C/2025/6469

3.12.2025

Statement of the Council's reasons: Position (EU) No 12/2025 of the Council at first reading with a view to the adoption of a Regulation of the European Parliament and of the Council on the safety of toys and repealing Directive 2009/48/EC

(C/2025/6469)

I. INTRODUCTION

- On 28 July 2023, the Commission adopted a proposal for a Regulation of the European Parliament and of the Council
 on the safety of toys and repealing Directive 2009/48/EC (¹).
- 2. The proposal is based on Article 114 of the Treaty on the Functioning of the European Union (TFEU).
- 3. On 5 September 2023, the European Parliament's Committee on Internal Market and Consumer Protection (IMCO) appointed Marion Walsmann (EPP, DE) as rapporteur for the proposal. The Committee on the Environment, Public Health and Food Safety (ENVI) of the European Parliament delivered its opinion on the proposal on 12 February 2024. IMCO voted on its final report on the proposal on 13 February 2024, which was adopted in the plenary on 13 March 2024.
- 4. The European Economic and Social Committee gave an opinion on the proposal on 13 December 2023 (2).
- 5. The Working Party on Technical Harmonisation (Safety of Toys) started the examination of the proposal on 3 October 2023 under the Spanish Presidency. Since then, 19 additional Working Party meetings have taken place under the Spanish, Belgian, Hungarian and Polish presidencies.
- 6. Following the examination of the text under the Belgian Presidency, the Permanent Representatives Committee (hereafter 'Committee') adopted the Council's mandate on 15 May 2024.
- 7. The interinstitutional negotiations started with the first trilogue on 20 November 2024 under the Hungarian Presidency. Second and third trilogues took place on 18 March and 10 April 2025 respectively. In the last trilogue on 10 April 2025, a provisional agreement was reached between co-legislators.
- 8. The European Parliament's IMCO Committee voted on 26 June 2025 in favour of the agreed text. On 30 June 2025, the Chair of the IMCO Committee addressed a letter to the Presidency indicating that, if the Council adopted its position at first reading in accordance with the agreed overall provisional agreement, she would recommend to the Plenary that the Council's position be accepted, subject to legal-linguistic verification, at Parliament's second reading.

II. OBJECTIVE

9. The overall objective of the proposal is to further improve the protection of children from potential risks in toys, in particular from harmful chemicals, and to strengthen enforcement, by requiring, among other things, that all toys to have a Digital Product Passport.

III. ANALYSIS OF THE COUNCIL'S POSITION AT FIRST READING

10. The Council's position at first reading contains the following main elements, on which agreement has been reached between the co-legislators:

⁽¹⁾ ST 12234/23 + ADD 1-5

⁽²⁾ ST 17090/23

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11. Detailed provisions on the obligations of fulfilment service providers and online marketplaces were added to the text. These provisions are in line with other Union acts like Construction Products Regulation and Digital Services Act, respectively.

- 12. The provisions on Digital Product Passport (DPP) are aligned with the Regulation on ecodesign requirements for sustainable products. The Commission is tasked to provide assistance to the SMEs in order to assist them in complying with the new requirements linked with the DPP. Furthermore, where the DPP includes all relevant information required under certain sectoral product legislation, the manufacturers are deemed to comply with the obligation to draw up an EU declaration of conformity under those sector specific rules.
- 13. The mental health aspect as proposed by the Commission in Article 5(2) was deleted from the essential safety requirements. Article 25 was supplemented with a requirement that the safety assessment must take into account the vulnerabilities of children, when the assessment is made on toys falling under the AI Act, the Cybersecurity act or the Radio Equipment Directive.
- 14. The scope of the Regulation was clarified by specifying that certain books and paintball equipment should not be considered as toys.
- 15. Particular safety requirements were clarified, notably as regards the level of sound that the toys may emit, the toys containing magnets or magnetic parts, and toys containing batteries.
- 16. On chemicals properties of toys:
 - a) the presence of certain chemicals in toys is prohibited:
 - (i) skin sensitizers category 1A;
 - (ii) per- and polyfluoroalkyl substances (PFAS) until the general restrictions under the Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) or the Regulation on persistent organic pollutants (POPs) will come into force;
 - (iii) certain allergenic fragrances;
 - (iv) ten bisphenols, which were added to a new Part D of the Appendix of Annex II. This Part D will also be under the Commission's empowerment to amend the Appendix by a delegated act;
 - (v) nitrosamines and nitrosatable substances where the migration of those substances is higher than the migration limits set out in the provisional agreement;
 - b) migration limits were established for four additional monomers (vinyl chloride, acrylonitrile, styrene, butadiene);
 - c) the Commission is empowered to amend the parts A, B and D of the Appendix of Annex II, including the provisions on nitrosamines and on the four heavy metals. These delegated powers of the Commission are spelled out in separate paragraphs for nitrosamines and the heavy metals, obliging the Commission to request an opinion from the European Chemicals Agency (ECHA) first.
- 17. The Commission was empowered to adopt delegated acts for the establishment of technical requirements for the digital product passport. The text lays down what those technical requirements should cover and specifies the date of application of such delegated act, which shall not be earlier than 18 months from its entry into force.
- 18. The text includes the non-opinion clause for all implementing acts.
- 19. The Commission is requested to present the evaluation report by a date set at 38 months after the date of application of the Regulation. The content of the review is also clarified in the Regulation.
- 20. The date of application of the new Regulation was set at 54 months after its entry into force.

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IV. CONCLUSION

21. The Council's position at first reading fully reflects the compromise reached in the negotiations between the European Parliament and the Council, facilitated by the Commission.

22. The Council therefore believes that its position at first reading is a balanced representation of the outcome of the negotiations and that, once adopted, the Regulation on the safety of toys will contribute to further improving the protection of children from potential risks in toys, in particular from harmful chemicals, and strengthening enforcement, by requiring, among other things, that all toys to have a Digital Product Passport.