

Brussels, 24.10.2022 C(2022) 7410 final

ANNEXES 1 to 2

ANNEXES

to the

COMMISSION IMPLEMENTING DECISION

on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation as regards toys in support of Directive 2009/48/EC of the European Parliament and of the Council

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ANNEX I

List of new standards to be drafted and list of existing standards to be revised as referred to in Article 1

Table 1: List of new harmonised standards to be drafted and deadlines for their adoption

Reference information		Deadline for the adoption by the ESOs
1.	Flame retardants TCEP, TCPP, TDCP Elaboration of a new standard on 'TCEP and alternative flame retardants'	25 October 2025
2.	Bisphenol A Elaboration of a new standard on 'Bisphenol A'	25 October 2025
3.	Formamide Elaboration of a new standard on 'Formamide in foamed toy materials'	25 October 2026
4.	Isothiazolinones (CMI, MI and BIT) Elaboration of a new standard on 'Isothiazolinones'	25 October 2026
5.	Phenol Elaboration of a new standard on 'Phenol'	25 October 2026

Table 2: List of existing standards to be revised and deadlines for their adoption

Reference information		Deadline for the adoption by the ESOs
1.	EN 71-1 'Mechanical and physical properties'	25 October 2025
2.	EN 71-2 'Flammability'	25 October 2025
3.	EN 71-3 'Migration of certain elements'	25 October 2025
4.	EN 71-4 'Experimental sets for chemistry and related activities'	25 October 2025
5	EN 71-5 'Chemical toys (sets) other than experimental sets'	25 October 2025
6.	EN 71-7 'Finger paints – Requirements and test methods'	25 October 2025
7.	EN 71-8 'Activity toys for domestic use'	25 October 2025
8.	EN 71-13 'Olfactory board games, cosmetic kits and gustative games'	25 October 2025
9.	EN 71-14 'Trampolines for domestic use'	25 October 2025
10.	EN 62115 'Electric toys – Safety'	25 October 2025

ANNEX II

Requirements for the standards referred to in Article 1

Part A. General requirements for standards listed in Annex I

1. Legal requirements to be supported by the harmonised standards

The harmonised standards shall support the application of the relevant essential safety requirements set out in Article 10 of Directive 2009/48/EC and Annex II to that Directive. On the basis of Article 10(2) of Directive 2009/48/EC, this includes also support on requirements for "Warnings" as provided for in Article 11(1) and (2) of that Directive and Annex V to that Directive.

The harmonised standards shall provide detailed technical specifications of essential safety requirements, with regard to the design and manufacture of toys and their packages with the purpose of allowing compliance with the relevant essential safety requirements of Directive 2009/48/EC.

The structure of a harmonised standard shall be such that a clear distinction can be made between those clauses and sub-clauses which are necessary for compliance with the essential safety requirements and those which are not. The essential safety requirements shall be taken into account from the beginning of and throughout the entire process of developing the standards.

The harmonised standards shall give only toy-related specifications, which shall include methods for the verification of compliance with such specifications. The harmonised standards must not support any legal requirements other than those referenced in the first paragraph of point 1 and in particular shall not:

- (a) make any reference to Directive 2009/48/EC or reproduce its requirements in their normative body, with the exception of written or visual warnings which could be
- (b) modify any definitions set by Directive 2009/48/EC or define any legally relevant terms not defined by Directive 2009/48/EC itself;
- (c) address any requirements, responsibilities, contractual arrangements or obligations for any economic operator including notified or other bodies or market surveillance authorities, and
- (d) contain any provisions concerning conformity assessment procedures, related documents or technical documentation as regulated by Directive 2009/48/EC.

Each harmonised standard developed on the basis of the request referred to in Article 1 shall refer to this Decision.

CEN and Cenelec shall include in each harmonised standard revised in accordance with Article 1 information on significant changes introduced in that standard.

Each harmonised standard shall clearly state that compliance with its specifications and, in particular, the application of written or visual warnings or signs as specified in it, shall not be subject to any fee by CEN and Cenelec.

