

Position Paper

Response to the proposal for a Regulation on the safety of toys and repealing Directive 2009/48/EC (COM (2023)462)

February 2024

Background Information

General overview

The European Commission published its legislative proposal for a Regulation on the safety of toys on 28 July 2023, which will replace the Directive 2009/48/EC.

CEN and CENELEC support the objectives of the revision of the safety of toys Directive (2009/48/EC) and the proposal for a safety of toys Regulation (COM (2023)462) to increase children's safety and improve protection from harmful chemicals.

We welcome that standards continue to play an important role in achieving these goals, as they specify technical details and thus help toy manufacturers to comply with the essential requirements set out in the Regulation. Since the European standardization organizations review each European standard at least every five years to ensure that it is up to date, the reference to harmonized European standards ensures that toys placed on the European internal market are state of the art.

A summary of the CEN and CENELEC key messages is presented below.

- Harmonized European standards should always take precedence over common specifications in the implementation of the Regulation¹.
- There needs to be a horizontal approach to common specifications across all European Union Single Market Legislation/ European Union Legislation under the New Legislative Framework
- Annex III of the proposed Toy Safety Regulation should refer to the general warning sign ISO 7010-W001.
- Analytical feasibility, e.g., for chromium (VI), should be taken into account when

¹ Note ANEC disagreement about the CEN-CLC position on this point.

setting limit values.

- Organic tin limit values should be removed from the “element” migration limit table.
- The harmonization between several directives is key to enable an interoperable digital product passport.

In the following, we would like to draw attention to some passages of the proposed Regulation that could be further specified or improved in the legislative process.

Common Specifications: Precedence for harmonized European standards

In comparison to the current safety of toys (2009/48/EC), the proposal for a Regulation introduces “common specifications” (Article 14) as a second instrument to specify technical details. Following the principle of proportionality, Europe should continue to rely on voluntary and consensus-based standards that ensure compliance of products with Union legislation and provide a clear separation between legislation, standardization and conformity assessment, as well as include all stakeholders.

Harmonized European standards (hEN) according to their definition in Regulation 1025/2012 ²offer significant added value over common specifications resulting from implementing acts of the Commission:

- They respect European values through:
 - transparency in the development process and via the Annual Union Work programme for standardization;
 - openness and inclusiveness of all relevant and interested stakeholders representing the widest possible technical expertise as well as consumers’ interests, and by offering a right balance of participation among these stakeholders;
 - taking into account environmental, health and occupational safety aspects;
 - the consensus-based development of standards with a bottom-up approach.
- They offer technological leadership potential through the European standardization organization’s strong links to international standardization at ISO and IEC.
- They respect the World Trade Organization’s (WTO) Agreement on Technical Barriers to Trade (TBT Agreement).
- They are trusted by manufactures and consumers alike, market relevant and fit-for-purpose because the requirements of potential users of the standards are taken into account in the drafting process.
- They ensure the inclusion of small and medium-sized enterprises (SMEs) and of societal stakeholders in the standardization process.

The use of common specifications instead of harmonized standards would lead to a loss of

² According to Regulation 1025/2012 Article 2 paragraph 1c a „harmonized standard“ is a „ a European standard adopted on the basis of a request made by the Commission for the application of Union harmonisation legislation“.

these benefits and significantly weaken the participation opportunities of SMEs, and civil society in the development of a responsible framework for the safety of toys.³

Recommendation⁴

Harmonised standards should always be preferred to common specifications. Common specifications should be a fallback option only and must be subject to clear conditions for enactment and requirements for a transparent developing process involving all stakeholders. Furthermore, it is important to develop a horizontal approach for this instrument across all internal market legislation. The agreement reached in the Machinery Regulation should serve as a blueprint for future regulation of common specifications. The present text for the safety of toys Regulation deviates from this regulation and alignment would be recommended.

Generic warning pictogram (Annex III, 1.)

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CEN and CENELEC welcome that the word 'Warning' may be replaced by a generic pictogram. We would, however, like to point out that a general warning sign (ISO 7010-W001) already exists and is part of

- EN ISO 7010:2019, Graphical symbols —Safety colours and safety signs — Registered safety signs as well as of
- COUNCIL DIRECTIVE 92/58/EEC of 24 June 1992 on the minimum requirements for the provision of safety and/or health signs at work (ninth individual Directive within the meaning of Article 16 (1) of Directive 89/391/EEC)

A warning sign consists of three elements: geometric shape (triangle), safety colour (yellow), graphical symbol.

Specific warnings

There are other graphical safety signs available in EN ISO 7010:2019 that could be candidates for inclusion in the toy safety standards that will support the new regulation, to be used instead of the written warning. It would be beneficial if the Toy Safety Regulation ensured that this option was available for risks covered from point 3 to 11 in the Annex III.

