







# Procedure file

Basic information	
COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2023/0290(COD) Awaiting Council's 1st reading position
Safety of toys Repealing Directive 2009/48 <a href="#">2008/0018(COD)</a>	
Subject 2.10.03 Standardisation, EC/EU standards and trade mark, certification, compliance 4.60.04.02 Consumer security 4.60.08 Safety of products and services, product liability	

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	 <a href="#">Internal Market and Consumer Protection</a>	<a href="#">EPP</a> <a href="#">WALSMANN Marion</a>	01/08/2024
		Shadow rapporteur	
		<a href="#">Renew</a> <a href="#">STÜRGKH Anna</a>	
		<a href="#">Greens/EFA</a> <a href="#">LANGENSIEPEN Katrin</a>	
	Former committee responsible		05/09/2023
	 <a href="#">Internal Market and Consumer Protection</a>	 <a href="#">WALSMANN Marion</a>	
Former committee for opinion		24/10/2023	
	 <a href="#">Environment, Public Health and Food Safety</a> (Associated committee)	 <a href="#">CERDAS Sara</a>	
Council of the European Union	Commission DG	Commissioner	
European Commission	<a href="#">Internal Market, Industry, Entrepreneurship and SMEs</a>	<a href="#">BRETON Thierry</a>	
European Economic and Social Committee			


Key events			
28/07/2023	Legislative proposal published	<a href="#">COM(2023)0462</a>	Summary
19/10/2023	Committee referral announced in		

	Parliament, 1st reading		
19/10/2023	Referral to associated committees announced in Parliament		
13/02/2024	Vote in committee, 1st reading		
20/02/2024	Committee report tabled for plenary, 1st reading	<a href="#">A9-0044/2024</a>	Summary
13/03/2024	Results of vote in Parliament		
13/03/2024	Decision by Parliament, 1st reading	<a href="#">T9-0144/2024</a>	Summary
05/09/2024	Committee decision to open interinstitutional negotiations after 1st reading in Parliament		
16/09/2024	Committee decision to enter into interinstitutional negotiations announced in plenary (Rule 72)		

### Technical information

Procedure reference	2023/0290(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Repealing Directive 2009/48 <a href="#">2008/0018(COD)</a>
Legal basis	Treaty on the Functioning of the EU TFEU 114; Rules of Procedure EP 57_o
Other legal basis	Rules of Procedure EP 165
Mandatory consultation of other institutions	<a href="#">European Economic and Social Committee</a>
Stage reached in procedure	Awaiting Council's 1st reading position
Committee dossier	IMCO/9/13050

### Documentation gateway

Legislative proposal		<a href="#">COM(2023)0462</a>	28/07/2023	EC	Summary
Document attached to the procedure		<a href="#">SEC(2023)0297</a>	28/07/2023	EC	
Document attached to the procedure		<a href="#">SWD(2023)0268</a>	28/07/2023	EC	
Document attached to the procedure		<a href="#">SWD(2023)0269</a>	28/07/2023	EC	
Document attached to the procedure		<a href="#">SWD(2023)0270</a>	28/07/2023	EC	
Committee draft report		<a href="#">PE754.649</a>	08/11/2023	EP	
Amendments tabled in committee		<a href="#">PE757.094</a>	05/12/2023	EP	
Amendments tabled in committee		<a href="#">PE757.095</a>	05/12/2023	EP	
Amendments tabled in committee		<a href="#">PE757.116</a>	05/12/2023	EP	
Economic and Social Committee: opinion, report		<a href="#">CES3708/2023</a>	13/12/2023	ESC	
Committee opinion		<a href="#">PE758.211</a>	12/02/2024	EP	

Committee report tabled for plenary, 1st reading/single reading	<a href="#">A9-0044/2024</a>	20/02/2024	EP	Summary
Text adopted by Parliament, 1st reading/single reading	<a href="#">T9-0144/2024</a>	13/03/2024	EP	Summary
Commission response to text adopted in plenary	<a href="#">SP(2024)350</a>	22/07/2024	EC	

<b>Additional information</b>				
Research document	<a href="#">Briefing</a>	20/11/2023		

## Safety of toys

**PURPOSE:** to replace Directive 2009/48/EC on the safety of toys with a Regulation to ensure its uniform application.

**PROPOSED ACT:** Regulation of the European Parliament and of the Council.

**ROLE OF THE EUROPEAN PARLIAMENT:** the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

**BACKGROUND:** Directive 2009/48/EC of the European Parliament and of the Council was adopted to ensure a high level of safety of toys and their free movement on the internal market.

