SCHEDULE 15 Regulation 18

Amendment of the Toys (Safety) Regulations 2011

Interpretation

1. The Toys (Safety) Regulations 2011are amended in accordance with paragraphs 2 to 43.

Amendment to regulation 2

2.—(1) In regulation 2(2) (revocation, saving and amendment)—

(a) before "as if" insert "subject to the modifications in paragraph (2A);

(b) after paragraph (2) insert—

"(2A) The modifications referred to in paragraph (2) are—

(a) that references to "the Community" are to be read as including the United Kingdom; and

(b) paragraph (5) of regulation 9 is to be read as if ", the Commission of the Communities, the other member States and other approved bodies" were omitted."

Insertion of regulation 2A

3. After regulation 2 insert—

"**Transitional provision in relation to EU Exit**

2A.—(1) In this regulation—

"pre-exit period" means the period beginning with 19th August 2011 and ending immediately before exit day;

"product" means a toy to which these Regulations apply.

(2) Subject to paragraphs (3) and (4), where a product was made available on the market during the pre-exit period, despite the amendments made by Schedule 15 to the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019(**1**), any obligation or prohibition to which a person was subject under these Regulations as they had effect immediately before exit day, continues to have effect as it did immediately before exit day, in relation to that product.

(3) Paragraph (2) does not apply to—

(a) any obligation of any enforcement authority to inform the European Commission or the member States of any matter; or

(b) any obligation to take action outside of the United Kingdom in respect of that product.

(4) Where an EC-type examination was issued in relation to a product to which paragraph (2) applies references to "Type examination" in regulations 22 and 45 are to be read as referring to an EC-type examination referred to in regulation 44 as it had effect immediately before exit day.

(5) Where during the pre-exit period—

(a) a product has not been placed on the market; and

(**1**) S.I. 2019/XXXX.

(b) a manufacturer has taken any action under regulations 11 to 13 as they had effect immediately before exit day in relation to that product,

that action has effect as if it had been done under regulations 11 to 13 as they have effect on and after exit day.".

Amendment to regulation 3

4. In regulation 3 (interpretation)—

(a) in the definition of "the Directive" at the end insert "(as it has effect immediately before exit day)";

(b) after the definition of "the GPSR" insert—

""approved body requirements" has the meaning given to it in regulation 40A;";

(c) for the definition of "authorised representative" substitute—

""authorised representative" means—

(a) a person who—

(i) immediately before exit day was established in the United Kingdom or an EEA state and was appointed by a manufacturer by written mandate to perform specified tasks for that manufacturer, in accordance with regulation 25, as it had effect immediately before exit day; and

(ii) on or after exit day continues to be so established and appointed by the manufacturer to perform those tasks; or

(b) a person who, on or after exit day, is appointed in accordance with regulation 25;";

(d) omit the definition of "CE marking";

(e) before the definition of "distributor" insert—

""designated standard" has the meaning given to it in regulation 3A;";

(f) omit the definition of "harmonised standard";

(g) in the definition of "importer"—

(i) in paragraph (a) for "within the EU" substitute "in the United Kingdom"; and

(ii) in paragraph (b) for "third country on the EU market" substitute "country outside the United Kingdom on the market";

(h) in the definition of "make available on the market" for "EU" substitute "United Kingdom";

(i) for the definition of "Module" substitute—

""Module" means a Module set out in Schedule 6 and Module A, B or C is to be construed accordingly;";

(j) omit the definition of "notified body designation";

(k) in the definition of "place on the market" for "EU" substitute "United Kingdom";

(l) after the definition of "place on the market" insert—

""RAMS" means Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93;";

(m) after the definition of "toy" insert—

""UK marking" means the marking in the form set out in Annex 2 of RAMS;

"UK national accreditation body" means the body appointed by the Secretary of State in accordance with Article 4 of RAMS;";

(n) omit the definition of "UK notified body".

Insertion of Regulations 3A and 3B

5. After regulation 3, insert—

"**Designated standard**

3A.—(1) Subject to paragraphs (6) and (7) in these Regulations a "designated standard" means a technical specification which is—

(a) adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory; and

(b) designated by the Secretary of State by publishing the reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate;

(2) For the purposes of subparagraph (a), a "technical specification" means a document that prescribes technical requirements to be fulfilled by a product, process, service or system and which lays down one of more of the following—

(a) the characteristics required of a product including—

(i) levels of quality, performance, interoperability, environmental protection, health, safety or dimensions, and

(ii) the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures; or

(b) production methods and processes relating to the products, where these have an effect on their characteristics;

(3) For the purposes of this regulation a "recognised standardisation body" means any one of the following organisations—

(a) the European Committee for Standardisation (CEN);

(b) the European Committee for Electrotechnical Standardisation (Cenelec);

(c) the European Telecommunications Standards Institute (ETSI);

(d) the British Standards Institution (BSI);

(4) When considering whether the manner of publication of a reference in accordance with paragraph (1)(b), the Secretary of State must have regard to whether the publication will draw the standard to the attention of any person who may have an interest in the standard;

(5) Before publishing the reference to a technical specification adopted by the British Standards Institution, the Secretary of State must have regard to whether the technical specification is consistent with technical specifications adopted by the other recognised standardisation organisations;

(6) The Secretary of State may remove from publication the reference to a standard which has been published in accordance with paragraph (1)(b).

(7) Where the Secretary of State removes the reference to a standard from publication, that standard is no longer a designated standard.

(8) In this regulation a reference to a "product" is a reference to a toy to which these Regulations apply

(9) The Secretary of State may by regulations amend paragraph (3) to reflect any changes in the name or structure of the recognised standardisation bodies.

(10) Regulations made under paragraph (9) are to be made by statutory instrument.

(11) A statutory instrument containing regulations made under paragraph (9) is subject to annulment in pursuance of a resolution of either House of Parliament.

Annexes to EU legislation as Schedules

3B.—(1) Schedules 1, 2, 4 and 5 reproduce provisions of the Annexes I, II, IV and V (respectively) to the Directive with amendments to correct deficiencies in retained EU law.

(2) A reference to a provision of Schedules 1, 2, 4, 5 is a reference to the equivalent provision of the relevant Annex to the Directive as set out in the relevant Schedule.

(3) Schedule 6 reproduces provisions of Annex II to Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC(**2**) ("Decision No 768/2008/EC") which are relevant to these Regulations, as it has effect immediately before exit day, with amendments to correct deficiencies in retained EU law.

(4) A reference to a provision of Schedule 6 is a reference to the equivalent provision of Annex II of Decision No 768/2008/EC as set out in that Schedule.".

Amendment to regulation 4

6. In regulation 4 (toys to which these Regulations apply) in paragraph (3)(f) for "Annex I to the Directive" substitute "Schedule 1".

Amendment to regulation 5

7. In regulation 5(1)(b) (essential safety requirement) for "Annex II to the Directive (as amended from time to time)" substitute "Schedule 2".

Omission of regulation 6

8. Regulation 6 (toys placed on the market before 20th July 2013) is omitted.

Amendment to regulation 7

9. In regulation 7 (presumption of conformity) for "harmonised" substitute "designated".

Amendment to regulation 8

10. In regulation 8 (exception for trade fairs or exhibitions)—

(a) in paragraph (1) for "CE" substitute "UK";

(b) in paragraph (2) in both places in which it occurs for "the Directive" substitute "these Regulations";

(c) in paragraph (2)(b) for "EU" substitute "United Kingdom".

(**2**) OJ L 218, 13.8.2008, p30.

Amendment to regulation 10

11. In regulation 10 (prohibitions on placing toys on the market) in paragraph (2)(d)—

(a) omit "EC";

(b) for "CE" substitute "UK".

