EUROPEAN
COMMISSION

Brussels, 28.7.2023
SWD(2023) 268 final

# COMMISSION STAFF WORKING DOCUMENT

## Subsidiarity Grid

*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) 269 final} - {SWD(2023) 270 final}

# Subsidiarity Grid

| 1. Can the Union act? What is the legal basis and competence of the Unions' intended action? |
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| **1.1 Which article(s) of the Treaty are used to support the legislative proposal or policy initiative?** |
| This initiative has the same legal basis as Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys: Article 114 of the Treaty on the functioning of the European Union on the approximation of national rules for the establishment and well-functioning of the internal market. |
| **1.2 Is the Union competence represented by this Treaty article exclusive, shared or supporting in nature?** |
| In the case of internal market, the Union competence is shared according to Article 4(2) of the Treaty on the functioning of the European Union. |
| **2. Subsidiarity Principle: Why should the EU act?** |
| **2.1 Does the proposal fulfil the procedural requirements of Protocol No. 2[1]:**<br>- Has there been a wide consultation before proposing the act?<br>- Is there a detailed statement with qualitative and, where possible, quantitative indicators allowing an appraisal of whether the action can best be achieved at Union level? |
| For the preparation of this proposal, the Commission has consulted national authorities, industry associations, companies (including SMEs), consumer associations and civil society. It has also consulted the Expert Group on Toy Safety. The proposal is based on a comparative impact assessment of a number of policy options, and reflects the option that scored best in terms of economic, social, environmental and health impacts, effectiveness, efficiency and coherence. The proposal will replace Directive 2009/48/EC on the safety of toys. The Evaluation of this Directive[2] concluded on the added value of the Directive in terms of toy safety and the creation of a large internal market for safe toys, the EU added value of the Toy Safety Directive. In particular, without the Directive, Member States could set diverging limit values for chemicals, which would be to the detriment of the internal market. The Evaluation also concluded that all categories of stakeholders welcomed the existence of harmonised safety requirements across the EU, and companies valued the creation of a large market for toys and the simplification of trade as major achievements. This is why the Regulation is considered to maintain the EU added-value of the current Directive. The explanatory memorandum and the impact assessment (chapter 3) contain a section on the principle of subsidiarity. For more details, see question 2.2 below. |
| **2.2 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the conformity with the principle of subsidiarity?** |
| Yes, those documents contain such a justification.<br><br>Both the Impact Assessment and the Explanatory Memorandum recall that regulating at EU level the safety of toys is considered to have added value for all stakeholders, to ensure a high level of protection of children and the free movement of toys within the EU. There was widespread |

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:12016E/PRO/02&from=EN

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

consensus among all interested stakeholders during the consultation process that the issues addressed by the Directive continue to require action at the EU level. In order to ensure the internal market of toys and a high level of protection of children, the safety of toys cannot be addressed at national level. Further, since the Directive fully harmonises the matters it explicitly covers, Member States are not allowed to make changes to the scope, concepts and definitions or other requirements of the Directive: these must therefore be made at EU level. In the absence of a uniform set of rules applicable to toys, manufacturers would be faced with 27 different sets of rules, leading to different levels of protection for consumers and professional users, market barriers and distorted competition among market operators from different Member States.

**2.3 Based on the answers to the questions below, can the objectives of the proposed action be achieved sufficiently by the Member States acting alone (necessity for EU action)?**

The objectives of the proposed action cannot be achieved sufficiently by the Member States acting alone. The problems identified in the impact assessment are widespread across the EU and cannot be solved individually by the Member States. The absence of EU level action would conflict with the objectives of the Treaty. Member States cannot deviate from the provisions of the proposal, as the requirements for making toys available are common across all Member States. Member States are not overstretched in achieving the objectives of the planned measure and are therefore largely supportive for the adoption.

(a) Are there significant/appreciable transnational/cross-border aspects to the problems being tackled? Have these been quantified?

Yes. The current Directive aims at ensuring the free movement of toys by setting common requirements for the safety of toys at EU level. The problems identified in the Evaluation with the functioning of the current Directive must be necessarily addressed at EU level by a revision of the Directive. In particular, the Evaluation found that the Directive did not sufficiently protect children when playing with toys from the risks of the most harmful chemicals. In addition, a high number of non-compliant and unsafe toys can be found in the internal market. Those problems and their impacts were quantified and, where not possible, a qualitative analysis was carried out.

(b) Would national action or the absence of the EU level action conflict with core objectives of the Treaty[3] or significantly damage the interests of other Member States?

Yes, this would be the case, as possible upcoming divergences of measures taken by Member States would disrupt the functioning of the internal market and would lead to different levels of protection of health and safety of children. Different national rules would lead to obstacles to the free movement of toys in the Single Market.

(c) To what extent do Member States have the ability or possibility to enact appropriate measures?

