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To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2023) 270 final
Subject:	REGULATORY SCRUTINY BOARD OPINION 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

Delegations will find attached document SWD(2023) 270 final.

Encl.: SWD(2023) 270 final

EUROPEAN COMMISSION

Brussels, 28.10.2022
SEC(2023) 297 final

REGULATORY SCRUTINY BOARD OPINION

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}
{SWD(2023) 268 final} {SWD(2023) 269 final} {SWD(2023) 270 final}

EUROPEAN COMMISSION
Regulatory Scrutiny Board

Brussels,
RSB/

Opinion

Title: Impact assessment / Revision of the Toy Safety Directive

Overall opinion: POSITIVE

(A) Policy context

The Toy Safety Directive aims to ensure that toys marketed in the EU are safe and to allow the free movement of toys in the internal market. The Directive lays down safety requirements for toys, while harmonised standards set more specific requirements or processes. The use of standards is voluntary. Manufacturers have to demonstrate that toys conform to the safety requirements imposed by the Directive, via self-verification or by third party verification in certain cases. The Directive has been amended several times to adapt requirements on chemicals to the latest technical and scientific developments.

An evaluation found shortcomings in ensuring a high level of protection of children, in particular from risks posed by harmful chemicals. The enforcement of the Directive is not fully effective, resulting in a high number of non-compliant and unsafe toys on the market. The Directive is also not adapted to address new risks posed by digital technologies, but this should be addressed by new and upcoming legislation.

This initiative aims to ensure protection of children against the most harmful chemicals and to reduce the number of non-compliant and unsafe toys on the market.

(B) Summary of findings

The Board notes the written reply submitted ahead of the meeting and the commitments to make changes to the draft report.

The Board gives a positive opinion. The Board also considers that the report should further improve with respect to the following aspects:

(1) The report does not provide sufficient information about the process to grant derogations for the most harmful chemicals under the preferred option. It does not explain how this process will ensure that children's safety is not compromised.

(2) The report is not sufficiently clear about the robustness of the cost and benefit estimates. It does not explain sufficiently why granting derogations does not have any impact on the expected health benefits.

This opinion concerns a draft impact assessment which may differ from the final version.

Commission européenne, B-1049 Bruxelles - Belgium. Office: BERL 02/352. E-mail: regulatory-scrutiny-board@ec.europa.eu

(C) What to improve

(1) The report should provide additional information about the scientific assessment to be carried out by the European Chemicals Agency to grant derogations for harmful substances. It should discuss to what extent this approach is future-proof in view of the experience with certain substances, which new scientific knowledge found more toxic than known before. The report should also consider the expected costs of requesting and assessing derogations under the preferred policy option.

(2) The report should better explain the evidence base, reliability and robustness of the estimates of costs to businesses. In particular, it should explain why the industry would bear high costs in case derogations are not allowed, considering the low number of derogations on Carcinogenic, Mutagenic or toxic for Reproduction substances having been requested and granted under the current Directive. It should also clarify how the business-as-usual costs are taken into account in the estimates.

(3) The report should clarify the analysis of the expected health benefits. It should better explain the methodology used (in particular, whether the estimates are only based on the value of the avoided health damage from exposure to endocrine disruptors) and what the limitations of these estimates are. It should also explain why the overall health benefits for the options with derogations and without are quantitatively the same given that a derogation could potentially allow for minimum exposure to a specific substance.

(4) The report should further elaborate on the articulation between this initiative and other related proposals. It should clarify that this initiative builds on the forthcoming inclusion of new hazard classes in the Classification, Labelling and Packaging Regulation but is independent from the revision of the REACH Regulation, the revision of the Union Customs Code and the proposal for a Regulation on Ecodesign for Sustainable Products. It should also clarify the role of the existing CE label in this initiative.

(5) The report should explain how a Digital Product Passport under the preferred option would address the problems related to an exponential increase in small individual parcels containing toys and the incorrect and questionable quality of the EC declaration of conformity.

The Board notes the estimated costs and benefits of the preferred option in this initiative, as summarised in the attached quantification tables.

Some more technical comments have been sent directly to the author DG.

(D) Conclusion **The DG may proceed with the initiative.** **The DG must take these recommendations into account before launching the interservice consultation.** **If there are any changes in the choice or design of the preferred option in the final version of the report, the DG may need to further adjust the attached quantification tables to reflect this.**

Full title	Proposal for a Regulation of the European Parliament and of the Council on the safety of toys
Reference number	PLAN/2021/11623
Submitted to RSB on	29 September 2022
Date of RSB meeting	26 October 2022

ANNEX – Quantification tables extracted from the draft impact assessment report

The following tables contain information on the costs and benefits of the initiative on which the Board has given its opinion, as presented above.

If the draft report has been revised in line with the Board's recommendations, the content of these tables may be different from those in the final version of the impact assessment report, as published by the Commission.

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
Direct benefits		
Improved well-being and health	Total amount not quantifiable with precision but generated from the improved protection from harmful chemicals and the reduction of non-compliant toys on the market. Estimates €240 million to €1.2 billion per year materialising within 30 years at least	Consumers and in particular children
Efficiency gains in market surveillance and customs controls	Facilitation of checks for market surveillance authorities leading to lower costs per inspection, generated by the DPP, as the information will be readily available. Automated customs controls will ensure more efficient checks at the border of toys. Estimated increase of inspections by a maximum of 2500- 5000 per year.	Market surveillance authorities Customs authorities
Efficiency gains in providing compliance information	Savings generated from digitalisation of the compliance information and the possibility to quickly update it, which could range from € 2.62 million to € 3.93 million per year. There will also be savings from dealing with inspections on products by market surveillance authorities; estimates range from € 13 million to € 20 million	Businesses
Indirect benefits		
Competitiveness in the Single Market	Total amount not quantifiable but generated by the introduction of the DPP with compliance information and its verification at customs.	Businesses
Administrative cost savings related to the 'one in, one out' approach*		
direct	Savings in the provision of compliance information digitally, which could range from € 2.62 million to € 3.93 million per year. Savings from dealing with inspections by market surveillance authorities which could range between € 13 million and € 16 million in case inspections remain at the same levels or increase only slightly, or even up to € 20 million per year in case of increased number of inspections.	Businesses

II. Overview of costs – Preferred option							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent
Action (a)	Direct adjustment costs	N/a	N/a	€23.5m to €396.66m in product adaptations	€7.31m to €11.70m per year in increased testing	N/a	N/a
	Direct administrative costs	N/a	N/a	€18m on setting up the DPP	€10.5m yearly costs for DPP	N/a	N/a
	Direct regulatory fees and charges	N/a	N/a	N/a	N/a	N/a	N/a
	Direct enforcement costs	N/a	N/a	N/a	N/a	N/a	N/a
	Indirect costs	N/a	N/a	€249.21m to €367.25m worth of toys that could no longer be made available on the market	N/a	N/a	N/a
Costs related to the 'one in, one out' approach							
Total	Direct adjustment costs	N/a	N/a	€ 23.5m to €396.66m	€7.31m to €11.70m per year		
	Indirect adjustment costs	N/a	N/a	€249.21m to €367.25m worth of toys	n/a		
	Administrative costs (for offsetting)	N/a	N/a	€18m	€10.5m per year		