Amendment to regulation 13

12. In regulation 13 (applicable conformity assessment procedures)—

(a) in paragraphs (2) and (3)(a) to (c) for "harmonised" substitute "designated";

(b) in paragraph (3) for "EC-type" substitute "Type".

Amendment to regulation 14

13. In regulation 14 (application for EC-type examination)—

(a) in the heading and in the regulation for "EC-type" substitute "Type"

(b) in paragraph (a) for "a notified" substitute "an approved";

(c) in paragraph (e)—

(i) omit the words beginning with "if" and ending with "UK notified body,";

(ii) for "by UK notified" substitute "by approved".

Amendment to regulation 15

14. In regulation 15 (EC declaration of conformity and CE marking)—

(a) in the heading—

(i) for "EC declaration" substitute "Declaration"; and

(ii) for "CE" substitute "UK";

(b) in paragraph (a) for "an EC" substitute "a";

(c) in paragraph (b) for "CE" substitute "UK".

Amendment to regulation 16

15. In regulation 16—

(a) omit "EC" in each place in which it occurs;

(b) in paragraph 2(a) for "Annex III to the Directive" substitute "Schedule 3";

(c) omit paragraph (5).

Amendment to regulation 17

16. In regulation 17 (technical documentation and correspondence)—

(a) in the heading for "EC-type" substitute "Type";

(b) for paragraph (2) substitute—

"(2) The technical documentation must be drawn up in English.";

(c) in paragraph (3) for "Annex IV of the Directive" substitute "Schedule 4";

(d) for paragraph (4) substitute—

"(4) Any correspondence relating to the Type examination of a toy must be drawn up in English.";

(e) in paragraph (5) omit "EC";

(f) in paragraph (10)—

(i) for "a notified" substitute "an approved";

(ii) for "the notified" substitute "the approved" in both places in which it occurs;

(iii) for "harmonised" substitute "designated".

Amendment to regulation 18

17. In regulation 18 (toys to bear CE marking) in the heading and in each place in which it occurs for "CE" substitute "UK".

Amendment to regulation 20

18. In regulation 20 (instructions for use, safety information and warnings)—

(a) omit paragraph (10);

(b) in each place in which it occurs for "Annex V to the Directive" substitute "Schedule 5".

Amendment to regulation 21

19. In regulation 21(2)(b) (compliance procedures for series production)—

(a) for "harmonised" substitute "designated";

(b) omit "EC".

Amendment to regulation 22

20. In regulation 22 (submission of EC-type examination certificate for review)—

(a) in the heading for "EC-type" substitute "Type";

(b) for "An EC-type" substitute "A Type";

(c) for "a notified" in each place in which it occurs substitute "an approved".

Amendment to regulation 25

21. In regulation 25 (manufacturer's authorised representative)—

(a) in paragraph (1) for "within the EU" substitute "in the United Kingdom";

(b) in paragraph (2)(a) omit "or translation".

Amendment to regulation 26

22. Regulation 26 (prohibitions on placing toys on the market) in paragraph 2(a)(iii) for "CE" substitute "UK".

Amendment to regulation 27

23. In regulation 27 (information identifying importer) for paragraph (2) substitute—

"(2) Paragraph (1) does not apply where—

(a) either—

(i) the size or nature of the toy precludes the information from being marked on the toy;

(ii) the importer would have to open the toy's packaging in order to mark the information on the toy; or

(iii) the importer imported the toy from an EEA state and places it on the market within the period of 18 months beginning with exit day; and

(b) the importer ensures that the information referred to in paragraph (1) is set out in a document accompanying the toy.".

Amendment to regulation 31

24. In regulation 31 (duties to retain and provide information) omit "EC".

Amendment to regulation 33

25. In regulation 33 (duty to act with due care and prohibitions) in paragraph (3)(a)(i) for "CE" substitute "UK".

Amendment to regulation 39

26. In regulation 39 (protection of CE marking)—

(a) in the heading and in each place in which it occurs for "CE" substitute "UK";

(b) in paragraph (1)(a)(ii) omit "in accordance with regulation 25(1)".

Insertion of regulation 39A and Part 2A

27. After regulation 39 insert—

"**Obligations which are met by complying with obligations in the Directive**

39A.—(1) In this regulation—

(a) any reference to an Article or an Annex is a reference to an Article of or an Annex to the Directive;

(b) "CE marking" has the meaning given to it in Article 3(16);

(c) "harmonised standard" has the meaning given to it in Article 3(8);

(2) Subject to paragraphs (6) and (7) paragraph (3) applies where, before placing a toy on the UK market, a manufacturer—

(a) ensures that the toy has been designed and manufactured in accordance with the requirements set out in—

(i) in Article 10 (essential safety requirements); and

(ii) Annex II (particular safety requirements);

(b) carries out the safety assessment in accordance with Article 18;

(c) ensures that the relevant conformity assessment procedure has been carried out in accordance with Article 19;

(d) in cases where the manufacturer considers that Article 19(3) applies, ensures that the provisions of Article 20 are complied with;

(e) draws up the technical documentation in accordance with Article 21(1);

(f) ensures that the technical documentation and other records and correspondence relating to the conformity assessment procedures are prepared in or translated into English;

(g) affixes the CE marking in accordance with Articles 16 and 17;

(h) draws up an EC declaration of conformity, in accordance with Article 15; and

(i) ensures that the EC declaration of conformity is prepared in or translated into English.

(3) Where this paragraph applies—

(a) the requirements of regulations 10 to 15, 16(1) to (2), 17(1) to (4) and 18, are to be treated as being satisfied;

(b) regulations 16(4) to (5), 17(5) and (10), 21, 22, 39 and 44 are to be read subject to the modifications in paragraph (10);

(c) regulations 42 to 44 do not apply; and

(d) regulation 52 does not apply.

(4) Subject to paragraphs (6) and (7), paragraph (5) applies, where before placing a toy on the market, the importer ensures that—

(a) the relevant conformity assessment procedure that applies to that toy has been carried out in accordance with Article 19;

(b) the manufacturer has drawn up the technical documentation in accordance with Article 21(1); and

(c) the toy bears the CE marking affixed in accordance with Articles 16 and 17.

(5) Where this paragraph applies—

(a) the requirements in regulation 26(a)(i) to (iii) are to be treated as being satisfied; and

(b) regulations 26(1), 28 and 30 to 32 are to be read subject to the modifications in paragraph (10).

(6) This paragraph applies where there is no designated standard or part of a designated standard which corresponds exactly to a harmonised standard or part of a harmonised standard.

(7) Where paragraph (6) applies paragraphs (2)(c) and (4)(a) are to be treated as requiring the manufacturer to carry out the conformity assessment procedure referred to in Article 19(3).

(8) Paragraph (9) applies where before making a toy available on the market, a distributor ensures that the manufacturer has affixed the CE marking in accordance with Articles 16 and 17.

(9) Where this paragraph applies—

(a) regulation 33(3)(a)(i) is to be treated as being satisfied;

(b) regulation 33(2), 34, 35 and 37 are to be read subject to the modifications in paragraph (10).

(10) The modifications referred to in paragraphs (3)(b), (5)(b) and (9)(b) are that—

(a) any reference to "declaration of conformity" is to be read as a reference to the EC declaration of conformity;

(b) any reference to "UK marking" is to be read as a reference to the CE marking;

(c) any reference to "essential safety requirements" is to be read as a reference to the requirements set out in—

(i) in Article 10 (essential safety requirements); and

(ii) Annex II (particular safety requirements);

(d) any reference to "designated standard" is to be read as a reference to a harmonised standard;

(e) any reference to "applicable conformity assessment procedure" is to be read as a reference to the applicable conformity assessment procedures referred to in Article 19;

(f) any reference to "technical documentation" is a reference to the technical documentation referred to in Article 21(1);

(g) any reference to "authorised representative" is a reference to a person appointed in accordance with Article 5; and

(h) any reference to "Type examination" is a reference to "EC-type examination".