Conformity with a toy safety standard shall not depend on specifications of an administrative or organisational nature like management system specifications for organisations, competence specifications for natural persons or through normative references to management system standards of any kind.

2. Legal requirements to be covered by an individual harmonised standard

In the event that a harmonised standard does not cover all the essential safety requirements which are applicable and relevant to the toys falling under the scope of that standard, it shall indicate the requirements which are not covered by it. Where a harmonised standard contains technical specifications which do not support the application of essential safety requirements set out in Article 10 of Directive 2009/48/EC and Annex II to that Directive, such technical specifications shall be clearly distinguished from the specifications supporting the essential safety requirements.

3. Risk assessment and risk reduction to include safety aspects in harmonised standards

The specifications of the harmonised standards concerning the design, manufacture and packaging of toys shall guarantee the safety of toys and a high level of protection of the health and safety of children and third parties. They shall reflect the generally acknowledged state of the art.

The harmonised standards concerning safety of toys shall be drafted and revised by applying the iterative process of risk assessment and risk reduction. This process shall take into consideration the intended use and the reasonably foreseeable use of toys in order to minimise hazards and to support the execution of safety assessments according to Article 18 of Directive 2009/48/EC, bearing in mind the behaviour of children, as provided for in Article 10(2) of that Directive.

4. Correspondence between the clauses of the standard and the legal requirements

CEN and Cenelec shall include in each harmonised standard a clear and precise description of the correspondence between the clauses of the standard and the essential safety requirements set out in Article 10 of Directive 2009/48/EC and Annex II to that Directive that it aims to cover.

Part B. Specific requirements for drafting new standards listed in Table 1 of Annex I

1. Requirements for all standards

Standards shall reflect the generally acknowledged state of the art. In particular, the requested harmonised standards shall be based on reliable procedures and methods for testing, which take into account the generally acknowledged state of the art.

CEN and Cenelec shall update the information on the correspondence between the clauses of the standard and the applicable essential safety requirements in standards listed in Table 1 of Annex I.

When a standard includes a test method (or several test methods) that allows checking for compliance with a limit value for a chemical substance, it should, as far as reasonable, include the following sections:

- (a) scope;
- (b) normative references;
- (c) terms and definitions;
- (d) requirements;
- (e) principle, reagents and apparatus;
- (f) sample preparation;

- (g) method of analysis;
- (h) method performance, including the limits of detection (LOD) and limits of quantification (LOQ) with regard to the sample material;
- (i) appropriate reference on how to carry out a single laboratory or in-house validation, such as by referring to guidelines of the Commission's Joint Research Centre (JRC)¹, ² or other publications^{3, 4};
- (j) calculation of the results;
- (k) test report;
- (l) background and rationale;
- (m) bibliography.

Where the development of a standard is accompanied by a study (or studies) related to the subject matter of the standard, it should take account of the study results; if not, substantial reasons should be provided for deviating from the study results.

2. Requirements for specific standards

2.1 Standard on flame retardants TCEP, TCPP, TDCP listed in point 1 of table 1 of Annex I

CEN shall elaborate a new standard on 'TCEP and alternative flame retardants', based on a validated test method and including definitions, requirements, test methods, warnings and rationale to check compliance of polymeric toy materials with the limit values of Tris(2-chloroethyl)phosphate (TCEP), Tris [2-chloro-1-(chloromethyl)ethyl]phosphate (TDCP) and Tris-(2-chloro-1-methylethyl)phosphate (TCPP), in order to ensure conformity of TCEP, TCPP and TDCP with the content limit values set out in Appendix C of Annex II to Directive 2009/48/EC.

2.2 Standard on bisphenol A listed in point 2 of table 1 of Annex I

CEN shall elaborate a new standard on 'Bisphenol A', based on a validated test method and including definitions, requirements, test methods, warnings and rationale in order to ensure conformity of polymeric toy materials with the content limit value of bisphenol A (migration limit) set out in Appendix C of Annex II to Directive 2009/48/EC.

