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EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT

Accompanying the document

PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the safety of toys and repealing Directive 2009/48/EC

{COM(2023) 462 final} - {SEC(2023) 297 final} - {SWD(2023) 268 final} - {SWD(2023) 269 final}

Executive Summary Sheet
Impact assessment on a proposal for a regulation of the European Parliament and of the Council on the safety of toys
A. Need for action
What is the problem and why is it a problem at EU level?
The evaluation of the Toy Safety Directive (TSD)[1] (the Evaluation) identified a number of deficiencies in the TSD in ensuring a high level of protection of children from possible risks in toys, and in particular from risks posed by harmful chemicals. The Evaluation also concluded that there remain many non-compliant and unsafe toys on the EU market.
What should be achieved?
This initiative should achieve a higher level of protection of children from the most harmful substances and reduce the number of non-compliant and unsafe toys on the EU market.
What is the value added of action at the EU level (subsidiarity)?
The TSD harmonises toy-safety rules across Member States based on Article 114 TFEU. Any changes to the scope or requirements of such a directive must be made at EU level to avoid: (i) distorting the market; (ii) creating barriers to the free movement of products; or (iii) undermining the protection of human health and well-being.
B. Solutions
What are the various options to achieve the objectives? Is there a preferred option or not? If not, why?
In addition to the baseline of no action, the impact assessment identifies three policy options (POs) to address the two problems identified, the first problem being the need to better protect children from harmful chemicals, and the second problem being the many non-compliant/unsafe toys on the EU market. To strengthen the requirements to protect children from harmful chemicals: • **PO1a** would empower the Commission to add and amend limit values for chemicals in any toy; • **PO1b** is similar to PO1a but also includes generic bans for the most harmful chemicals in toys, allowing derogations; • **PO1c** is similar to PO1b but would not allow derogations to the generic bans. To reduce the many non-compliant and unsafe toys: • **PO2a** would extend the requirement for third-party conformity assessment to: (i) toys for children under the age of 3; (ii) toys to be put in the mouth; and (iii) toys which are chemical mixtures; • **PO2b** would require the compliance documentation to accompany the product digitally, relying on the product passport under the Ecodesign for Sustainable Products Regulation (ESPR)[2], and would also require this product passport to be presented at customs; • **PO2c** would combine the requirements of PO2a and PO2b. The preferred option is **PO1b** together with **PO2b**. **PO1b** would significantly improve children's protection from harmful substances while limiting the negative impacts for industry by providing for derogations to generic bans. **PO2b** would ensure that toys presented at customs without the product passport would be automatically prevented from being released for free circulation. In addition, there would be significant efficiency gains for market surveillance authorities when inspecting toys. Thus PO2b would have the potential to significantly reduce the number of non-compliant toys on the EU market. Other policy options that included third-party conformity assessment were not considered to be as effective or efficient; it was assessed that they would increase costs for compliant manufacturers while not leading to a significant reduction of non-compliant toys.

[1] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/1852-Evaluation-of-the-Toy-Safety-Directive.

[2] Proposal for a Regulation of the European Parliament and of the Council establishing a framework for setting ecodesign requirements for sustainable products and repealing Directive 2009/125/EC of 30 March 2022, COM(2022) 142 final.

What are different stakeholders' views? Who supports which option?

Industry stakeholders supported PO1a but not PO1b, and strongly opposed PO1c. Industry was also opposed to PO2a, but supported the digitalisation of compliance information in PO2b. Member States expressed clear support for strengthening the requirements for chemicals, both with specific limit values and with additional generic prohibitions for certain substances (PO1a and PO1b). They supported PO2b. They also supported PO2a, but to a lesser extent. Consumers favoured PO1b and PO1c. Consumers also favoured introducing the product passport (PO2b) as well as the extension of the requirement for third-party conformity assessment (PO2a and PO2c).

C. Impacts of the preferred option

What are the benefits of the preferred option (if any, otherwise main ones)?

The impact assessment considers that PO1b would have considerable **health benefits (between EUR 240 million and EUR 1.2 billion per year) in terms of avoided health damage for endocrine disruptors alone**. PO2b would lead to significant efficiency gains for market surveillance authorities. Moving to **digital information could lead to savings of between EUR 2.62 million and EUR 3.93 million (EUR 3.275 million on average) per year for industry**. PO2b would also lead to **savings for industry in dealing with inspections** by market surveillance authorities that could range from **EUR 13 million to EUR 20 million per year**. Both options combined would improve the protection of children and reduce the number of non-compliant and unsafe toys; thus improving the functioning of the single market and the competitiveness of industry.The savings from moving to digital information of between EUR 2.62 million and EUR 3.93 million per year were considered as administrative savings within the scope of the 'one in, one out' approach.

What are the costs of the preferred option (if any, otherwise the main ones)?

The generic prohibition could affect a significant number of toy models that would need to be subject to product adaptations or which could no longer be made available, but derogations would limit this impact. PO1b could result in total incremental one-off adjustment costs associated with **product redesign and redevelopment of an additional EUR 23.5 to EUR 396.66 million**. **Yearly testing** costs could **increase compared to the baseline by around EUR 7.31-11.70 million**. In terms of products that could no longer be made available, based on EU industry turnover, **this option could affect EUR 249-367 million worth of products**[3]. This is not expected to lead to a direct market contraction of that size due to manufacturers shifting resources and production to alternative toys as well as consumers buying alternative toys. The costs of requesting derogations could range between EUR 100 000 to EUR 300 000 per year. PO2b could lead to **EUR 18 million of one-off administrative costs and subsequent costs of EUR 10.5 million per year for industry**. These costs, together with the costs for requesting derogations were accounted for as administrative burden to be offset as part of the 'one in, one out' approach.

What are the impacts on SMEs and competitiveness?

PO2b would allow SMEs to reap the benefits of the digital age. It would also potentially reduce the burden faced by both SMEs and larger companies. PO1b and PO2b would have synergistic impacts in improving competitiveness. Although PO1b would impose costs on industry to comply with new requirements on chemical substances, it would be accompanied by effective measures under PO2b to significantly reduce unfair competition from non-compliant toys. This would help preserve the competitiveness of compliant businesses in the toy industry. Without PO2b, PO1b could lead to more rogue traders benefiting from selling non-compliant (and often cheaper) toys.

Will there be significant impacts on national budgets and administrations?

Although Member States may face some adaptation costs to adjust to the product passport, these should be already incurred within the ESPR. Having the compliance information readily available will lead to significant efficiency gains and savings for market surveillance authorities.

Will there be other significant impacts?

No other significant impacts have been identified.

[3] Based on provisional EU industry turnover of EUR 6.56 billion for 2020.

Proportionality?
The preferred option does not exceed what it is needed to achieve the objectives. The most harmful substances will be subject to generic bans in toys, but derogations will be possible. The product passport will lead to initial costs but also generate savings for industry and efficiency gains for authorities. It will significantly reduce the number of non-compliant toys on the EU market thereby strengthening the competitiveness of industry.
D. Follow-up
When will the policy be reviewed?
The new regulation will be evaluated after 5 years.