PART 2A

Powers and duties of the Secretary of State in relation to toys

Power to amend Schedules 1, 2 and 5

39B.—(1) The Secretary of State may by regulations amend the provision of the Schedules referred to in paragraph (2) where the Secretary of State considers it necessary to do so in order to take technical progress and scientific developments into account.

(2) The provisions referred to in paragraph (1) are—

(a) any provision in Schedule 1;

(b) points 11 and 13 of Part 3 of Schedule 2; and

(c) any provision of Schedule 5.

(3) The power to make regulations made under paragraph (1) includes power—

(a) to make different provisions for different cases; and

(b) to make such supplemental, consequential and transitional provisions as the Secretary of State considers appropriate.

(4) Regulations made under this regulation are to be made by statutory instrument subject to annulment in pursuance of a resolution of either House of Parliament.

Power to amend Appendix C to Schedule 2

39C.—(1) The Secretary of State may by regulations amend Appendix C to Schedule 2 to add specific values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth.

(2) Regulations made under paragraph (1) may—

(a) make different provisions for different cases; and

(b) make such supplemental, consequential and transitional provisions as the Secretary of State considers appropriate.

(3) Regulations made under this regulation are to be made by statutory instrument subject to annulment in pursuance of a resolution of either House of Parliament.

Powers to amend Appendix A to Schedule 2

39D.—(1) Where the conditions set out in paragraph (3)(a) and (b) are met, the Secretary of State may by regulations amend Appendix A to Schedule 2 to allow substances or mixtures classified as carcinogenic, mutagenic or toxic for reproduction of the categories laid down in Section 4 of Appendix B of Schedule 2 to be used in toys, in components of toys or micro-structurally distinct parts of toys.

(2) Where the conditions set out in paragraphs (3)(a), (b) and (c) are met, the Secretary of State may by regulations amend Appendix A to Schedule 2 to allow substances or mixtures classified as carcinogenic, mutagenic or toxic for reproduction of the categories laid down Section 3 of Appendix B of Schedule 2 to be used in toys, in components of toys or micro-structurally distinct parts of toys.

(3) The conditions referred to in paragraphs (1) and (2) are—

(a) the Secretary of State considers that there is sufficient scientific evidence to demonstrate that the use of substances or mixtures that are classified as carcinogenic, mutagenic or toxic for reproduction of the categories laid down in Section 5 of Appendix B to Schedule 2 are safe for use in toys, particularly in view of exposure;

(b) the substance or mixture is not prohibited for use in consumer articles by Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) establishing a European Chemicals Agency, amending Directive 19999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/105/EC and 2000/21/EC.

(c) there are no suitable alternative substances or mixtures available, as documented in an analysis of alternatives; and

(4) Regulations made under paragraph (1) or (2) may—

(a) make different provisions for different cases; and

(b) make such supplemental, consequential and transitional provisions as the Secretary of State considers appropriate.

(5) Regulations made under this regulation are to be made by statutory instrument subject to annulment in pursuance of a resolution of either House of Parliament.

(6) The Secretary of State must—

(a) carry out a review of regulations made under paragraph (1) or (2);

(b) set out the conclusions of the review in a report; and

(c) publish the report.

(7) A review to which paragraph (6) refers must be made—

(a) as soon as any safety concerns arise; and

(b) at intervals not exceeding five years beginning with the date regulations made under paragraph (1) or (2) come into force.

Duty of the Secretary of State to evaluate use of hazardous substances

39E.—(1) The Secretary of State must—

(a) evaluate the occurrence of hazardous substances of materials in toys;

(b) set out the conclusions of the evaluation in a report; and

(c) publish the report.

(2) During the evaluation the Secretary of State must consult—

(a) any enforcement authority which is not the Secretary of State; and

(b) any person that the Secretary of State considers appropriate.

(3) The first report must be published before the end of the period of five years beginning on exit day.

(4) Subsequent reports are to be published at intervals not exceeding five years.".

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 40B (approval of conformity assessment bodies); or

(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 a 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

(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 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(**3**).

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.".

Amendment to Part 4

29. In the heading of Part 4 (Functions of UK Authorised Bodies) for "UK Notified" substitute "Approved".

Amendment to regulation 42

30. In regulation 42 (duty to perform EC-type examinations)—

(a) in the heading and in paragraph (1) in both places in which it occurs for "EC-type" substitute "Type";

(b) in paragraph (1) for "A UK notified" substitute "An approved";

(c) in paragraph (2) for "a UK notified" substitute "an approved";

(d) in paragraph (2)(d)—

(**3**) 2006 c.46.

(i) for "designation" substitute "approval";

(ii) for "notified" substitute "approved".

Amendment to regulation 43

31. In regulation 43 (performance of EC-type examinations)—

(a) in the heading and in paragraph (2) for "EC-type" substitute "Type";

(b) in paragraph (1)—

(i) for "A UK notified" substitute "An approved";

(ii) for "an EC-type" substitute "a Type".

Amendment of regulation 44

32. In regulation 44 (issue and content of EC-type examination certificate)—

(a) in the heading and in paragraph (2)(d) for "EC-type" substitute "Type";

(b) in each place in which it occurs for "an EC-type" substitute "a Type";

(c) in paragraphs (1) and (3) for "A UK notified" substitute "An approved";

(d) in paragraph (2)(a) for "the Directive" substitute "these Regulations";

(e) in paragraph (3)(b) for "notified" substitute "approved";

(f) in paragraph (3)(c) for "a notified" substitute "an approved";

(g) in paragraphs (4), (5) and (6) for "a UK notified body" substitute "an approved body".

Amendment of regulation 45

33. In regulation 45 (action after issue of EC-type examination certificate)—

(a) in the heading and in paragraphs (2)(a)(ii), (3) and (3)(a) for "EC-type" substitute "Type";

(b) in paragraph (1)(a) and (4) for "an EC-type" substitute "a Type";

(c) in paragraph (1)(b) for "a UK notified" substitute "an approved";

(d) for "the UK notified" in each place in which it occurs substitute "the approved".

Amendment to regulation 46

34. In regulation 46 (provision of information by UK notified bodies)—

(a) in the heading—

(i) for "UK notified" substitute "approved";

(ii) for "other notified" substitute "other approved";

(b) for "A UK notified" substitute "An approved";

(c) for "other notified" substitute "other approved".

Amendment of regulation 47

35. In regulation 47 (instructions to UK notified bodies)—

(a) in the heading, in paragraph (3) and paragraph (7) for "UK notified" substitute "approved";

(b) in the title for "EC-type" substitute "Type";

(c) for "a notified" in each place in which it occurs substitute "an approved";

(d) for "a UK notified" in each place in which it occurs substitute "an approved";

(e) for "an EC-type" in each place in which it occurs substitute "a Type".

Omission of regulations 48 and 49

36. Regulations 48 (participation by UK notified bodies) and 49 (subcontracting by a UK notified body) are omitted.

Amendment to regulation 50

37. In regulation 50 (charging of fees by UK notified body)—

(a) in the heading for "UK notified" substitute "approved";

(b) for "A UK notified" in both places in which it occurs substitute "An approved".

