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# **COVER NOTE**

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	14 October 2025
То:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2025) 635 final
Subject:	COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT pursuant to Article 294(6) of the Treaty on the Functioning of the European Union concerning the position of the Council on the adoption of a regulation of the European Parliament and of the Council on the safety of toys and repealing Directive 2009/48/EC

Delegations will find attached document COM(2025) 635 final.

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Brussels, 14.10.2025 COM(2025) 635 final 2023/0290 (COD)

# COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT

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# pursuant to Article 294(6) of the Treaty on the Functioning of the European Union

# concerning the

position of the Council on the adoption of a regulation of the European Parliament and of the Council on the safety of toys and repealing Directive 2009/48/EC

#### 1. BACKGROUND

Date of transmission of the proposal to the European Parliament and 28 July 2023 to the Council (document COM(2023) 462 - 2023/0290 COD):

Date of the opinion of the European Economic and Social 13 December 2023

Committee:

Date of the position of the European Parliament, first reading: 13 March 2024

Date of transmission of the amended proposal: N/A

Date of adoption of the position of the Council: 13 October 2025

# 2. OBJECTIVE OF THE PROPOSAL FROM THE COMMISSION

The Commission proposal pursues two objectives: (i) to improve the protection of children from harmful chemicals when playing with toys; and (ii) to reduce the number of non-compliant toys which can still be found on the Union market, in particular through online sales.

#### 3. COMMENTS ON THE POSITION OF THE COUNCIL

The position of the Council as adopted at first reading fully reflects the political agreement reached between the European Parliament and the Council on 10 April 2025. The Commission supports this agreement, the main points of which are set out below.

- Precautionary principle: The co-legislators have agreed to introduce a reference to the precautionary principle in Article 1 of the regulation, as an inspirational principle, which is acceptable to the Commission.
- Mental health of children: The co-legislators have agreed to enlarge the concept of toy safety to include mental health and well being of children for digitally connected toys. Article 21 concerning the safety assessment of toys will require that toys within the scope of the Radio Equipment Directive 2014/53/EU, the Cyber Resilience Act Regulation (EU) 2024/2847 or Regulation (EU) 2024/1689 on Artificial Intelligence take account of the vulnerabilities of children when assessing under the Toy Safety Regulation the hazards they present. This is in line with the objective of the Commission proposal and is acceptable to the Commission.

- The Digital Product Passport was agreed by the co-legislators, and it may also be used to replace the declaration of conformity under other legislation applicable to the toy. This will lead to simplification in case of toys within the scope of other Union law requiring a declaration of conformity. The technical requirements for the digital product passport supplementing the regulation (Article 17) will be established via delegated acts, in line with the provisions on the digital product passport set out in Regulation (EU) 2024/1781 on ecodesign requirements for sustainable products (ESPR).
- Online sales of toys: The co-legislators agreed to introduce in the regulation provisions on fulfilment service providers and on the online sale of toys. These provisions intend to "plug in" into Regulation 2022/2065 (the Digital Services Act) and converge with the General Product Safety Regulation, by specifying information requirements to be included in offers through marketplaces. Thus, these provisions respect the enforcement structure between consumer's law (mainly based on the country of destination principle) and the Digital Services Act (based on the country of establishment/ origin principle).
- Chemicals in toys: The following provisions were agreed by the co-legislators:
  - The generic ban of harmful substances in toys will include carcinogenic, mutagenic or toxic for reproduction substances (CMRs), endocrine disruptors, respiratory sensitisers and substances toxic to a specific organ, as proposed by the Commission. In addition, it was agreed to include substances classified as skin sensitisers category 1A in the generic ban, as set out in the Council mandate. This is a limited category of substances, presenting the highest potential for sensitisation, and excluding substances showing a low to moderate frequency of occurrence in humans, or a probability of occurrence of a low to moderate sensitisation rate in humans. Therefore, this addition is acceptable to the Commission. The generic ban relies on the harmonised classification of chemical substances as set out under Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (the CLP Regulation)<sup>1</sup>, as proposed by the Commission.
  - A ban on the intentional use of per- and polyfluoroalkyl substances (PFAS) in toys was included, as included in the European Parliament position, until the universal restriction on PFAS under Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) becomes applicable.
  - A ban on the presence of ten bisphenols for which the European Chemicals Agency (ECHA) recommended regulatory measures, and which are not otherwise banned under other provisions of the regulation. This is acceptable to the Commission as these substances can be harmful for children.
  - All allergenic fragrances will be banned in toys intended for children under 36 months and for toys to be put in the mouth. This provision is acceptable as it targets the younger children; exposure to allergenic fragrances can cause sensitisation and lead to allergy outbreaks.
  - On nitrosamines, the co-legislators agreed to keep different limit values for different types of toys, which are based on the current scientific evidence and

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available testing methods. For heavy metals (lead, cadmium, mercury and chromium vi), the migration limits proposed by the Commission were maintained. In both cases, to facilitate an agreement, the co-legislators requested that the Commission issue a statement indicating that it would request ECHA to provide a new scientific assessment on nitrosamines in toys within 12 months of the entry into force of the regulation and, on heavy metals in toys, within 24 months.

- <u>Transition period:</u> The co-legislators agreed to include a transition period of 54 months.

## 4. CONCLUSION

The Commission supports the results of the interinstitutional negotiations and can therefore accept the Council's position at first reading.

#### 5. DECLARATIONS FROM THE COMMISSION

The Commission has prepared one unilateral declaration which can be found in the appendix.

## **Appendix**

# **Declarations from the Commission**

#### Commission declaration:

"The Commission regularly and systematically evaluates the occurrence of hazardous chemicals in toys, taking into account available scientific evidence, with a view to adapting the limit values or the conditions for the presence of specific chemical substances or mixtures in toys in accordance with Article 46 of Regulation 2025/... on the safety of toys. For that purpose, the Commission will request an opinion from the European Chemicals Agency on the safety of nitrosamines and nitrosatable substances in toys, in view of the overall exposure, within 12 months of the entry into force of this Regulation. For the same purpose, the Commission will request an opinion from the European Chemicals Agency on the safety of lead, cadmium, mercury and chromium vi in toys, in view of the overall exposure, within 24 months of the entry into force of this Regulation."