before exit day to suspend or withdraw the body’s status as UK notified body.

(2) Paragraph (1) has effect subject to regulation 40E (restriction, suspension or withdrawal of approval).

(3) In this Part—

“UK notified body” means a body—

- (a) which the Secretary of State had before exit day notified to the European Commission and the member States of the European Union, in accordance with Article 31 of the Directive; and
- (b) in respect of which no objections had been raised, as referred to in regulation 40(2), as it had effect immediately before exit day;

“approved body requirements” means the requirements set out in Schedule 7.

Approval of conformity assessment bodies

40B.—(1) The Secretary of State may approve only those conformity assessment bodies that qualify for approval.

(2) A conformity assessment body qualifies for approval if the first and second conditions below are met.

(3) The first condition is that the conformity assessment body has applied to the Secretary of State to become an approved body and that application is accompanied by—

- (a) a description of—
 - (i) the conformity assessment activities that the conformity assessment body intends to carry out;
 - (ii) the conformity assessment module in respect of which the conformity assessment body claims to be competent;
 - (iii) the category of toys in respect of which the conformity assessment body claims to be competent; and

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(b) either—

(i) an accreditation certificate; or

(ii) the documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body's compliance with the approved body requirements.

(4) The second condition is that the Secretary of State is satisfied that the conformity assessment body meets the approved body requirements.

(5) For the purposes of paragraph (4), the Secretary of State may accept an accreditation certificate, provided in accordance with paragraph (3)(b), as sufficient evidence that the conformity assessment body meets the approved body requirements.

(6) When deciding whether to approve a conformity assessment body that qualifies for approval, the Secretary of State may—

(a) have regard to any other matter which appears to the Secretary of State to be relevant; and

(b) set conditions that the conformity assessment body must meet.

(7) For the purposes of this regulation “accreditation certificate” means a certificate issued by the UK national accreditation body attesting that a conformity assessment body meets the approved body requirements.

Presumption of conformity of approved bodies

40C.—(1) Where a conformity assessment body demonstrates its conformity with the criteria laid down in a designated standard (or part of such standard), the Secretary of State is to presume that the conformity assessment body meets the approved body requirements covered by that standard (or that part of that standard).

(2) The presumption in paragraph (1) is rebuttable.

Monitoring

40D. The Secretary of State must monitor each approved body with a view to verifying that the body—

(a) continues to meet the approved body requirements;

(b) meets any conditions set—

(i) in accordance with regulation 40B(6)(b); or

(ii) by the Secretary of State before exit day in that body's capacity as a UK notified body; and

(c) carries out its functions in accordance with these Regulations.

Restriction, suspension or withdrawal of approval

40E.—(1) Where the Secretary of State determines that an approved body—

(a) no longer meets an approved body requirement; or

(b) is failing to fulfil its obligations under these Regulations, other than a condition referred to in regulation 40D(b), the Secretary of State must restrict, suspend or withdraw the body's status as an approved body under regulation 40A (approved bodies).

(2) Where the Secretary of State determines that an approved body no longer meets a condition referred to in regulation 40D(b), the Secretary of State may restrict, suspend or withdraw the body's status as an approved body under regulation 40A.

(3) In deciding what action is required under paragraph (1) or (2), the Secretary of State must have regard to the seriousness of the non-compliance.

(4) Before taking action under paragraph (1) or (2), the Secretary of State must—

- (a) give notice in writing to the approved body of the proposed action and the reasons for it;
- (b) give the approved body an opportunity to make representations to the Secretary of State regarding the proposed action within a reasonable period from the date of the notice; and
- (c) consider any such representations made by the approved body.

(5) Where the Secretary of State has taken action in respect of an approved body under paragraph (1) or (2), or where an approved body has ceased its activity, the approved body must, at the request of the Secretary of State—

- (a) transfer its files relating to the activities it has undertaken as an approved body to another approved body or to the Secretary of State; or
- (b) keep its files relating to the activities it has undertaken as an approved body available for the Secretary of State and other enforcement authorities for a period of 10 years from the date they were created.

(6) The activities undertaken as an approved body referred to in paragraph (5) include any activities that the body has undertaken as a UK notified body.

Operational matters in relation to approved bodies

40F.—(1) Subject to the terms of its appointment and to regulation 44, an approved body must carry out the conformity assessment activities and modules—

- (a) in respect of which the body's approval was given under regulation 40B; or
- (b) in respect of which body's notification as a notified body was made.

(2) Where an approved body carries out a conformity assessment procedure, it must do so in accordance with Schedule 6.

Subsidiaries and contractors

40G.—(1) An approved body may subcontract specific conformity assessment activities, or use a subsidiary to carry out such activities provided—

- (a) the body is satisfied that the subcontractor or subsidiary meets the approved body requirements;
- (b) the body has informed the Secretary of State that it is satisfied that the subcontractor or subsidiary meets those requirements; and
- (c) the economic operator for whom the activities are to be carried out has consented to the activities being carried out by that person.

(2) The approved body which subcontracts specific conformity assessment activities or uses a subsidiary to carry out such activities remains responsible for the proper performance of those activities (irrespective of where the subcontractor or subsidiary is established).

(3) Where an approved body subcontracts, or uses a subsidiary to carry out, a specific conformity assessment activity, the approved body must, for a period of 10 years beginning

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on the day on which the activity is first carried out, keep available for inspection by the Secretary of State all relevant documentation concerning—

- (a) the assessment of the qualifications of the subcontractor or the subsidiary; and
- (b) the conformity assessment activity carried out by the subcontractor or subsidiary.

(4) In this regulation “subsidiary” has the meaning given to it in section 1159 of the Companies Act 2006⁽¹⁾.

Register of approved bodies

40H.—(1) The Secretary of State must—

- (a) assign an approved body identification number to each approved body; and
- (b) compile and maintain a register of—
 - (i) approved bodies;
 - (ii) their approved body identification numbers;
 - (iii) the activities for which they have been approved; and
 - (iv) any restrictions on those activities.

(2) The register referred to in paragraph (1) must be made publicly available.

UK national accreditation body

41. The Secretary of State may authorise the UK national accreditation body to carry out the following activities on behalf of the Secretary of State—

- (a) assessing whether a conformity assessment body meets the approved body requirements;
- (b) monitoring approved bodies in accordance with regulation 40D; and
- (c) compiling and maintaining the register of approved bodies, in accordance with regulation 40H.”.

⁽¹⁾ 2006 c.46.