Amendment to regulation 51

38. In regulation 51 (provision of information by UK notified bodies)—

(a) in the heading and in paragraph (3) for "UK notified" substitute "approved";

(b) for "a UK notified" in both places in which it occurs substitute "an approved";

(c) for "an EC-type" in both places in which it occurs substitute "a Type";

(d) for "designation" in each place in which it occurs substitute "approval";

(e) in paragraph (2)(c) for the words beginning with "paragraphs" and ending in "bodies)" substitute "the approved body requirements".

Amendment to regulation 52

39. In regulation 52 (enforcement action in cases of formal non-compliance)—

(a) for "CE" in both places in which it occurs substitute "UK";

(b) for "an EC" in both places in which it occurs substitute "a".

Amendment to regulation 53

40. In regulation 53 (enforcement action in cases of toys presenting a risk) omit paragraph (5).

Amendment to regulation 54

41. In regulation 54 (notification of enforcement action)—

(a) for paragraph (1) substitute—

"(1) Where a person or an enforcing authority is not the Secretary of State and it has taken action under regulation 53, it must notify the Secretary of State of—

(a) the results of the evaluation; and

(b) the corrective actions which it requires the relevant economic operator to take.";

(b) in paragraph (2) for "notified" substitute "approved".

Amendment to regulation 55

42. In regulation 55 omit paragraph (4).

Insertion of Schedules

43. At the end of the Regulations insert—

"SCHEDULE 1 Regulations 3B and 4(3)

PRODUCTS THAT ARE NOT TOYS (Annex I to the Directive)

1. Products listed in paragraphs 2 to 20 are not to be considered as toys.

2. Decorative objects for festivities and celebrations.

3. Products for collectors, provided that the product or its packaging bears a visible and legible indication that it is intended for collectors of 14 years of age and aboveExamples of this category are—

(a) detailed and faithful scale models;

(b) kits for the assembly of detailed scale models;

(c) folk dolls and decorative dolls and other similar articles;

(d) historical replicas of toys; and

(e) reproductions of real fire arms.

4. Sports equipment, including roller skates, inline skates, and skateboards intended for children with a body mass of more than 20 kg.

5. Bicycles with a maximum saddle height of more than 435 mm, measured as the vertical distance from the ground to the top of the seat surface, with the seat in a horizontal position and with the seat pillar set to the minimum insertion mark.

6. Scooters and other means of transport designed for sport or which are intended to be used for travel on public roads or public pathways.

7. Electrically driven vehicles which are intended to be used for travel on public roads, public pathways, or the pavement thereof.

8. Aquatic equipment intended to be used in deep water, and swimming learning devices for children, such as swim seats and swimming aids.

9. Puzzles with more than 500 pieces.

10. Guns and pistols using compressed gas, with the exception of water guns and water pistols, and bows for archery over 120 cm long.

11. Fireworks, including percussion caps which are not specifically designed for toys.

12. Products and games using sharp-pointed missiles, such as sets of darts with metallic points.

13. Functional educational products, such as electric ovens, irons or other functional products operated at a nominal voltage exceeding 24 volts which are sold exclusively for teaching purposes under adult supervision.

14. Products intended for use for educational purposes in schools and other pedagogical contexts under the surveillance of an adult instructor, such as science equipment.

15. Electronic equipment, such as personal computers and game consoles, used to access interactive software and their associated peripherals, unless the electronic equipment or the associated peripherals are specifically designed for and targeted at children and have a play value on their own, such as specially designed personal computers, key boards, joy sticks or steering wheels.

16. Interactive software, intended for leisure and entertainment, such as computer games, and their storage media, such as compact disks.

17. Babies' soothers.

18. Child-appealing luminaires.

19. Electrical transformers for toys.

20. Fashion accessories for children which are not for use in play.

SCHEDULE 2

Regulations 3B and 5(1)

PARTICULAR SAFETY REQUIREMENTS (Annex II to the Directive)

Part 1 Physical and Mechanical Properties

1. Toys and their parts and, in the case of fixed toys, their anchorages, must have the requisite mechanical strength and, where appropriate, stability to withstand the stresses to which they are subjected during use without breaking or becoming liable to distortion at the risk of causing physical injury.

2. Accessible edges, protrusions, cords, cables and fastenings on toys must be designed and manufactured in such a way that the risks of physical injury from contact with them are reduced as far as possible.

3. Toys must be designed and manufactured in such a way as not to present any risk or only the minimum risk inherent to their use which could be caused by the movement of their parts.

(a) Toys and their parts must not present a risk of strangulation.

(b) Toys and their parts must not present a risk of asphyxiation by closing off the flow of air as a result of airway obstruction external to the mouth and nose.

(c) Toys and their parts must be of such dimensions as to not present a risk of asphyxiation by closing off the flow of air as a result of internal airway obstruction by objects wedged in the mouth or pharynx or lodged over the entrance to the lower airways.

(d) Toys, which are clearly intended for use by children under 36 months, and their component parts and any of their detachable parts must be of such dimensions as to prevent their being swallowed or inhaled. This also applies to other toys which are intended to be put in the mouth, and to their component parts and any of their detachable parts.

(e) The packaging in which toys are contained for retail sale must not present a risk of strangulation or asphyxiation caused by airway obstruction external to the mouth and nose.

(f) Toys contained within food or co-mingled with food must have their own packaging. This packaging, as it is supplied, must be of such dimensions as to prevent its being swallowed and/or inhaled.

(g) Toy packaging, as referred to in points (e) and (f), which is spherical, egg-shaped or ellipsoidal, and any detachable parts of this or of cylindrical toy packaging with rounded ends, must be of such dimensions as to prevent it from causing airway obstruction by being wedged in the mouth or pharynx or lodged over the entrance to the lower airways.

(h) Toys firmly attached to a food product at the moment of consumption, in such a way that the food product needs to be consumed in order to get direct access to the toy, are

prohibited. Parts of toys otherwise directly attached to a food product must fulfil the requirements set out in points (c) and (d).

5. Aquatic toys must be designed and manufactured so as to reduce as far as possible, taking into account the recommended use of the toy, any risk of loss of buoyancy of the toy and loss of support afforded to the child.

6. Toys which it is possible to get inside and which thereby constitute an enclosed space for occupants must have a means of exit which the intended user can open easily from the inside.

7. Toys conferring mobility on their users must, as far as possible, incorporate a braking system which is suited to the type of toy and is commensurate with the kinetic energy generated by it. Such a system must be easy for the user to operate without risk of ejection or physical injury for the user or for third parties.

The maximum design speed of electrically driven ride-on toys must be limited so as to minimise the risk of injury.

8. The form and composition of projectiles and the kinetic energy they may generate when fired from a toy designed for that purpose must be such that, taking into account the nature of the toy, there is no risk of physical injury to the user or to third parties.

9. Toys must be manufactured so as to ensure that:

(a) the maximum and minimum temperature of any accessible surfaces does not cause injury when touched; and

(b) liquids and gases contained within the toy do not reach temperatures or pressures which are such that their escape from the toy, other than for reasons essential to the proper functioning of the toy, might cause burns, scalds or other physical injury.

10. Toys which are designed to emit a sound must be designed and manufactured in such a way in terms of the maximum values for impulse noise and continuous noise that the sound from them is not able to impair children's hearing.

11. Activity toys must be manufactured so as to reduce the risk of crushing or trapping of body parts or trapping of clothing and of falls, impacts and drowning as far as possible. In particular, any surface of such a toy accessible for one or more children to play on must be designed to bear their load.

Part 2 Flammability

1. Toys must not constitute a dangerous flammable element in the child's environment. They must therefore be composed of materials which fulfil one or more of the following conditions:

(a) they do not burn if directly exposed to a flame or spark or other potential source of fire;

(b) they are not readily flammable (the flame goes out as soon as the fire cause disappears);

(c) if they do ignite, they burn slowly and present a low rate of spread of the flame;

(d) irrespective of the toy's chemical composition, they are designed so as to mechanically delay the combustion process.

