DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2021/867

of 28 May 2021

on harmonised standards for toys drafted in support of Directive 2009/48/EC of the European Parliament and of the Council

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council ([1]), and in particular Article 10(6) thereof,

Whereas:

(1) In accordance with Article 13 of Directive 2009/48/EC of the European Parliament and of the Council ([2]), toys which are in conformity with harmonised standards or parts thereof, the references of which have been published in the *Official Journal of the European Union*, are to be presumed to be in conformity with the requirements covered by those standards or parts thereof set out in Article 10 of Directive 2009/48/EC and Annex II to that Directive.

(2) Directive 2009/48/EC lays down, in Part III of Annex II thereto, specific requirements in order to ensure 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. Directive 2009/48/EC also lays down, in Part IV of Annex II thereto, specific requirements in order to ensure a high level of toy safety with regard to electrical hazards.

(3) By letter M/445 ([3]) of 9 July 2009 the Commission made a request to the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) for the drafting of new and the revision of existing harmonised standards in support of Directive 2009/48/EC.

(4) On the basis of the request M/445 of 9 July 2009, CEN revised harmonised standard EN 71-7:2014+A2:2018 'Safety of toys – Part 7: Finger paints – Requirements and test methods', the reference of which was published by Commission Implementing Decision (EU) 2019/1728 ([4]). This resulted in the adoption of harmonised standard EN 71-7:2014+A3:2020.

(5) Harmonised standard EN 71-7:2014+A3:2020 provides for an updated reference to the applicable Union legislation as regards the use of a number of colourants listed in tables A.1 and A.2 of Annex A to that standard, taking into account the latest specifications and purity criteria laid down in Commission Regulation (EU) No 231/2012 ([5]). The list of preservatives allowed for use in finger paints, set out in table B.1 of Annex B to harmonised standard EN 71-7:2014+A3:2020, reduces the maximum allowed concentration of climbazole to 0,2 % in line with latest scientific advice provided in the addendum to the opinion of the Scientific Committee on Consumer Safety ([6]).

([1]) OJ L 316, 14.11.2012, p. 12.

([2]) Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1).

([3]) M/445 of 9 July 2009 on a standardisation mandate addressed to CEN and CENELEC within the framework of Directive 2009/48/EC revising Directive 88/378/EEC concerning the safety of toys.

([4]) Commission Implementing Decision (EU) 2019/1728 of 15 October 2019 on harmonised standards for toys drafted in support of Directive 2009/48/EC of the European Parliament and of the Council (OJ L 263, 16.10.2019, p. 32).

([5]) Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

([6]) The Opinion on Climbazole (P64) ref. SCCS/1506/13.

(6) On the basis of the request M/445 of 9 July 2009, CEN revised harmonised standard EN 71-12:2013 'Safety of toys – Part 12: N-Nitrosamines and N-nitrosatable substances', the reference of which was published by Implementing Decision (EU) 2019/1728. This resulted in the adoption of harmonised standard EN 71-12:2016.

(7) Harmonised standard EN 71-12:2016 provides for improved test methods for N-Nitrosamines and N-nitrosatable substances in elastomers, in particular concerning the ability to detect (the often carcinogenic) N-nitrosamines even at low levels, as well as concerning practical test details thus leading to a more consistent application of the test method. The standard also includes alternative ways to measure and identify any N-nitrosamines potentially present in certain toys. Furthermore, the scope of the standard has been extended with regard to the materials to be tested and the duration of the migration step for elastomers, which is the core part of the related test method for those toy materials.

(8) On the basis of the request M/445 of 9 July 2009, Cenelec revised harmonised standard EN 62115:2005 'Electric toys – Safety' and its related amendments, the references of which were published by Implementing Decision (EU) 2019/1728. This resulted in the adoption of harmonised standard EN IEC 62115:2020 and its amendment EN IEC 62115:2020/A11:2020.

