BRIEFING
EU Legislation in Progress

European Parliament

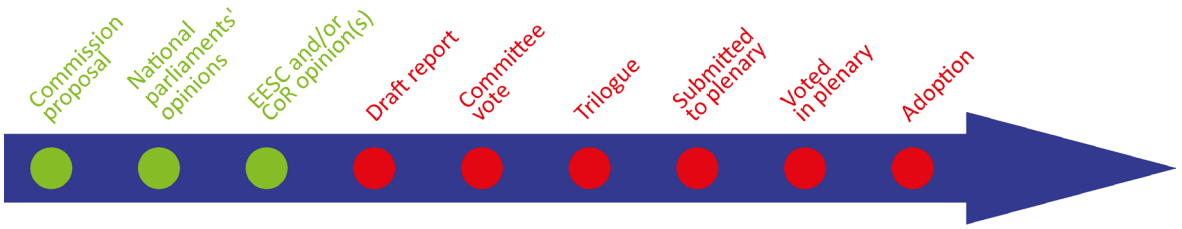
Toy safety regulation

OVERVIEW

On 28 July 2023, the European Commission adopted a proposal to revise EU toy safety legislation with a new regulation and repealing Directive 2009/48/EC. The proposal pursues two main objectives: a) achieving a higher level of child protection, including from the most harmful substances; and b) reducing the number of non-compliant and unsafe toys on the EU market. In relation to the first objective, the proposal extends the definition of health to children's psychological and mental health and to their wellbeing and cognitive development. It also extends the current ban on substances classified as carcinogenic, mutagenic and toxic for reproduction to include endocrine disruptors, as well as chemicals that are toxic to a specific organ or affect the immune, neurological or respiratory system. The proposal's second objective provides for the creation of a digital product passport to facilitate traceability.

In the European Parliament, the file was referred to the Committee on Internal Market and Consumer Protection (IMCO). The working party on technical harmonisation in the Council of the European Union, has begun its examination of the proposal.

Proposal for a regulation of the European Parliament and of the Council on the safety of toys and repealing Directive 2009/48/EC		
Committee responsible:	Internal Market and Consumer Protection (IMCO)	COM(2023) 462 28.7.2023
Rapporteur:	Marion Walsmann (EPP, Germany)	2023/0290(COD)
Shadow rapporteurs	Brando Benifei (S&D, Italy) Vlad-Maruis Botoş (Renew, Romania) Katrin Langensiepen (Greens/EFA, Germany) Beata Mazurek (ECR, Poland) Alessandra Basso (ID, Italy)	Ordinary legislative procedure (COD) (Parliament and Council on equal footing – formerly 'co-decision')
Next steps expected:	Adoption of the draft report	



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Introduction

On 28 July 2023, the Commission adopted a proposal for a regulation on the safety of toys, repealing Directive 2009/48/EC. Whilst the evaluation of the Directive conducted by the Commission substantiated shortcomings, such as a significant share of unsafe toys placed on the EU market, the proposed overhaul of EU product safety and sustainability legislation also represents an opportunity to update the legislation more generally.

The Commission explains the choice of a regulation to achieve these goals by the need to ensure the uniform application of specific new provisions for timely and uniform implementation throughout the single market, such as the proposed toy passport, and the related customs verifications. A regulation also neutralises the risk of Member States creating supplementary obligations (gold plating), and improves the legal certainty for stakeholders, not least manufacturers.

Existing situation

Toys belong to the 'harmonised products' category, which defines those goods subject to Union harmonisation legislation (Annex I of Regulation (EU) 2019/1020 on market surveillance and compliance of products provides a list of such legislation). This means that the relevant provisions for toys are laid down in by the Toy Safety Directive, (pursuant with the requirements set in Decision 768/2008 on a common framework for the marketing of products). In addition, the relevant provisions of Regulation (EU) 2019/1020 and Regulation (EU) 2023/988 on general product safety also apply.

Toy Safety Directive

The current Toy safety Directive spells out the safety requirements for toys to be placed on the EU market, as well as the processes to ensure their conformity with such requirements, regardless of the place of their production in the EU or beyond. It qualifies as a total harmonisation directive on safety requirements, in the sense that it does not allow Member States to include additional or different safety requirements as part of their transposition into national legislation.

The directive, in particular its Annex II, lays down a list of general requirements, which aim to ensure that the appropriate use of a toy does not jeopardise the safety or health of users or third parties, and takes a differentiated approach for children younger than 36 months. Annex II of the directive then includes a set of particular safety requirements, relating to the physical, mechanical and chemical properties of the toys. For instance, substances classified as carcinogenic, mutagenic and toxic for reproduction (CMRs), pursuant with Regulation EC) 1272/2008, are forbidden by default.