2.3 Standard on formamide listed in point 3 of table 1 of Annex I

CEN shall elaborate a new standard on 'Formamide in foamed toy materials', based on validated test methods and including definitions, requirements, test methods, warnings and rationale in order to ensure conformity of foam toy materials with the cut-off limit value (based on content) of formamide set out in Appendix C of Annex II to Directive 2009/48/EC.

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Guidelines for performance criteria and validation procedures of analytical methods used in controls of food contact materials. JRC Scientific and Technical Report EUR 24105 (2009).

JRC Working Document, EURL-FA. Guide: Protocol for verification studies of single-laboratory/in- house validated methods (2014).

³ IUPAC Technical Report: Harmonized Guidelines for Single-laboratory Validation of Methods of Analysis. Pure Appl Chem (2002) 74/5, p. 835 – 855.

International standard ISO/IEC 17025:2005 on General requirements for the competence of testing and calibration laboratories.

2.4 Standard on isothiazolinones (CMI, MI and BIT) listed in point 4 of table 1 of Annex I

CEN shall elaborate a new standard on 'Isothiazolinones', based on a validated test method and including definitions, requirements, test methods, warnings and rationale to check compliance of aqueous toy materials with the limit values of 5-chloro-2- methyl-4-isothiazolin-3-one (CMI) and 2-methyl-2H -isothiazol-3-one (MI), both individually and in a ratio of 3:1, and 1,2-benzisothiazol-3(2H)-one (BIT), in order to ensure conformity with the content limit values set out in Appendix C of Annex II to Directive 2009/48/EC.

2.5 Standard on phenol listed in point 5 of table 1 of Annex I

CEN shall elaborate a new standard on 'Phenol', based on validated test methods and including definitions, requirements, test methods, warnings and rationale to check compliance with the limit values of phenol (in polymeric materials (migration limit) and as a preservative (content limit) in order to ensure conformity with the content limit values set out in Appendix C of Annex II to Directive 2009/48/EC.

Part C. Specific requirements for revising existing standards listed in Table 2 of Annex I 1. EN 71-1 'Mechanical and physical properties' listed in point 1 of table 2 of Annex I

CEN shall revise EN 71-1 in order to ensure conformity with part I (physical and mechanical properties) of Annex II to Directive 2009/48/EC.

The revision of EN 71-1 shall include the definitions, technical requirements, warnings, test methods and rationale for:

- (a) the soaking test and its applicability;
- (b) expanding toys, such as expandable toy pearls and aqueous toy pearls, to consider alignment with international standards, and respond to potential emerging hazards, where necessary;
- (c) microwavable warmers in the form of plush toys, to include the requirements for the notified bodies set out in 'EC type approval Protocol No. 5 Microwavable toys';
- (d) yoyo balls, to ensure exemptions from the requirements for products not presenting a strangulation hazard;
- (e) toys, intended for children of any age, and their components, which, although not foodstuff, resemble foodstuff such that it is likely that they are confused with foodstuff by children, in particular due to the form, odour, colour, appearance, packaging, labelling, volume or size; the revision shall include appropriate tests in EN 71-1 in order to evaluate the potential presence or release of small parts in any kind of materials unless exempted;
- (f) aquatic ride-on toys, ensuring requirements are adapted to new designs, that the scope is linked to a method of measurement, that references to other standards are updated and that there are no overlapping marking requirements;
- (g) the seam strength of plush toys, ensuring risks related to potential release of components are addressed;
- (h) neck straps, clarifying requirements for release mechanisms;
- (i) paper and paperboard toys, ensuring any choking hazards are minimised;
- (i) projectiles, further specifying test method for kinetic energy density;