As an example, Annex III point 6.6. Refers to skates, roller skates, inline skates, skateboards, scooters, and toy bicycles. There is an existing symbol from EN ISO 7010:2019 which covers this written warning:

"Where skates, roller skates, inline skates, skateboards, scooters and toy bicycles are offered for sale as toys, they shall bear the following warning: 'Protective equipment should be worn. Not to be used in traffic'."

³ Note ANEC disagreement about the CEN-CLC position on this point.

We suggest using this symbol as the possibility for manufacturers to place it on products.



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Recommendation

We recommend referring to the general warning sign ISO 7010-W001 in Annex III, no. 1, and to the specific safety signs available in EN ISO 7010:2019 for the risks covered from point 3 to 11 in the Annex III

Potential reduction of current limit values (chromium VI)

In recital 21 of the draft regulation it is stated that “limit values for arsenic, cadmium, chromium VI, lead, mercury and organic tin, which are particularly toxic and which should therefore not be intentionally used in toys, should be set out at half the values that are considered safe by the relevant scientific body, in order to ensure that only traces that are compatible with good manufacturing practice are present in the toy”.

CEN and CENELEC acknowledge the need to specify safe limit values for toxic substances. For chromium (VI) in particular, it should, however, be noted that the currently valid limit value in routine analysis already cannot always be reliably determined for all materials on the market, as the analysis tolerances vary with different materials and matrix types and are partly very high. This also affects very well-equipped commercial as well as market surveillance authority laboratories. A further reduction of the limit value into the range of the LOQ of the method would lead to even higher analytical tolerances. The Cr (VI) values determined in routine would then no longer be "court-proof".

It is also true for other elements and also for bisphenol A that reducing the limit values greatly complicates routine analysis and also increases measurement uncertainties.

Recommendation:

In general, the analytical feasibility should be considered when setting limit values.

Limit values for organic tin (Annex II, Appendix, Part A, 1.)

Annex II, Appendix, Part A, 1. specifies migration limits for several “elements” but also for organic tin. These limit values correspond to the limit values in Directive

⁵ See EN ISO 7010:2019

2009/48/EC which are covered by the harmonized standard EN 71-3:2019 "Safety of toys - Part 3: Migration of certain elements". Addressing migration of organic tin (non-polar organic bound tin compound) and of elements in one standard with the same acidic (polar) migration conditions has, however, created problems as different migration conditions for organic tin would be needed to achieve fully satisfactory and reproducible results.

Recommendation:

We suggest removing the organic tin limit values from the "element" migration limit table to allow an alternative migration and determination.

Amending Annex I – Part II 'Products that are not considered as toys within the meaning of this Regulation as follows:

The overlap with sports and other recreational equipment remains unclear for scooters. There has been an overlap of the weight classes from 20kg to 50kg for toys according to EN 71-1 and scooters that are classified as sports equipment according to EN 14619 for many years.

This overlap could be clarified by deleting point 5 of Annex I - Products to which this regulation do not apply, Part II of the EC proposal and by introducing scooters in point 3 of the same Part II.

Scooters are similar products to roller skates, inline skates and skateboards, as indicated in Annex III, point 6 of the EC proposal.

*"3. sports equipment, including roller skates, inline skates, skateboards, **scooters and other means of transport** intended for children with a body mass of more than 20 kg.*

~~5. scooters and other means of transport designed for sport or which are intended to be used for travel on public roads or public pathways;"~~

Digital Product Passport

The harmonization between several directives is key to enable an interoperable digital product passport. Hence the Proposed Toy Safety Regulation is referring to the proposal for an Ecodesign for Sustainable Products Regulation (ESPR), it is necessary that a harmonization of the final ESPR is ensured. Discrepancies might occur through changes, which must be addressed and clarified in the sense of a harmonization.

Recommendation: For this new system to work well, it is also key to give adequate time to develop the necessary standards before the requirements in the safety of toys Regulation become applicable and ensure this horizontal application.

Transition period

Given that toy manufacturers can only start applying the new rules once the standards are in place or revised, the transition period (Article 54) of 30 months is too short. A range of implementing or delegated acts and updates of standards need to happen before the new rules become applicable.

Recommendation:

The transition period should therefore be extended to 54 months.

About CEN and CENELEC

CEN (European Committee for Standardization) and CENELEC (European Committee for Electrotechnical Standardization) are recognized by the European Union (EU) and the European Free Trade Association (EFTA) as European Standardization Organizations responsible for developing standards at European level, as per European Regulation 1025/2012. The members are the National Standards Bodies (CEN) and National Electrotechnical Committees (CENELEC) from 34 European countries. European Standards (ENs) and other standardization deliverables are adopted by CEN and CENELEC, are accepted and recognized in all of these countries. These standards contribute to enhancing safety, improving quality, facilitating cross-border trade and strengthening of the European Single Market. They are developed through a process of collaboration among experts nominated by business and industry, research institutions, consumer and environmental organizations, trade unions and other societal stakeholders. CEN and CENELEC work to promote the international alignment of standards in the framework of technical cooperation agreements with ISO (International Organization for Standardization) and the IEC (International Electrotechnical Commission).