The directive also prescribes the process to place toys on the EU market. A manufacturer can opt either for self-verification by using the European harmonised standards, or for third-party verification through a notified body. The European harmonised standards are technical specifications, developed by one of the European standards organisations, which aim to ensure that a product complies with the technical requirements defined by the EU legislation.

Market Surveillance and Compliance of Products Regulation

Regulation (EU) 2019/1020 on market surveillance and compliance of products complements the EU legislation on harmonised products. It notably extends the cooperation between national market surveillance authorities, and updates their remit regarding the economic actors operating along the value chain (manufacturers, importers, distributors). For instance, they can require economic operators to take action to remediate a situation of non-compliance with EU legislation, to eliminate an identified safety risk.

General Product Safety Regulation

Regulation (EU) 2023/988 on general product safety complements the EU legislation on toy safety, not least by improving consumers' rights should a product be recalled.

Parliament's starting position

Parliament adopted a resolution on the implementation of Directive 2009/48/EC on toy safety on 16 February 2022. It acknowledged the directive's positive contribution to improving the safety of children throughout the EU, whilst ensuring enough legal certainty for economic operators (manufacturers, importers, distributors). Parliament particularly stressed the efforts undertaken by those operators to ensure compliance. Regarding the processes laid down by the directive, the key roles of the standards and of the notified bodies were highlighted, even if the need to increase the presence of such notified bodies in some EU regions was flagged. Parliament also highlighted the opportunities to improve the involvement of online market places to strengthen the implementation of the toy safety provisions.

On the directive's substance, Parliament supported the extension of the generic ban on CMRs to include endocrine disruptors, on the basis of the World Health Organization (WHO) definition. However, Parliament also flagged that derogations to the generic ban on CMRs allow in specific cases for the presence of those chemicals in concentrations that appear to be too high to ensure the protection of children. It then called on the Commission to take into account children's combined exposure to chemicals as well as potential low-dose effects. Parliament also stressed that the differentiated approach towards children younger or older than 36 months should not provide an opportunity to reduce child safety. It associated this call with the request to the Commission to set up a public data repository of accidents involving toys across the Union. With a view to the future of the legislation, Parliament expressed its preference for a regulation, rather than an amended directive, noting that the directive was already specific, as it 'acts as a de facto regulation'.

Preparation of the proposal

Several strategies adopted by the Commission since 2019 feed into the proposal. With the 2020 Commission communication on a chemicals strategy for sustainability, several commitments are expected to contribute directly to the enhancement of toy safety, along the three complementary priorities of promoting safe and sustainable chemicals, minimising human exposure and eliminating the substances of concern. For instance, under the goal of minimising exposure, the objective to extend the generic ban on specific substances ('the generic approach') in consumer products is expected to reinforce protection against harmful chemicals affecting the immune, neurological, or respiratory systems, as well as chemicals toxic to a specific organ. The communication also highlights the specific relevance of international cooperation – 90 % of the dangerous products placed on the EU market and signalled as posing a risk due to chemical content come from outside the EU. The Commission therefore suggests to promote the sound management of chemicals in bilateral, regional and multilateral fora. With its 2021 communication on the EU strategy on the rights of the child, the Commission also identified health as one of the six priorities to enforce and promote child rights in the EU.

The Commission held several public and stakeholder consultations during the preparation of the proposal. For instance, on 26 April 2022, the Commission gathered 120 industry stakeholders, together with representatives from consumer organisations and the Member States, to gather their opinions on the update of the EU legislation on toy safety. The Commission services stress the existence of a consensus on two relevant points: a) defining new limit values for toys for children both under and beyond 36 months, and b) tackling the high number of non-compliant toys on the Union market. In addition, between 2 March and 25 May 2022, the Commission organised a public consultation on how to improve the Toy Safety Directive. Among the 196 respondents, businesses represented 34 %, citizens 22 %, public authorities 16 %, business associations 12 %, and consumer

organisations and non-governmental organisations 12 %. A majority of the respondents support the definition of stricter rules, in comparison to the provisions currently in force. In particular, a majority of national authorities and consumer organisations stressed a desire to see endocrine and immune system disruptors tackled in the legislation. However, no such consensus was reached on the approach to address these preferences: whereas a significant share of national authorities and consumer organisations consider the option to include general bans without derogations to avoid use of such substances, a majority of industry representatives disagreed with such an approach.

The Commission's impact assessment identifies two main objectives for the proposal: a) achieving a higher level of protection of children, including from the most harmful substances; and b) reducing the number of non-compliant and non-safe toys on the EU market. The Commission proposes three policy options for each of the two main objectives.