- (k) remote controlled flying toys and close-to-the-ear toys, ensuring that the standard is sufficiently clear;
- (l) trampolines, to ensure there is no conflict between the requirements of EN 71-1 and 71-14 on 'trampolines for domestic use';
- (m) hygiene related requirements, to include the requirements for microbiological safety of toys containing accessible aqueous media;
- (n) general clarifications and improvements, including the following:
 - (i) a definition for 'direct transmission' (used in clause 4.15.1.5) in clause 3;
 - (ii) clarification on hemispherically shaped toys that have surface irregularities on the border, in clause 5.12, including whether clause 5.12 is applicable in such cases; this requirement should be discussed in the interpretation panel of CEN/TC 52;
 - (iii) toys intended for children under 36 months which are made of very elastic material, to include a stretching limit in clause 5.1 of EN 71-1;
 - (iv) more details with regard to protruding parts in clause 4.9 of EN 71-1 and the risk of perforation, in order to better enable laboratories to test this point, in particular for functional toys such as gardening articles.

Additionally, the revision of EN 71-1 shall include provisions regarding ride-on toys, toys propelled by a child, bicycles, scooters and similar toys, based on the corresponding and related definitions, technical requirements, warnings, test methods and rationale of EN 71-1. The standard shall include improvements of these contents and in particular address:

- (a) toy balance bicycles;
- (b) braking performance requirements and test methods;
- (c) consumer information on maintenance;
- (d) explanatory rationale.

2. EN 71-2 'Flammability' listed in point 2 of table 2 of Annex I

CEN shall revise EN 71-2 in order to ensure conformity with part II (flammability) of Annex II to Directive 2009/48/EC.

The revision of EN 71-2 shall include the definitions, technical requirements, warnings, test methods and rationale for:

- (a) toys to be worn on the head, considering a categorisation of those toys on the basis of their risk;
- (b) general clarifications and improvements.

3. EN 71-3 'Migration of certain elements' listed in point 3 of table 2 of Annex I

CEN shall revise EN 71-3 in order to ensure conformity with part III (chemical properties) of Annex II to Directive 2009/48/EC.

The revision of EN 71-3 shall include:

- (a) bad recovery of specific organic tin compounds due to adsorption (e.g. to containers, vessels, filters) during sample preparation tests;
- (b) adaptation of the limit values to changes of legal limit values;

(c) general clarifications, including similar materials for grease, oil, wax or similar material, and improvements.

4. EN 71-4 'Experimental sets for chemistry and related activities' listed in point 4 of table 2 of Annex I

CEN shall revise EN 71-4 in order to ensure conformity with part III (chemical properties) of Annex II to Directive 2009/48/EC.

The revision of EN 71-4 shall include:

- (a) revision of requirements on packaging and closures;
- (b) general clarifications and improvements.

5. EN 71-5 'Chemical toys (sets) other than experimental sets' listed in point 5 of table 2 of Annex I

CEN shall revise EN 71-5 in order to ensure conformity with part III (chemical properties) of Annex II to Directive 2009/48/EC.

The revision of EN 71-5 shall include:

- (a) clarification of the scope, to include kits for the preparation of slime;
- (b) requirements for slime kits regarding the content of boron, fragrances, colourants and preservatives, taking into consideration the provisions of Regulation (EC) No 1223/2009 of the European Parliament and of the Council⁵
- (c) the labelling of chemical substances in slime kits.

6. EN 71-7 'Finger paints – Requirements and test methods' listed in point 6 of Table 2 of Annex I

CEN shall revise EN 71-7 in order to ensure conformity with part III (chemical properties) of Annex II to Directive 2009/48/EC.

The revision of EN 71-7 shall include its definitions, requirements, test methods, warnings and rationale, as appropriate, addressing changes introduced by Regulation (EC) No 1907/2006 of the European Parliament and of the Council⁶ and Regulation (EC) No 1272/2008 of the European Parliament and of the Council⁷ for:

- (a) review of list of preservatives taking into account e.g. the use of molecules that are known to improve preservative efficacy ("boosters");
- (b) review of list of colourants;
- (c) pH range and pH measurement;
- (d) general clarifications and improvements.

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Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (*OJ* L 342, 22.12.2009, p. 59).

Regulation (EC) No 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 1999/45/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 91/555/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).

