

SCHEDULE 15

Amendment of the Toys (Safety) Regulations 2011

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 above. Examples 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 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

Draft Legislation: This is a draft item of legislation. This draft has since been made as a UK Statutory Instrument: *The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 No. 696*

<i>No</i>	<i>Name of the allergenic fragrance</i>	<i>CAS number</i>
(20)	trans-2-Hexenal dimethyl acetal	18318-83-7
(21)	Hydroabietyl alcohol	13393-93-6
(22)	4-Ethoxy-phenol	622-62-8
(23)	6-Isopropyl-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

<i>No</i>	<i>Name of the allergenic fragrance</i>	<i>CAS number</i>
(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:

<i>No</i>	<i>Name of the allergenic fragrance</i>	<i>CAS number</i>
(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:

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

<i>Substance</i>	<i>Classification</i>	<i>Permitted use</i>
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.

<i>Substance</i>	<i>CAS No</i>	<i>Limit value</i>
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

<i>Substance</i>	<i>CAS No</i>	<i>Limit value</i>
		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, inline 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 remuneration 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.”.