(9) The revised standard EN IEC 62115:2020 and its amendment EN IEC 62115:2020/A11:2020 provides for the addition of further warnings to ensure better consumer information on the hazards associated with swallowing coin batteries. It updates the accessibility requirements for coin and button batteries, in order to ensure a higher level of protection, and it adds new requirements for toys connected to domestic appliances, including computers, in order to protect users from electric shock. It further modifies the criteria for reduced testing to allow simplified requirements for electric toys with low levels of power, and provides for further requirements for the safety of LEDs in toys in order to minimise the risk of ocular injury. It adds new requirements to address hazards associated with the use of remote-controlled electric ride-on toys. It further specifies the type of batteries to be used for testing electric toys that are provided without batteries, in order to improve the reproducibility of the testing, due to the increase in available battery types. It further provides for the categorisation of the general conditions for tests to ensure that the test conditions are appropriate for each type of toy and its power supply.

(10) The Commission together with CEN has assessed whether harmonised standard EN 71-7:2014+A3:2020 drafted by CEN complies with the request M/445 of 9 July 2009. Harmonised standard EN 71-7:2014+A3:2020 satisfies the requirements which it aims to cover and which are set out in Directive 2009/48/EC. It is therefore appropriate to publish the reference of that standard in the *Official Journal of the European Union*.

(11) Harmonised standard EN 71-7:2014+A3:2020 replaces harmonised standard EN 71-7:2014+A2:2018. It is therefore necessary to withdraw the reference of that standard from the *Official Journal of the European Union*. In order to afford toy manufacturers sufficient time to adapt their products to the revised specifications in harmonised standard EN 71-7:2014+A3:2020, it is necessary to defer the withdrawal of the reference of harmonised standard EN 71-7:2014+A2:2018.

(12) The Commission together with CEN has assessed whether harmonised standard EN 71-12:2016 drafted by CEN complies with the request M/445 of 9 July 2009. Harmonised standard EN 71-12:2016 satisfies the requirements it aims to cover and which are set out in Directive 2009/48/EC. However, point a) of table 2 of harmonised standard EN 71-12:2016 goes beyond the requirements set out in point 8 of part III of Annex II to that Directive, by providing for a limit value for N-nitrosamines of 0,01 mg/kg instead of 0,05 mg/kg, and a limit value for N-nitrosatable substances of 0,1 mg/kg instead of 1 mg/kg. Given that the limit values set in Directive 2009/48/EC are the limit values to be complied with, it is necessary to add an informative note in this regard when publishing standard EN 71-12:2016.

(13) Harmonised standard EN 71-12:2016 replaces harmonised standard EN 71-12:2013. It is therefore necessary to withdraw the reference of that standard from the *Official Journal of the European Union*. In order to afford toy manufacturers sufficient time to adapt their products to the revised specifications in harmonised standard EN 71-12:2016, it is necessary to defer the withdrawal of the reference of harmonised standard EN 71-12:2013.

(14) The Commission together with Cenelec has assessed whether harmonised standard EN IEC 62115:2020 and its amendment EN IEC 62115:2020/A11:2020 drafted by Cenelec, comply with the request M/445 of 9 July 2009. Harmonised standards EN IEC 62115:2020 and EN IEC 62115:2020/A11:2020 satisfy the requirements which they aim to cover and which are set out in Directive 2009/48/EC. It is therefore appropriate to publish the reference of those standards in the *Official Journal of the European Union*.

(15) Harmonised standard EN IEC 62115:2020 and its amendment EN IEC 62115:2020/A11:2020 replace harmonised standard EN 62115:2005 and its related amendments. It is therefore necessary to withdraw the reference of standard EN 62115:2005 and its related amendments from the *Official Journal of the European Union*. In order to afford toy manufacturers sufficient time to adapt their products to the revised specifications in harmonised standard EN IEC 62115:2020 and its amendment EN IEC 62115:2020/A11:2020, it is necessary to defer the withdrawal of the reference of harmonised standard EN 62115:2005 and its related amendments.

(16) In the interests of clarity, rationality and simplification, a complete list of references of harmonised standards drafted in support of Directive 2009/48/EC and satisfying the requirements they aim to cover should be published in a single act. The references of harmonised standards drafted in support of Directive 2009/48/EC are currently published by Implementing Decision (EU) 2019/1728. Consequently, it is necessary to replace Decision (EU) 2019/1728 by a new Decision.