To achieve the first objective, its preferred option is to empower the Commission to add and amend limit values for chemicals in toys, as well as allowing it to include generic bans with possible derogations. This would imply a one-off cost adjustment of €23.5 to €397 million to redesign products, as well as a permanent increase in annual testing costs of a range of €7 to €11.5 million. On the other hand, banning the most harmful substances is expected to lead to health benefits more than proportional with the costs, measured annually in a range between €240 million and €1.2 billion.

To achieve the second objective, the Commission's preferred option is to rely on the product passport created by the proposal for a regulation establishing a framework for setting ecodesign requirements for sustainable products. The data on compliance would be provided digitally with the product passport, and would have to be presented to customs authorities as appropriate. This option is expected to lead to a one-off administrative cost of €18 million, and to additional annual costs of €10.5 million for the industry. At the same time, the digitalisation of the safety information would generate annual savings between €2.6 million and almost €4 million for the industry.

The changes the proposal would bring

Scope of the regulation, and definitions

The scope of the proposed regulation remains almost unchanged in comparison with Directive 2009/48/EC, with an exception regarding the inclusion of catapults and slings now included. Similarly, 29 out of the 36 definitions correspond to the definitions set out in the directive. The new definitions find their origin in other EU legislative acts adopted since 2019, in particular: Regulation (EU) 2019/1020 on market surveillance, Regulation (EU) 2023/988 of 10 May 2023 on general product safety, and the proposal for a regulation (EU) on ecodesign requirements for sustainable products.

Article 4 on free movement also sets out a new provision ensuring the free movement of compliant toys. Article 4(2) even authorises the display of non-compliant toys at trade fairs, exhibitions and demonstrations, provided they are identified with a visible explanatory sign.

Toy safety

Article 5 on product requirements defines two additional sets of compliance criteria:

- **essential safety requirements**, defined in Article 5(2). This provision includes an obligation to ensure that the proper and foreseeable use of toys does not present a risk to the safety or health of users and third parties. Health includes children's psychological and mental health, well-being and cognitive development. The assessment of the risk should take into account the users' ability, not least due to their specific age group.
- **particular safety requirements** defined in Annex II to the proposal. These requirements refer to six specific properties: physical and mechanical; flammability;

chemical properties; electrical properties; hygiene; radioactivity. Among the chemical properties, the proposal extends the ban of CMR substances to include: endocrine disruptors, specific target organ toxicity substances (either in single or repeated exposure) and respiratory sensitisation substances. The appendix to Annex II contains the 19 substances subject to specific limit values, the maximum level for several of them, such as aluminium, barium or lead, having been lowered. The list of substances subject to specific labelling requirements is composed of 71 elements (instead of the 11 elements contained in the current Toy Safety Directive).

Roles and obligations along the toy value chain

The proposed regulation allocates the obligations to economic actors along the value chain (manufacturers, importers and distributors), according to the principles set out in Decision 768/2008 mentioned above. Article 7 obliges manufacturers to ensure that the design and production of toys they want to place on the market comply with the essential safety requirements. Consequently, manufacturers would be responsible for the drawing up of the technical documentation, and the performance of the conformity assessment, including the creation of the product passport. Article 8 on authorised representatives specifies that those tasks cannot be delegated to an authorised representative. Article 9 and Article 10 would oblige importers and distributors to ensure respectively that the toys they place or make available on the market are compliant. Importers and distributors would also have to participate in market surveillance activities as appropriate. Article 11 allows to shift manufacturer obligations to an importer or a distributor where a specific toy is placed on the market under the name or trademark of the importer or distributor, or where the toy already placed on the market is modified by the importer or distributor.

Assessment of toy conformity

Two main conformity procedures are laid down in Article 22: one in-house process managed by the manufacturer, and one process conducted by a third party to check manufacturer compliance.

When a manufacturer applies harmonised standards, the references to which have been published in the Official Journal, or a common specification adopted by the Commission as an implementing act, pursuant with Article 13, using the internal production control process laid down in Annex IV of the proposal is permitted.

If the manufacturer does not apply such standards or common specifications, it would be requested to undergo an EU-type examination, as laid down in Annex IV of the proposal. Such an examination will be conducted by a third party, one of the notified bodies mentioned in Article 28, which shall issue an EU-type examination certification in cases of compliance with the manufacturing process.

Subject to compliance with the appropriate conformity procedure, Article 16 of the proposed regulation provides for affixing the CE marking, visibly, legibly and indelibly to the toy, to a label attached to the toy, or to the packaging of the toy. Article 15 stresses that toys made available on the market should bear the CE marking.

