



An Roinn Fiontar,
Trádála agus Fostaíochta
Department of Enterprise,
Trade and Employment

Public Consultation on EU Proposal for a Regulation on the Safety of Toys and Repealing Directive 2009/48/EC

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Background

Toys are currently regulated by Directive 2009/48/EC¹ on the safety of toys (the Toy Safety Directive). This Directive lays down the safety requirements that toys must meet in order to be placed on the EU market, whether they are manufactured in the EU or in non-EU countries. At the same time, the Directive aims at ensuring the free movement of toys within the internal market.

The European Commission conducted an evaluation² of the Directive and identified several deficiencies that have emerged during the practical application of the Directive since it was adopted in 2009. The evaluation identified certain shortcomings in ensuring a high level of protection of children from possible risks in toys, in particular from risks posed by harmful chemicals. The evaluation concluded that the Directive was generally effective in protecting children when playing with toys, however it identified two main issues. The first identified that there are certain shortcomings in ensuring a high level of protection of children from possible risks in toys, from risks posed by harmful chemicals. The second identified is that the enforcement of the Directive lacks effectiveness, in the context of online sales, and that there remain many unsafe toys on the Union market.

¹ [Directive 2009/48/EC on the safety of toys \(europa.eu\)](#)

² [European Commission Evaluation on Directive 2009/48/EC](#)

Objectives of the Proposal

Building on the existing rules, this proposal updates the safety requirements that toys must meet to be marketed in the EU, whether they are manufactured in the EU or elsewhere. More specifically, the proposal will:

- **Increase protection from harmful chemicals:** The proposal not only maintains the current prohibition of substances that are carcinogenic, mutagenic or toxic for reproduction (CMRs), but it also prohibits the use of other harmful chemicals in toys. The proposal targets chemicals that are particularly harmful for children. For instance, it will prohibit the use in toys of chemicals that affect the endocrine system (endocrine disruptors), and chemicals affecting the respiratory system or are toxic to a specific organ.
- **Strengthen enforcement:** The proposal aims to ensure that only safe toys will be sold in the EU. All toys will be required to have a Digital Product Passport, which will include information on compliance with the proposed Regulation. Importers will have to submit digital product passports for all toys at the EU borders, including for those sold online. A new IT system will screen all digital product passports at the external borders and will identify the shipments that need detailed controls at customs. National inspectors will continue to be responsible for carrying out checks on toys. In addition, if there are unsafe toys presenting risks not clearly foreseen by the Regulation, the proposal ensures that the Commission or Market Surveillance Authority has the power to require that these toys are taken off the market.

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The main objectives of this regulation are to ensure the highest level of safety for children, and to enable the free circulation of toys in the EU. The Commission's proposal for a Toy Safety Regulation, sets out the essential requirements for toys with the general safety requirement in that toys must not jeopardise the health and safety, including psychological well-being and cognitive development, of children.

The Department of Enterprise, Trade and Employment recommends stakeholders visit the European Commission website¹ which provides further information on the proposal.

¹[Proposal for a Regulation of the European Parliament and of the Council on the safety of toys and repealing Directive 2009/48/EC](#)

Breakdown of the Proposed Regulation

This Regulation contains 10 Chapters and 56 Articles.

CHAPTER I - GENERAL PROVISIONS

This Chapter sets out the subject matter, scope of the proposal and the main terms used in the proposed Regulation. It sets out the definitions for the value chain, key stakeholders and clarifies product requirements and warning labels for toys.

CHAPTER II - OBLIGATIONS OF ECONOMIC OPERATORS

This Chapter sets out the obligations of manufacturers, importers, and the distributors. The Chapter also outlines the responsibilities of the authorised representative and of the economic operators.

CHAPTER III: CONFORMITY OF TOYS

This Chapter outlines the presumption of conformity of toys which are in conformity with harmonised standards. It also outlines the common specifications and the rules and requirements for affixing the CE marking on toys.

CHAPTER IV: PRODUCT PASSPORT

This Chapter sets out the requirements and technical design for manufacturers to create a Digital Product Passport. It also confirms the operation of the product passport, the central registry and the customs control requirements relating to the product passport.

CHAPTER V: CONFORMITY ASSESSMENT

This Chapter outlines the safety assessment and conformity assessment procedures which manufacturers must adhere to. It also sets out the obligation of manufacturers with respect to the technical documentation to ensure the toy complies with the essential safety requirements.

CHAPTER VI: NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

This Chapter sets out the requirements of notifying authorities and of notified bodies. It further details the operational obligations and the presumption of conformity of notified bodies, the application, and the procedure for the notification process.

CHAPTER VII: MARKET SURVEILLANCE

This Chapter details the procedure for dealing with toys presenting a risk at national level. It also refers to the safeguard procedure, the national measures concerning toys which are compliant with the particular safety requirements, but which present a risk, and the Commission action concerning toys that present a risk.

CHAPTER VIII: DELEGATED POWERS AND COMMITTEE PROCEDURE

This Chapter sets out the delegated powers which the Commission can adopt. It also outlines the requests for assessment for the purposes of Article 46(6) and the opinion from ECHA.

CHAPTER IX: CONFIDENTIALITY AND PENALTIES

This Chapter outlines the confidentiality requirements between competent national authorities, notified bodies and the Commission. It also indicates the penalties applicable to infringements of this Regulation.

CHAPTER X: FINAL PROVISIONS

This Chapter sets out the repeal date of the Directive and the transition period for toys placed on the market in conformity with Directive 2009/48/EC. It also refers to the evaluation and review period set out for the Commission and the entry into force of the Regulation.

Questions

Question 1:

What are your views on the scope of the proposed Regulation? In your response, please provide specific details to support your position.

Question 2:

What are your views on the definitions included in the proposed Regulation? In your response, please provide specific details to support your position.

Question 3:

What are your views on the obligations of manufacturers, importers, and distributors proposed in Chapter II?

Question 4:

What are your views on the proposed responsibilities of authorised representatives and economic operators outlined in Chapter II?

Question 5:

What are your views on the digital product passport? In your response, please provide specific details to support your position.

Question 6

If you have any other comments on the proposal not covered in the questions above, including specific suggestions or amendments, please set them out below:

Deadline for Submissions

The deadline for responses is 22nd May 2024. Submissions should be sent to: conspol@enterprise.gov.ie.

When making your submission please provide the name of the individual, firm or organisation, contact details and briefly describe your interest in the subject matter.

Freedom of Information Act 2014 and publication of submissions

The Department will make public on its website all submissions received under this consultation. Your attention is also drawn to the fact that information provided to the Department may be disclosed in response to a request under the Freedom of Information Act 2014. Therefore, should you consider that any information you provide is commercially sensitive, please identify same, and specify the reason for its sensitivity. The Department will consult with you regarding information identified by you as sensitive before publishing or otherwise disclosing it.

General Data Protection Regulation

Respondents should note that the General Data Protection Regulation entered into force in Ireland on 25th May 2018 and it is intended to give individuals more control over their personal data.

The key principles under the Regulation are as follows:

- Lawfulness, fairness and transparency;
- Purpose limitation;
- Data minimisation;
- Accuracy;

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- Storage limitation;
- Integrity and confidentiality, and
- Accountability.

The Department of Enterprise, Trade and Employment is subject to the provisions of the Regulation in relation to personal data collected by it from 25 May 2018. Any personal information which you volunteer to this Department, will be treated with the highest standards of security and confidentiality, strictly in accordance with the Data Protection Acts 1988 to 2018.

Appendix – Reply Forms