A Commission evaluation of Directive 2009/48/EC concluded that the Directive is relevant and generally effective in protecting children. However, it also identified a number of deficiencies that have emerged during the practical application of the Directive since its adoption in 2009. In particular, the evaluation identified certain shortcomings with regard to possible risks arising from harmful chemicals in toys. The evaluation also concluded that many non-compliant and unsafe toys remain on the Union market. Moreover, the reliance on digital technologies has led to new hazards in toys. Radio toys are to comply with essential requirements for the protection of privacy and internet-connected toys are to incorporate safeguards towards cybersecurity and protection from fraud.

Since the rules setting out the requirements for toys, in particular the essential requirements and the conformity assessment procedures, need to be of uniform application across the Union, and not give room for divergent implementation by Member States, Directive 2009/48/EC should be replaced by a regulation.

**CONTENT:** the aim of this proposed Regulation is to change the directive to a regulation with a view to simplifying the regulatory environment and to ensure uniform implementation throughout the EU of the proposed legislation.

### Exclusions

The products that are not covered by the proposed regulation have been set out in Annex I, which is now a single list. The products exempted from the scope of the proposed regulation remain the same as in the current Directive, with the exception of slings and catapults, which are no longer excluded from the scope of the Regulation. The proposal also empowers the Commission to determine via implementing acts whether a specific product or category of products should be considered as a toy or not.

### Requirements for toys

The proposal contains the obligation: (i) for toys to conform with the general and particular safety requirements; and (ii) to affix specific warnings when these are necessary for the safe use of the toys. While the categories of particular safety requirements in Annex II remain the same as for Directive 2009/48/EC, the general safety requirement goes beyond protecting the physical health and safety of users, to include the psychological well-being and cognitive development of children.

### Particular safety requirements for toys

The main categories of essential requirements for toys are set out in Annex II and they concern:

- physical and mechanical properties;
- flammability;
- chemical properties;
- electrical properties;
- hygiene;
- radioactivity.

The chemical properties are amended and simplified.

The generic restrictions of particularly harmful substances now include: (i) substances which are carcinogenic, mutagenic or toxic for reproduction; (ii) endocrine disruptors, (iii) respiratory sensitisers and (iv) substances toxic to a specific organ.

The possibilities for a derogation to this ban have been limited.

### Obligations of economic operators

The proposal incorporates obligations for manufacturers, importers and distributors aligned with Decision 768/2008/EC, as is already the case

in the current Directive. This clarifies the respective obligations, which are proportionate to the economic operators role. The manufacturer is required to create a product passport for the toy including the relevant compliance information which will replace the EU declaration of conformity.

#### Presumption of conformity of toys

The presumption of conformity of toys when manufacturers apply the relevant harmonised standards or parts thereof published in the Official Journal of the European Union remains. However, in order to ensure the presumption of conformity when there are no relevant harmonised standards the Commission will be empowered to adopt common specifications. This will be a fall-back option to be used only when the standardisation bodies are not able to provide standards or provide standards that do not respond to the Commission standardisation request and the essential requirements of Annex II.

#### Product passport

The EU declaration of conformity is replaced by the obligation to have a product passport available for toys to declare compliance with the requirements of this proposed regulation. The product passport will be connected through a data carrier to a unique product identifier and meet the same technical requirements for a product passport contained in the ESPR. The reference of the product passport must be included in a Commission central registry that will be set up under the regulation on ecodesign requirements for sustainable products (ESPR) and this information needs to be indicated at customs when toys coming from outside the EU are placed under the customs procedure of release for free circulation.

## Safety of toys

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The Committee on the Internal Market and Consumer Protection adopted the report by Marion WALSMANN (EPP, DE) on the proposal for a regulation of the European Parliament and of the Council on the safety of toys and repealing Directive 2009/48/EC.