Digital product passport

Article 17 defines the granularity and purpose of a specific product passport for toys. It would have to be created for each specific toy model, state the compliance of the toys with the requirements set in the proposal, and be available through a data carrier, in the languages requested by the Member State where the toy is made available, and for a period of 10 years. The data carrier should be physically present on the toy, or on a label attached to the toy. It shall be visible to the consumer before the purchase. Article 18 on technical design and operation of the product passport provides for additional information technology (IT) requirements for such a tool, including its interoperability with other product passports established under EU legislation. The information included in the product passport would have to be available free of charge to economic operators and consumers, and be based on open standards.

Market surveillance

The proposal contains specific provisions regarding the market surveillance of toys, in addition to the rules laid down in Regulation (EU) 2019/1020 on market surveillance. Article 45 on Commission action concerning toys that present a risk, empowers the Commission to adopt implementing acts setting out measures concerning toys compliant with the particular safety requirements but nevertheless presenting a risk to individuals' health and safety. Such measures would include market withdrawal or product recall.

Delegated powers and committee procedure

The proposal provides for significant delegation powers to be awarded to the Commission, under Article 46 on delegated powers and Article 47 on the exercise of delegation. Under Article 46(1), the Commission is empowered to adopt delegated acts to adapt the information contained in the product passport, to reflect the scientific and technological developments. Under Article 46(3) and Article 46(4), the Commission is empowered to adopt a delegated act to determine the information and verification to be scrutinised by the custom authorities. Under Article 46(6) and Article 46(7), the Commission is empowered to adopt delegated acts to permit derogations to the ban on substances listed in Annex II of the proposal, provided among other conditions that the European Chemical Agency has found the use of such a prohibited substance or mixture in toys to be safe.

Entry into force

Article 56 provides for the legislation to enter into force on the twentieth day following that of the publication of the adopted regulation. It would apply for 30 months following the date of entry into force. The proposal also provides for a specific entry into application of Article 17(10), Articles 24 to 40, and Articles 46 to 52, without setting a date. Article 54 provides for transitional provisions, in particular for toys placed on the market in conformity with Directive 2009/48/EC, which could continue to be made available on the market until the first day of the month following 42 months after the entry into force of the regulation.

Advisory committees

The European Economic and Social Committee is expected to adopt an opinion on the revision of the Toy Safety Directive (Directive 2009/48/EC) during its December 2023 plenary session. Two rapporteurs have been appointed: Ileana Izverniceanu de la Iglesia (Diversity Europe – GR III/Spain), Tymoteusz Adam Zych (Diversity Europe – GR III/Poland).

National parliaments

The deadline for the national parliaments to submit reasoned opinions on the grounds of subsidiarity was 2 November 2023. Five national Parliaments (Austria, Czechia, Ireland, Lithuania, Portugal), have already communicated that the proposal raises no subsidiarity issues.

Stakeholder views

The Commission published a call for feedback on the proposal, with a deadline of 31 October 2023.

Following the consultations on and the Commission's adoption of the proposal, stakeholders have already shared their views on the new propositions. The European Consumer Organisation (BEUC), and the European consumer voice in standardisation (ANEC) adopted statements on 28 July 2023, welcoming the proposal, not least by praising the extension of the generic ban on endocrine disruptors. The organisations consider the ban to be a 'milestone to protect the health of children'.

Industry stakeholders convey more nuanced opinions. In an interview on 18 September 2023, European toy industry representatives approve the choice of legal instrument, considering that a regulation would limit interpretive divergences between national authorities. However, they voice concern over the transition costs associated with the extension of generic bans on substances. They

also flag the need for the digital passport to safeguard trade secrets. The interview largely reiterates the early assessment of the proposal published by Toys Industries of Europe earlier in 2023.

On 19 September 2023, the IMCO committee hosted a public discussion with the Commission and stakeholder representatives on the state of play on toy safety legislation. Beyond the stakeholders mentioned above, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC), two of the three European standardisation organisations, provided views on the proposed regulation. They stressed standardisation should remain the primary solution to defining harmonised technical specifications, whereas the adoption of common specifications by EU implementing act should be exceptional, and justified.

Legislative process

In the European Parliament, the file was referred to the Committee on the Internal Market and Consumer Protection (IMCO). Marion Walsmann (EPP, Germany) was appointed as rapporteur.

In the Council of the EU, the working party on technical harmonisation began its examination of the proposal on 3 October 2023.

EUROPEAN PARLIAMENT SUPPORTING ANALYSIS

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Evroux C., General Product Safety Regulation, EPRS, European Parliament, February 2023.

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