(17) Compliance with a harmonised standard confers a presumption of conformity with the corresponding essential requirements set out in Union harmonisation legislation from the date of publication of the reference of such standard in the *Official Journal of the European Union*. This Decision should therefore enter into force on the date of its publication,

HAS ADOPTED THIS DECISION:

Article 1

The references of the harmonised standards for toys drafted in support of Directive 2009/48/EC, listed in Annex I to this Decision, are hereby published in the *Official Journal of the European Union*.

Article 2

Implementing Decision (EU) 2019/1728 is repealed.

However, Article 1 of Implementing Decision (EU) 2019/1728 shall continue to apply to the references of the harmonised standards for toys drafted in support of Directive 2009/48/EC, listed in Annex II to this Decision, until the dates set out in that Annex.

Article 3

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

Done at Brussels, 28 May 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

<table>
<tr><th>No</th><th>Reference of the standard</th></tr>
<tr><td>1.</td><td>EN 71-1:2014+A1:2018 Safety of toys — Part 1: Mechanical and physical properties</td></tr>
<tr><td>2.</td><td>EN 71-2:2011+A1:2014 Safety of toys — Part 2: Flammability</td></tr>
<tr><td>3.</td><td>EN 71-3:2019 Safety of toys - Part 3: Migration of certain elements</td></tr>
<tr><td>4.</td><td>EN 71-4:2013 Safety of toys — Part 4: Experimental sets for chemistry and related activities</td></tr>
<tr><td>5.</td><td>EN 71-5:2015 Safety of toys — Part 5: Chemical toys (sets) other than experimental sets</td></tr>
<tr><td>6.</td><td>EN 71-7:2014+A3:2020 Safety of toys — Part 7: Finger paints — Requirements and test methods</td></tr>
<tr><td>7.</td><td>EN 71-8:2018 Safety of toys — Part 8: Activity toys for domestic use</td></tr>
<tr><td>8.</td><td>EN 71-12:2016 Safety of toys — Part 12: N-Nitrosamines and N-nitrosatable substances
Informative note: The limit values in point a) of Table 2 of clause 4.2 of standard ‘EN 71-12:2016 Safety of toys — Part 12: N-Nitrosamines and N-nitrosatable substances’ are lower than the limit values to be complied with set in point 8 of part III of Annex II to Directive 2009/48/EC. In particular those values are as follows:
<table>
<tr><th>Substance</th><th>Standard EN 71-12:2016</th><th>Directive 2009/48/EC</th></tr>
<tr><td>N-nitrosamines</td><td>0,01 mg/kg</td><td>0,05 mg/kg</td></tr>
<tr><td>N-nitrosatable</td><td>0,1 mg/kg</td><td>1 mg/kg</td></tr>
</table></td></tr>
<tr><td>9.</td><td>EN 71-13:2014 Safety of toys — Part 13: Olfactory board games, cosmetic kits and gustative games</td></tr>
<tr><td>10.</td><td>EN 71-14:2018 Safety of toys - Part 14: Trampolines for domestic use</td></tr>
<tr><td>11.</td><td>EN IEC 62115:2020 Electric toys — Safety
EN IEC 62115:2020/A11:2020</td></tr>
</table>

ANNEX II

No	Reference of the standard	Date of withdrawal
1.	EN 71-7:2014+A2:2018 Safety of toys - Part 7: Finger paints – Requirements and test methods Note: For the allowed preservative climbazole (entry 22 in Table B.1 of Annex B to this standard) the presumption of conformity applies up to a maximum allowed concentration of 0,2 % (not: 0,5 %). This is based on the 'ADDENDUM to the Opinion on Climbazole (P64) ref. SCCS/1506/13' of the Scientific Committee on Consumer Safety (SCCS) that was adopted after the publication of the standard by CEN. https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_212.pdf	28 November 2021
2.	EN 71-12:2013 Safety of toys — Part 12: N-Nitrosamines and N-nitrosatable substances	28 November 2021
3.	EN 62115 :2005 Electric toys – Safety IEC 62115:2003 (Modified) + A1:2004 EN 62115:2005/A11:2012/AC:2013 EN 62115:2005/A11:2012 EN 62115:2005/A12:2015 EN 62115:2005/A2:2011/AC:2011 EN 62115:2005/A2:2011 IEC 62115:2003/A2:2010 (Modified)	21 February 2022