The committee responsible recommended that the European Parliament's position adopted at first reading under the ordinary legislative procedure should amend the proposal as follows:

#### Subject matter

The objective of this Regulation is to improve the functioning of the internal market while providing for a high level of consumer protection and a high level of protection of health and safety of children and other persons. This Regulation lays down rules on the safety of toys and on the free movement of toys in the Union, contributing to strengthening of the internal market. It should be implemented taking due account of the precautionary principle.

#### Product requirements

Internet connected toys that have social interactive features (e.g. speaking or filming) may also require a third-party conformity assessment.

When assessing the risk to the safety or health of users or third parties, a manufacturer of digitally connected toys should, where appropriate, according to reasonable best efforts, also take into account any risk posed to mental health, as well as the cognitive development, of children, that may arise when such toys are used in accordance with their intended use.

Members stated that toys which include artificial intelligence are to comply with the Regulation laying down harmonised rules on artificial intelligence, which classifies them as high-risk, and subjects them to third-party assessments, risk management, transparency, and human oversight. Therefore, such toys should comply with standards of safety, security and privacy by design.

#### Warnings

Toys which are sold without packaging should have appropriate warnings affixed to them if the surface of the toy allows. If this is not possible, the warnings should be placed on the label. The manufacturer may add a QR-code which provides a link to the instructions in a digital format, but shall always mark warnings on the toy, on an affixed label or on the packaging.

Warnings which determine the decision to purchase the toy should be clearly visible to the consumer before the purchase. They should be of sufficient size to ensure that they are also immediately visible and legible online.

#### Obligations of online marketplaces

Toys should comply with the recently updated general rules on product safety, for example with regard to online sales, accident reporting and consumers' right to information and redress.

#### Delegated acts

The Commission may, by means of delegated acts supplementing the Regulation, establish common specifications for the essential safety requirements only where:

- it has requested one or more European standardisation organisations to develop or revise European standards for the requirements concerned, and the request has not been accepted; or
- no reference to harmonised standards covering product requirements has been published in the Official Journal of the European Union and no such reference is expected to be published within a reasonable period of time.

#### Digital product passport

Before placing a toy on the market, manufacturers should draw up a digital product passport for that toy. The digital product passport should meet the requirements laid down in this Regulation and other relevant Union harmonised legislation requiring an EU declaration of conformity and it should replace all EU declarations of conformity required.

All information included in the digital product passport should be based on open standards developed with an interoperable format, including for the purpose of transmitting information via the Safety Business Gateway and the Safety Gate Portal.

## Assistance for SMEs

The Commission should provide comprehensive assistance, in cooperation with the relevant national authorities, to SMEs that are required to establish a digital product passport for toys, by providing them with tailor-made guidance on how to efficiently set up and operate a digital product passport for toys and an automatic translation tool for the languages.

## Safety assessment

In order to demonstrate that a toy complies with the essential safety requirements, manufacturers should, before placing a toy on the market, carry out a safety assessment which should at least the following:

- cover all the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards and the potential exposure to such hazards;
- in relation to chemical hazards, take account of the possible exposure to individual chemicals, and any known additional hazards from combined exposure to the different chemicals present in the toy, taking into account the obligations under Regulation (EC) No 1907/2006 and the conditions set out therein;
- be updated whenever additional relevant information is available.

The safety assessment should be included in the technical documentation.

## Safety of toys

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The European Parliament adopted by 603 votes to 5, with 15 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on the safety of toys and repealing Directive 2009/48/EC.

The European Parliament's position adopted at first reading under the ordinary legislative procedure amends the proposal as follows:

### Subject matter

The objective of this Regulation is to improve the functioning of the internal market while providing for a high level of consumer protection and a high level of protection of health and safety of children and other persons. This Regulation lays down rules on the safety of toys and on the free movement of toys in the Union, contributing to strengthening of the internal market. It should be implemented taking due account of the precautionary principle.

### Ban on harmful chemicals

The Regulation will ban substances that are carcinogenic, mutagenic or toxic to reproduction (CRM). The existing prohibition on carcinogenic and mutagenic substances or substances toxic for reproduction (CRM) is extended to chemicals that are particularly harmful to children, such as endocrine disruptors or chemicals affecting the respiratory system. The rules also target chemicals that are toxic to specific organs or are persistent, bioaccumulative, and toxic.