Such combustible materials must not constitute a risk of ignition for other materials used in the toy.

2. Toys which, for reasons essential to their functioning, contain substances or mixtures that meet the classification criteria laid down in Section 1 of Appendix B, in particular materials and equipment for chemistry experiments, model assembly, plastic or ceramic moulding, enamelling, photography or similar activities, must not contain, as such, substances or mixtures which may become flammable due to the loss of non-flammable volatile components.

3. Toys other than toy percussion caps must not be explosive or contain elements or substances likely to explode when used as intended or in a foreseeable way, bearing in mind the behaviour of children.

4. Toys and, in particular, chemical games and toys, must not contain as such substances or mixtures:

(a) which, when mixed together, may explode through chemical reaction or through heating;

(b) which may explode when mixed with oxidizing substances; or

(c) which contain volatile components which are flammable in air and liable to form a flammable or explosive vapour/air mixture.

Part 3 Chemical Properties

1. Toys must be designed and manufactured in such a way that there are no risks of adverse effects on human health due to exposure to the chemical substances or mixtures of which the toys are composed or which they contain when the toys are used as intended or in a foreseeable way, bearing in mind the behaviour of children.

2. Toys that are themselves substances or mixtures must comply also with Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, as applicable, relating to the classification, packaging and labelling of certain substances and mixtures ("Regulation 1272/2008").

3. Without prejudice to the restrictions referred to in the second paragraph of point 1, substances that are classified as carcinogenic, mutagenic or toxic for reproduction (CMR) of category 1A, 1B or 2 under Regulation 1272/2008 must not be used in toys, in components of toys or in micro-structurally distinct parts of toys.

4. By way of derogation from point 3, substances or mixtures classified as CMR of the categories laid down in Section 3 of Appendix B may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that one or more of the following conditions is met:

(a) these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in Section 2 of Appendix B for the classification of mixtures containing these substances;

(b) these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as intended or in a foreseeable way, bearing in mind the behaviour of children;

(c) regulations have been made under regulation 39D.

5. By way of derogation from point 3, substances or mixtures classified as CMR of the categories laid down in Section 4 of Appendix B may be used in toys, in components of toys or micro-structurally distinct parts of toys provided that one of the following conditions is met:

(a) these substances and mixtures are contained in individual concentrations equal to or smaller than the relevant concentrations established in the Community legal acts referred to in Section 2 of Appendix B for the classification of mixtures containing these substances;

(b) these substances and mixtures are inaccessible to children in any form, including inhalation, when the toy is used as intended or in a foreseeable way, bearing in mind the behaviour of children; or

(c) regulations have been made under regulation 39D.

6. Points 3, 4 and 5 do not apply to nickel in stainless steel.

7. Points 3, 4 and 5 do not apply to materials that comply with the specific limit values set out in Appendix C.

8. Without prejudice to the application of points 3 and 4, nitrosamines and nitrosable substances are be prohibited for use in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth if the migration of the substances is equal to or higher than 0,05 mg/kg for nitrosamines and 1 mg/kg for nitrosable substances.

9. Not applicable.

10. Cosmetic toys, such as play cosmetics for dolls, must comply with the compositional and labelling requirements laid down in Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

11. Toys must not contain the following allergenic fragrances:

No	*Name of the allergenic fragrance*	*CAS number*
(1)	Alanroot oil (Inula helenium)	97676-35-2
(2)	Allylisothiocyanate	57-06-7
(3)	Benzyl cyanide	140-29-4
(4)	4 tert-Butylphenol	98-54-4
(5)	Chenopodium oil	8006-99-3
(6)	Cyclamen alcohol	4756-19-8
(7)	Diethyl maleate	141-05-9
(8)	Dihydrocoumarin	119-84-6
(9)	2,4-Dihydroxy-3-methylbenzaldehyde	6248-20-0
(10)	3,7-Dimethyl-2-octen-1-ol (6,7-Dihydrogeraniol)	40607-48-5
(11)	4,6-Dimethyl-8-tert-butylcoumarin	17874-34-9
(12)	Dimethyl citraconate	617-54-9
(13)	7,11-Dimethyl-4.6,10-dodecatrien-3-one	26651-96-7
(14)	6,10-Dimethyl-3.5,9-undecatrien-2-one	141-10-6
(15)	Diphenylamine	122-39-4
(16)	Ethyl acrylate	140-88-5
(17)	Fig leaf, fresh and preparations	68916-52-9
(18)	trans-2-Heptenal	18829-55-5
(19)	trans-2-Hexenal diethyl acetal	67746-30-9
(20)	trans-2-Hexenal dimethyl acetal	18318-83-7
(21)	Hydroabietyl alcohol	13393-93-6
(22)	4-Ethoxy-phenol	622-62-8

No	*Name of the allergenic fragrance*	*CAS number*
(23)	6-lsopropyl-2-decahydronaphthalenol	34131-99-2
(24)	7-Methoxycoumarin	531-59-9
(25)	4-Methoxyphenol	150-76-5
(26)	4-(p-Methoxyphenyl)-3-butene-2-one	943-88-4
(27)	1-(p-Methoxyphenyl)-1-penten-3-one	104-27-8
(28)	Methyl trans-2-butenoate	623-43-8
(29)	6-Methylcoumarin	92-48-8
(30)	7-Methylcoumarin	2445-83-2
(31)	5-Methyl-2,3-hexanedione	13706-86-0
(32)	Costus root oil (Saussurea lappa Clarke)	8023-88-9
(33)	7-Ethoxy-4-methylcoumarin	87-05-8
(34)	Hexahydrocoumarin	700-82-3
(35)	Peru balsam, crude (Exudation of Myroxylon pereirae (Royle) Klotzsch)	8007-00-9
(36)	2-Pentylidene-cyclohexanone	25677-40-1
(37)	3.6,10-Trimethyl-3.5,9-undecatrien-2-one	1117-41-5
(38)	Verbena oil (Lippia citriodora Kunth)	8024-12-2
(39)	Musk ambrette (4-tert-Butyl-3-methoxy-2,6-dinitrotoluene)	83-66-9
(40)	4-Phenyl-3-buten-2-one	122-57-6
(41)	Amyl cinnamal	122-40-7
(42)	Amylcinnamyl alcohol	101-85-9
(43)	Benzyl alcohol	100-51-6
(44)	Benzyl salicylate	118-58-1
(45)	Cinnamyl alcohol	104-54-1
(46)	Cinnamal	104-55-2
(47)	Citral	5392-40-5
(48)	Coumarin	91-64-5
(49)	Eugenol	97-53-0
(50)	Geraniol	106-24-1
(51)	Hydroxy-citronellal	107-75-5
(52)	Hydroxy-methylpentylcyclohexenecarboxaldehyde	31906-04-4
(53)	Isoeugenol	97-54-1
(54)	Oakmoss extracts	90028-68-5
(55)	Treemoss extracts	90028-67-4

However, the presence of traces of these fragrances is allowed provided that such presence is technically unavoidable under good manufacturing practice and does not exceed 100 mg/kg.