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 (*OJ* L 353, 31.12.2008, p. 1).

When revising the existing harmonised standard on finger paints, account should be taken, where relevant, of the provisions of Regulation (EC) No 1223/2009, in particular regarding bans or restrictions of chemicals such as colourants and preservatives.

7. EN 71-8 'Activity toys for domestic use' listed in point 7 of Table 2 of Annex I

CEN shall revise EN 71-8 in order to ensure conformity with part I (physical and mechanical properties) of Annex II to Directive 2009/48/EC.

The revision of EN 71-8 shall include its definitions, requirements, test methods, warnings and rationale for:

- (a) requirements and test methods on slides, such as requirements on handrails;
- (b) requirements and test methods on ropes and straps, including requirements with regard to diameter and width;
- (c) requirements for barriers linked to the free height of fall in order to ensure consistency between EN 71-8 and other related standards, such as EN 1176;
- (d) requirements and test methods on swings, including the following requirements:
 - (i) clarification of requirements on minimum clearances between adjacent swing elements and adjacent structures;
 - (ii) clarification of requirements/test methods on head and neck entrapment for swing devices in connection with slides;
- (e) requirements for a puncture test for inflatable toys;
- (f) requirements for inflatable terrestrial toys not covered by the standard;
- (g) a definition of the term 'opening' used in clause 4.3.1 of EN 71-8, in particular for seesaws and slides, in order that laboratories take account of openings in the same way when testing for the risk of entrapment of the head or the neck of a child;
- (h) general clarifications and improvements.

8. EN 71-13 'Olfactory board games, cosmetic kits and gustative games' listed in point 8 of Table 2 of Annex I

CEN shall revise EN 71-13 in order to ensure conformity with part III (chemical properties) of Annex II to Directive 2009/48/EC.

The revision of EN 71-13 shall include its definitions, requirements, test methods, warnings and rationale for:

- (a) requirements for closures of reagent containers;
- (b) revision of the lists of allergenic fragrances taking into account changes of legal requirements in Directive 2009/48/EC;
- (c) general clarifications and improvements.

9. EN 71-14 'Trampolines for domestic use' listed in point 9 of Table 2 of Annex I

CEN shall revise EN 71-14 in order to ensure conformity with part I (physical and mechanical properties) of Annex II to Directive 2009/48/EC.

The revision of EN 71-14 shall include its definitions, requirements, test methods, warnings and rationale for:

- (a) review of warnings: identify the hazards, prioritise the warnings for safe use, remove warnings and/or add new relevant warnings such as a warning emphasising the need to ensure that no one enters the area under the mat;
- (b) pinching, crushing and falling hazards;
- (c) general clarifications and improvements.

10. EN 62115 'Electric toys - Safety' listed in point 10 of Table 2 of Annex I

Cenelec shall revise EN 62115, in order to ensure conformity with part IV (electrical properties) of Annex II to Directive 2009/48/EC.

The revision of EN 62115 shall include its definitions, requirements, test methods, warnings and rationale for:

- (a) clarification of the scope and addition of test method for the applicability of warning on risk of epilepsy for modulated accessible emission;
- (b) further clarification of the existing clauses restricting accessibility for 'non-small-part' batteries to allow a consistent understanding;
- (c) review of the test method for electric strength to align with requirements for similar appliances with nominal voltage inferior to 24V;
- (d) review of requirements for experimental sets to allow exemptions from certain requirements of the standard;
- (e) general clarifications and improvements, including reviewing and modifying if necessary the standard format for the marking of toys using button cell or coin cell batteries.

11. Reporting on the application of the requirements set out in points 1 to 10 of this Part

CEN and Cenelec shall promptly report to the Commission any major concerns relating to the requirements set out in points 1 to 10 of this Part, where CEN and Cenelec consider that any of those requirements is not relevant for a specific standard or cannot be implemented in a specific standard. Such report shall include a detailed explanation of such concerns. Information included in the report shall also be included in the annual report referred to in Article 3.