The use in toys, components of toys or micro-structurally distinct parts of toys, of per- and polyfluoroalkyl substances (PFAS) and of bisphenols is prohibited. Toys intended for use by children under 36 months or other toys intended to be placed in the mouth shall not contain any fragrances.

### Product requirements

Internet connected toys that have social interactive features (e.g. speaking or filming) may also require a third-party conformity assessment.

When assessing the risk to the safety or health of users or third parties, a manufacturer of digitally connected toys should, where appropriate, according to reasonable best efforts, also take into account any risk posed to mental health, as well as the cognitive development, of children, that may arise when such toys are used in accordance with their intended use.

When assessing the safety of digitally connected toys likely to have an impact on children, manufacturers should ensure that the products they make available on the market meet the highest standards of safety, security and privacy by design, in the best interests of children.

Members stated that toys which include artificial intelligence are to comply with the Regulation laying down harmonised rules on artificial intelligence, which classifies them as high-risk, and subjects them to third-party assessments, risk management, transparency, and human oversight. Therefore, such toys should comply with standards of safety, security and privacy by design.

### Warnings

Toys which are sold without packaging should have appropriate warnings affixed to them if the surface of the toy allows. If this is not possible, the warnings should be placed on the label. The manufacturer may add a QR-code which provides a link to the instructions in a digital format, but shall always mark warnings on the toy, on an affixed label or on the packaging.

Warnings which determine the decision to purchase the toy should be clearly visible to the consumer before the purchase. They should be of sufficient size to ensure that they are also immediately visible and legible online.

Labels and instructions for use should draw the attention of children or their supervisors to the inherent hazards and risks to the health and safety of children considering the age group of children for which the toys are intended, and to the ways of avoiding such hazards and risks.

### Obligations of online marketplaces

Toys should comply with the recently updated general rules on product safety, for example with regard to online sales, accident reporting and consumers' right to information and redress.

### Digital product passport

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- cover all the chemical, physical, mechanical, electrical, flammability, hygiene and radioactivity hazards and the potential exposure to such hazards;
- in relation to chemical hazards, take account of the possible exposure to individual chemicals, and any known additional hazards from combined exposure to the different chemicals present in the toy, taking into account the obligations under Regulation (EC) No 1907/2006 and the conditions set out therein;
- be updated whenever additional relevant information is available.

The safety assessment should be included in the technical documentation.

Transparency					
BENIFEI Brando	Shadow rapporteur		IMCO	04/03/2024	Toy Industries of Europe
WALSMANN Marion	Rapporteur		IMCO	31/01/2024	Video Games Europe
WALSMANN Marion	Rapporteur		IMCO	30/01/2024	The LEGO Group
BOTO? Vlad-Marius	Rapporteur		IMCO	30/01/2024	The LEGO Group
BENIFEI Brando	Shadow rapporteur		IMCO	25/01/2024	Amazon Europe Core SARL
BENIFEI Brando	Shadow rapporteur		IMCO	25/01/2024	Amazon Europe Core SARL
WALSMANN Marion	Rapporteur		IMCO	16/01/2024	European Economic and Social Committee
WALSMANN Marion	Rapporteur		IMCO	08/01/2024	TIC Council Europe
WALSMANN Marion	Rapporteur		IMCO	13/12/2023	Chemsec
WALSMANN Marion	Rapporteur		IMCO	12/12/2023	CHEM Trust
ARIAS ECHEVERRÍA Pablo	Member	21/03/2024		AEFJ	
VAN BREMPT Kathleen	Member	11/03/2024		Toy Industries of Europe smart.be	
ZULLO Marco	Member	25/01/2024		Amazon Europe Core SARL	
ROSSI Maria Veronica	Member	19/01/2024		GEMAR SRL	
VANDENKENDELAERE Tom	Member	08/12/2023		Globetrade	
BALLARÍN CEREZA Laura	Member	05/12/2023		Mattel, Inc.	
LINS Norbert	Member	01/12/2023		Deutscher Verband der Spielwarenindustrie	

			e.V.
LUENA César	Member	30/11/2023	Asociacion Española de Fabricantes de Juguetes
COMI Lara	Member	28/11/2023	GEMAR SRL
SCHWAB Andreas	Member	23/11/2023	Börsenverein des Deutschen Buchhandels e.V.