In addition, the names of the following allergenic fragrances must be listed on the toy, on an affixed label, on the packaging or in an accompanying leaflet, if added to a toy, as such, at concentrations exceeding 100 mg/kg in the toy or components thereof:

No	*Name of the allergenic fragrance*	*CAS number*
(1)	Anisyl alcohol	105-13-5
(2)	Benzyl benzoate	120-51-4
(3)	Benzyl cinnamate	103-41-3
(4)	Citronellol	106-22-9
(5)	Farnesol	4602-84-0
(6)	Hexyl cinnamaldehyde	101-86-0
(7)	Lilial	80-54-6
(8)	d-Limonene	5989-27-5
(9)	Linalool	78-70-6
(10)	Methyl heptine carbonate	111-12-6
(11)	3-methyl-4-(2.6,6-trimethyl-2-cyclohexen-1-yl)-3-buten-2-one	127-51-5

12. The use of the fragrances set out in points 41 to 55 of the list set out in the first paragraph of point 11 and of the fragrances set out in points 1 to 11 of the list set out in the third paragraph of that point are allowed in olfactory board games, cosmetic kits and gustative games, provided that

(i) those fragrances are clearly labelled on the packaging, and the packaging contains the warning set out in point 10 of Part B of Annex V;

(ii) if applicable, the resulting products made by the child in accordance with the instructions comply with the requirements of Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products; and

(iii) if applicable, those fragrances comply with the relevant legislation on food.

Such olfactory board games, cosmetic kits and gustative games must not be used by children under 36 months and must comply with point 1 of Part B of Schedule 5.

13. Without prejudice to points 3, 4 and 5, the following migration limits, from toys or components of toys, must not be exceeded:

Element	*mg/kg in dry, brittle, powder-like or pliable toy material*	*mg/kg in liquid or sticky toy material*	*mg/kg in scraped-off toy material*
Aluminium	5 625	1 406	70 000
Antimony	45	11,3	560
Arsenic	3,8	0,9	47
Barium	1 500	375	18 570

Element	*mg/kg in dry, brittle, powder-like or pliable toy material*	*mg/kg in liquid or sticky toy material*	*mg/kg in scraped-off toy material*
Boron	1 200	300	15 000
Cadmium	1,3	0,3	17
Chromium (III)	37,5	9,4	460
Chromium (VI)	0,02	0,005	0,2
Cobalt	10,5	2,6	130
Copper	622,5	156	7 700
Lead	2,0	0,5	23
Manganese	1 200	300	15 000
Mercury	7,5	1,9	94
Nickel	75	18,8	930
Selenium	37,5	9,4	460
Strontium	4 500	1 125	56 000
Tin	15 000	3 750	180 000
Organic tin	0,9	0,2	12
Zinc	3 750	938	46 000

These limit values do not apply to toys or components of toys which, due to their accessibility, function, volume or mass, clearly exclude any hazard due to sucking, licking, swallowing or prolonged contact with skin when used as intended or in a foreseeable way, bearing in mind the behaviour of children.

Part 4 Electrical Properties

1. Toys must not be powered by electricity of a nominal voltage exceeding 24 volts direct current (DC) or the equivalent alternating current (AC) voltage, and their accessible parts must not exceed 24 volts DC or the equivalent AC voltage.

Internal voltages must not exceed 24 volts DC or the equivalent AC voltage unless it is ensured that the voltage and the current combination generated do not lead to any risk or harmful electric shock, even when the toy is broken.

2. Parts of toys which are connected to, or liable to come into contact with, a source of electricity capable of causing electric shock, together with the cables or other conductors through which electricity is conveyed to such parts, must be properly insulated and mechanically protected so as to prevent the risk of such shock.

3. Electric toys must be designed and manufactured in such a way as to ensure that the maximum temperatures reached by all directly accessible surfaces are not such as to cause burns when touched.

4. Under foreseeable fault conditions, toys must provide protection against electrical hazards arising from an electrical power source.

5. Electric toys must provide adequate protection against fire hazards.

6. Electric toys must be designed and manufactured in such a way that electric, magnetic and electromagnetic fields and other radiations generated by the equipment are limited to the extent necessary for the operation of the toy and must operate at a safe level in compliance with the generally acknowledged state of the art, taking account of specific Community measures.

7. Toys which have an electronic control system must be designed and manufactured in such a way that the toy operates safely even when the electronic system starts malfunctioning or fails due to failure of the system itself or an outside factor.

8. Toys must be designed and manufactured in such a way that they do not present any health hazards or risk of injury to eyes or skin from lasers, light-emitting diodes (LEDs) or any other type of radiation.

9. The electrical transformer of a toy must not be an integral part of the toy.

Part 5 Hygiene

1. Toys must be designed and manufactured in such a way as to meet hygiene and cleanliness requirements in order to avoid any risk of infection, sickness or contamination.

2. A toy intended for use by children under 36 months must be designed and manufactured in such a way that it can be cleaned. A textile toy must, to this end, be washable, except if it contains a mechanism that may be damaged if soak washed. The toy must fulfil the safety requirements also after having been cleaned in accordance with this point and the manufacturer's instructions.

Part 6 Radioactivity

Toys must comply with all retained EU law that was adopted for the purposes of implementing Chapter 3 of Euratom.

Appendix A

List of CMR substances and their permitted uses in accordance with points 4, 5 and 6 of Part III

Substance	*Classification*	*Permitted use*
Nickel	CMR 2	In toys and toy components made of stainless steel. In toy components which are intended to conduct an electric current

Appendix B

Classification of Substances and Mixtures

A1. In this Appendix—

"Regulation (EC) No 1272/2008" means Regulation (EC) 1272/2008 of the European Parliament and of the Council of 16th December 2008 on classifications, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC and amending Regulation (EC) 1907/2006.

1. Criteria for classifying substances and mixtures for the purposes of point 2 of Part 2

The substance or mixture fulfils the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) 1272/2008:

(a) hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;

(b) hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;

(c) hazard class 4.1;

(d) hazard class 5.1.

2. Enactments governing the use of certain substances for the purposes of points 4(a) and 5(a) of Part 3

The relevant concentrations for the classification of mixtures containing the substances are those established in accordance with Regulation (EC) No 1272/2008.

3. Categories of substances and mixtures classified as carcinogenic, mutagenic or toxic for reproduction (CMR) for the purposes of point 4 of Part 3.

Substances

Point 4 of Part 3 concerns substances classified as CMR category 1A and 1B under Regulation (EC) No 1272/2008.

Mixtures

Point 4 of Part 3 concerns mixtures classified as CMR category 1A and 1B under Regulation (EC) No 1272/2008.

4. Categories of substances and mixtures classified as carcinogenic, mutagenic or toxic for reproduction (CMR) for the purposes of point 5 of Part III

Substances

Point 5 of Part 3 concerns substances classified as CMR category 2 under Regulation (EC) No 1272/2008.

Mixtures

Point 5 of Part 3 concerns mixtures classified as CMR category 2 under Regulation (EC) No 1272/2008.

5. Categories of substances and mixtures classified as carcinogenic, mutagenic or toxic for reproduction (CMR) for the purposes of regulation 39D(3)(a).

Substances

Regulation 39D(3)(a) concerns substances classified as CMR category 1A, 1B and 2 under Regulation (EC) No 1272/2008.

Mixtures

Regulation 39D(3)(a) concerns mixtures classified as CMR category 1A, 1B and 2 under Regulation (EC) No 1272/2008.

Appendix C

Specific limit values for chemicals used in toys intended for use by children under 36 months or in other toys intended to be placed in the mouth adopted by the Secretary of State.

Substance	*CAS No*	*Limit value*
TCEP	115-96-8	5 mg/kg (content limit)
TCPP	13674-84-5	5 mg/kg (content limit)
TDCP	13674-87-8	5 mg/kg (content limit)
Bisphenol A	80-05-7	0,04 mg/l (migration limit) in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005.
Formamide	75-12-7	20μg/m^3 (emission limit) after a maximum of 28 days from commencement of the emission testing of foam toy materials containing more than 200 mg/kg (cut-off limit based on content)
1,2-benzisothiazol-3(2H)-one	2634-33-5	5 mg/kg (content limit) in aqueous toy materials, in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005
Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one (EC no. 247-500-7) and 2-methyl-2H -isothiazol-3-one (EC no. 220-239-6) (3:1)	55965-84-9	1 mg/kg (content limit) in aqueous toy materials
5-Chloro-2-methyl-isothiazolin-3(2H)-one	26172-55-4	0,75 mg/kg (content limit) in aqueous toy materials
2-methylisothiazolin-3(2H)-one	2682-20-4	0,25 mg/kg (content limit) in aqueous toy materials
Phenol	108-95-2	5mg/l (migration limit) in polymeric materials in accordance with the methods laid down in EN 71-10:2005 and EN 71-11:2005 10mg/kg (content limit) as a preservative in accordance with the methods laid down in EN 71-10: 2005 and EN 71-11:2005.

SCHEDULE 3

Regulation 16(2)

DECLARATION OF CONFORMITY

1. No (unique identification of the toy(s))

2. Name and address of the manufacturer or the manufacturer's authorised representative:

3. This declaration of conformity is issued under the sole responsibility of the manufacturer:

4. Object of the declaration (identification of toy allowing traceability). It must include a colour image of sufficient clarity to enable the identification of the toy.

5. The object of the declaration described in point 4 is in conformity with the following enactments:

6. References to the relevant designated standards used, or references to the specifications in relation to which conformity is declared:

7. Where applicable: the approved body … (name, number) … performed … (description of intervention) … and issued the certificate:

8. Additional information:

Signed for and on behalf of:

(place and date of issue)

(name, function) (signature)

SCHEDULE 4

Regulations 3B and 17(3)

TECHNICAL DOCUMENTATION (Annex IV to the Directive)

The technical documentation referred to in regulation 17(3) must contain so far as relevant for assessment:

(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 regulation 12.

(c) a description of the conformity assessment procedure followed;

(d) a copy of the declaration of conformity;

(e) the addresses of the places of manufacture and storage;

(f) copies of documents that the manufacturer has submitted to an approved body, if involved;

(g) test reports and description of the means whereby the manufacturer ensured conformity of production with designated standards, if the manufacturer followed the internal production control procedure set out in Module A; and

(h) a copy of the Type examination certificate, a description of the means whereby the manufacturer ensured conformity of the production with the product type as described in the Type examination certificate, and copies of the documents that the manufacturer submitted to the approved body, if the manufacturer submitted the toy to Type examination and followed the conformity to type procedure set out in Module C.

SCHEDULE 5 Regulations 3B and 20(3)

WARNINGS (Annex V to the Directive)

PART A

GENERAL WARNINGS

The user limitations referred to in regulation 20(3) must include at least the minimum or maximum age of the user and, where appropriate, the abilities of the user, the maximum or minimum weight of the user and the need to ensure that the toy is used only under adult supervision.

PART B

SPECIFIC WARNINGS AND INDICATIONS OF PRECAUTIONS TO BE TAKEN WHEN USING CERTAIN CATEGORIES OF TOYS

1. Toys not intended for use by children under 36 months

Toys which might be dangerous for children under 36 months of age must bear a warning such as ‘Not suitable for children under 36 months’ or ‘Not suitable for children under three years’ or a warning in the form of the following graphic:

These warnings must be accompanied by a brief indication, which may appear in the instructions for use, of the specific hazard calling for this precaution.

This point does not apply to toys which, on account of their function, dimensions, characteristics or properties, or on other cogent grounds, are manifestly unsuitable for children under 36 months.

2. Activity toys

Activity toys must bear the following warning:

‘Only for domestic use’.

Activity toys attached to a crossbeam as well as other activity toys, where appropriate, must be accompanied by instructions drawing attention to the need to carry out checks and maintenance of the main parts (suspensions, fixings, anchorages, etc.) at intervals, and pointing out that, if these checks are not carried out, the toy may cause a fall or overturn.

Instructions must also be given as to the correct assembly of the toy, indicating those parts which can present a danger if incorrectly assembled. Specific information regarding a suitable surface on which to place the toy must be given.

3. Functional toys

Functional toys must bear the following warning:

‘To be used under the direct supervision of an adult’.

In addition, these toys must be accompanied by directions giving working instructions as well as the precautions to be taken by the user, with the warning that failure to take these precautions will expose the user to the hazards – to be specified – normally associated with the appliance or product of which the toy is a scale model or imitation. It must also be indicated that the toy must be kept out of the reach of children under a certain age, which must be specified by the manufacturer.

4. Chemical toys

Without prejudice to the application of the provisions laid down in applicable enactments on the classification, packaging and labelling of certain substances or mixtures, the instructions for use of toys containing inherently dangerous substances or mixtures must bear a warning of the dangerous nature of these substances or mixtures and an indication of the precautions to be taken by the user in order to avoid hazards associated with them, which must be specified concisely according to the type of toy. The first aid to be given in the event of serious accidents resulting from the use of this type of toy must also be set out. It must also be stated that the toy must be kept out of reach of children under a certain age, which must be specified by the manufacturer.

In addition to the instructions provided for in the first subparagraph, chemical toys must bear the following warning on their packaging:

‘Not suitable for children under (insert appropriate age) years. For use under adult supervision’.

In particular, the following are regarded as chemical toys: chemistry sets, plastic embedding sets, miniature workshops for ceramics, enamelling or photography and similar toys which lead to a chemical reaction or similar substance alteration during use.

5. Skates, roller skates, online skates, skateboards, scooters and toy bicycles for children

Where these toys are offered for sale as toys, they must bear the following warning:

‘Protective equipment should be worn. Not to be used in traffic’.

Moreover, the instructions for use must contain a reminder that the toy must be used with caution, since it requires great skill, so as to avoid falls or collisions causing injury to the user or third parties. Some indication must also be given as to recommended protective equipment (helmets, gloves, knee-pads, elbow-pads, etc.).

6. Aquatic toys

Aquatic toys must bear the following warning:

‘Only to be used in water in which the child is within its depth and under adult supervision’.

7. Toys in food

Toys contained in food or co-mingled with food must bear the following warning:

‘Toy inside. Adult supervision recommended’.

8. Imitations of protective masks and helmets

Imitations of protective masks and helmets must bear the following warning:

‘This toy does not provide protection’.

9. Toys intended to be strung across a cradle, cot or perambulator by means of strings, cords, elastics or straps

Toys intended to be strung across a cradle, cot or perambulator by means of strings, cords, elastics or straps must carry the following warning on the packaging, which must also be permanently marked on the toy:

'To prevent possible injury by entanglement, remove this toy when the child starts trying to get up on its hands and knees in a crawling position'.

10. Packaging for fragrances in olfactory board games, cosmetic kits and gustative games

Packaging for fragrances in olfactory board games, cosmetic kits and gustative games that contain the fragrances set out in points 41 to 55 of the list set out in the first paragraph of point 11 of Part 3 of Schedule 2 and of the fragrances set out in points 1 to 11 of the list set out in third paragraph of that point must contain the following warning:

'Contains fragrances that may cause allergies'.

SCHEDULE 6

Regulations 3 and 3B

CONFORMITY ASSESSMENT PROCEDURES (Annex II to Decision No 768/2008/EC)

MODULE A

Internal production control

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on the manufacturer's sole responsibility that the products concerned satisfy the requirements of the legislative instrument that apply to them.

Technical documentation

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

— a general description of the product,

— conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.

— descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,

— a list of the designated standards and/or other relevant technical specifications applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of the enactments where those designated standards have not been applied. In the event of partly applied designated standards, the technical documentation must specify the parts which have been applied,

— results of design calculations made, examinations carried out, etc., and

— test reports.

Manufacturing

3. The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured products with the technical documentation referred to in point 2 and with the requirements of the legislative instruments that apply to them.

UK marking and declaration of conformity

4.1. The manufacturer must affix the UK marking to each individual product in accordance with regulation 18.

4.2. The manufacturer must draw up a written declaration of conformity for a product model and keep it together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market. The declaration of conformity must identify the product for which it has been drawn up.

A copy of the declaration of conformity must be made available to the relevant authorities upon request.

Authorised representative

5. The manufacturer's obligations set out in point 4 may be fulfilled by the manufacturer's authorised representative, on the manufacturer's behalf and under the manufacturer's responsibility, provided that they are specified in the mandate.

MODULE B

Type examination

1. Type examination is the part of a conformity assessment procedure in which an approved body examines the technical design of a product and verifies and attests that the technical design of the product meets the requirements of these Regulations.

2. Type examination may be carried out in either of the following manners:

— examination of a specimen, representative of the production envisaged, of the complete product (production type),

— assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence referred to in point 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the product (combination of production type and design type),

— assessment of the adequacy of the technical design of the product through examination of the technical documentation and supporting evidence referred to in point 3, without examination of a specimen (design type).

3. The manufacturer must lodge an application for Type examination with a single approved body of the manufacturer's choice.

The application must include:

— the name and address of the manufacturer and, if the application is lodged by the authorised representative, the name and address of the authorised representative as well,

— a written declaration that the same application has not been lodged with any other approved body,

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

  — a general description of the product,

- conceptual design and manufacturing drawings and schemes of components, sub-assemblies, circuits, etc.,
- descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the product,
- a list of the designated standards and/or other relevant technical specifications applied in full or in part, and descriptions of the solutions adopted to meet the essential safety requirements where those designated standards have not been applied. In the event of partly applied designated standards, the technical documentation must specify the parts which have been applied,
- results of design calculations made, examinations carried out, etc., and
- test reports,

— the specimens representative of the production envisaged. The approved body may request further specimens if needed for carrying out the test programme,

— the supporting evidence for the adequacy of the technical design solution. This supporting evidence must mention any documents that have been used, in particular where the relevant designated standards and/or technical specifications have not been applied in full. The supporting evidence must include, where necessary, the results of tests carried out by the appropriate laboratory of the manufacturer, or by another testing laboratory on the manufacturer's behalf and under the manufacturer's responsibility.

4. The approved body must:

For the product:

4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the product;

For the specimen(s):

4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant designated standards and/or technical specifications, as well as the elements which have been designed without applying the relevant provisions of those standards;

4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant designated standards and/or technical specifications, these have been applied correctly;

4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant designated standards and/or technical specifications have not been applied, the solutions adopted by the manufacturer meet the corresponding essential requirements of the legislative instrument;

4.5. agree with the manufacturer on a location where the examinations and tests will be carried out.

5. The approved body must draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations set out in paragraph 8, the approved body must release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of the specific legislative instrument that apply to the product concerned, the approved body must issue a Type examination certificate to the manufacturer. The certificate must contain the name and address of the manufacturer, the

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

The certificate and its annexes must 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.

Where the type does not satisfy the applicable requirements of these Regulations, the approved body must refuse to issue a Type examination certificate and must inform the applicant accordingly, giving detailed reasons for its refusal.

7. The approved body must keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of the legislative instrument, and must determine whether such changes require further investigation. If so, the approved body must inform the manufacturer accordingly.

The manufacturer must inform the approved body that holds the technical documentation relating to the Type examination certificate of all modifications to the approved type that may affect the conformity of the product with the essential safety requirements or the conditions for validity of the certificate. Such modifications must require additional approval in the form of an addition to the original Type examination certificate.

8. Each approved body must inform the Secretary of State concerning the Type examination certificates and/or any additions thereto which it has issued or withdrawn, and must, periodically or upon request, make available to the Secretary of State the list of certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each approved body must inform the other approved bodies concerning the Type examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning the certificates and/or additions thereto which it has issued.

The authorised body must keep a copy of the Type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, until the expiry of the validity of the certificate.

9. The manufacturer must keep a copy of the Type examination certificate, its annexes and additions together with the technical documentation at the disposal of the national authorities for 10 years after the product has been placed on the market.

10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7 and 9, provided that they are specified in the mandate.

MODULE C

Conformity to type based on internal production control

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares that the products concerned are in conformity with the type described in the type examination certificate and satisfy the requirements of the legislative instrument that apply to them.

Manufacturing

2. The manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured products with the approved type described in the Type examination certificate and with the requirements of these Regulations.

Conformity marking and declaration of conformity

3.1. The manufacturer must affix the UK marking to each individual product that is in conformity with the type described in the Type examination certificate and satisfies the applicable requirements of these Regulations.

3.2. The manufacturer must draw up a written declaration of conformity for a product model and keep it at the disposal of the enforcement authorities for 10 years after the product has been placed on the market. The declaration of conformity must identify the product model for which it has been drawn up.

A copy of the declaration of conformity must be made available to the enforcement authorities upon request.

Authorised representative

4. The manufacturer's obligations set out in point 3 may be fulfilled by the manufacturer's authorised representative, on the manufacturer's behalf and under the manufacturer's responsibility, provided that they are specified in the mandate.

SCHEDULE 7

Regulation 3 and 40A

Approved body requirements

1. A conformity assessment body must be established in the United Kingdom and must have legal personality.

2.—(1) A conformity assessment body must be a third-party body independent of the organisation or the toy it assesses.

(2) 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.

3.—(1) A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment activities must not be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the toys which they assess, not the authorised representative of any of those parties.

(2) Sub-paragraph (1) does 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.

4. A conformity assessment body, its top level management and the personnel responsible for carrying out the conformity assessment tasks must not be directly involved in the design or manufacture, the marketing, installation, use or maintenance of toys it assesses, or represent parties involved in those activities.

5. A conformity assessment body must not engage in any activity, including consultancy services, that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are approved.

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

7. Conformity assessment bodies and their personnel must carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and must 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.

8. Conformity assessment bodies must be capable of carrying out the conformity assessment tasks assigned to them by the provisions of regulation 14 or by their approval whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

9. At all times and for each conformity assessment procedure and each kind or category of toy in relation to which it has been approved, a conformity assessment body must have at its disposal—

(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 must have appropriate policies and procedures in place that distinguish between tasks it carries out as an approved 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.

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

11. The personnel responsible for carrying out the conformity assessment activities must have—

(a) sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been approved;

(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 safety requirements;

(d) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

12. A conformity assessment body must be able to demonstrate the impartiality of their top level management and personnel responsible for assessment.

13. The renumeration of the top level management and personnel responsible for assessment of a conformity assessment body must not depend on the number of assessments carried out or on the results of those assessments.

14. A conformity assessment body must have, and must satisfy the Secretary of State that it has, adequate civil liability insurance in respect of its activities.

15. A conformity assessment body must ensure that its personnel observe professional secrecy with regard to all information obtained in carrying out their tasks in accordance with these Regulations and that proprietary rights are protected.

16. Paragraph 15 does not prevent the personnel from providing information to the Secretary of State or an enforcement authority.

17. A conformity assessment body must participate in, or ensure that its personnel who are responsible for carrying out the conformity assessment activities are informed of, the relevant standardisation activities and the activities of any approved body coordination group established by the Secretary of State and must apply as general guidance the administrative decisions and documents produced as a result of the work of that group.".