The Treaty establishes the obligation that Member States shall exercise their competence to the extent that the Union has not exercised its competence (Article 2(2) TFEU); by adopting the Toy Safety Directive 2009/48/EU the Union has exercised its competence in the field.
In this framework, the current Directive or the proposal for a Regulation does not make it possible for Member States to deviate from its provisions. On the other hand, the proposal continues to rely on Member States for the enforcement of the Regulation.

(d) How does the problem and its causes (e.g. negative externalities, spill-over effects) vary

[3] https://europa.eu/european-union/about-eu/eu-in-brief_en

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| across the national, regional and local levels of the EU? |
| The problems identified exist everywhere in the EU. The need to better protect children against harmful chemicals should apply equally across the EU, and the lack of adequate provisions in the Directive is common for all EU Member States. Similarly, the high number of non-compliant toys affects all Member States, as toys enjoy free movement within the EU. |
| (e) Is the problem widespread across the EU or limited to a few Member States? |
| The problem is widespread across the EU. It concerns toys which move freely in the internal market. It is therefore relevant for all Member States. |
| (f) Are Member States overstretched in achieving the objectives of the planned measure? |
| No. Member States are largely supportive for the adoption of this legislative proposal. |
| (g) How do the views/preferred courses of action of national, regional and local authorities differ across the EU? |
| Public authorities are of the uniform view that further action is needed and an agreement exists to a large extent about the direction of the proposed measures. |
| **2.4 Based on the answer to the questions below, can the objectives of the proposed action be better achieved at Union level by reason of scale or effects of that action (EU added value)?** |
| Yes. The Evaluation concluded that the added value of having harmonised rules for the making available and placing on the market of toys was uncontested. |
| (a) Are there clear benefits from EU level action? |
| Yes. Regulatory action at EU level ensures the free movement of toys across the single market while providing a high and uniform level of protection of the health and safety of children. |
| (b) Are there economies of scale? Can the objectives be met more efficiently at EU level (larger benefits per unit cost)? Will the functioning of the internal market be improved? |
| By maintaining common requirements under the wider EU regulatory framework applicable to toys, and by strengthening the digital requirements for placing toys on the Union market, the proposal will reduce the regulatory burden on economic operators. Economic operators will be able to make available their toys complying with common requirements across all the Single Market. |
| (c) What are the benefits in replacing different national policies and rules with a more homogenous policy approach? |
| The issues related to toys, in terms of protection of human health and ensuring free movement, have already been harmonised at EU level. A homogeneous policy approach exists. This is why strengthening the requirements on chemical substances and improving the compliance of toys should also be addressed at EU level. Therefore, these elements cannot be addressed at national level in order to ensure the well-functioning of the internal market and an equal level of human health protection across the EU. |
| (d) Do the benefits of EU-level action outweigh the loss of competence of the Member States |

and the local and regional authorities (beyond the costs and benefits of acting at national, regional and local levels)?

In the absence of a uniform set of rules at EU level applicable to toys, manufacturers would be faced with 27 different sets of rules, leading to different levels of protection for children, market barriers and distorted competition among market operators from different Member States.

Finally, the strengthening of the requirements set out in Directive 2009/48/EC can only be achieved through a legal instrument at EU level. Furthermore, to ensure consistent application of the toy safety rules as well as of its possible subsequent amendments, the Directive should be converted into a Regulation.

(e) Will there be improved legal clarity for those having to implement the legislation?

The proposed Regulation aims at streamlining the requirements for toys concerning the presence of chemical substances and in that respect it aims at improving legal clarity.

**3. Proportionality: How the EU should act**

**3.1 Does the explanatory memorandum (and any impact assessment) accompanying the Commission's proposal contain an adequate justification regarding the proportionality of the proposal and a statement allowing appraisal of the compliance of the proposal with the principle of proportionality?**

The explanatory memorandum mentions that the proportionality of this proposal has been evaluated. The proposal is in the form of a Regulation to replace Directive 2009/48/EC. Given that this Directive is a total harmonisation Directive, Member States no longer have the possibility to add additional requirements for toys. Nevertheless, Member States are required to transpose the regular amendments of the Directive, which in the past has lead to regulatory amendments applying inconsistently across the EU. The regular adaptations of the Directive have proven to be ressource intensive for Member States. This is why a Regulation will allow for a more rapid and coherent application of the legislation adopted at EU level and will establish a clearer regulatory environment for economic operators.

**3.2 Based on the answers to the questions below and information available from any impact assessment, the explanatory memorandum or other sources, is the proposed action an appropriate way to achieve the intended objectives?**

This proposal is an appropriate way to achieve the intended objectives given that they can be better achieved at Union rather than at national level. The proposal is based on a comparative assessment of a number of policy options, and reflects the option that scored best in terms of economic, social, environmental and health impacts, effectiveness, efficiency and coherence.

(a) Is the initiative limited to those aspects that Member States cannot achieve satisfactorily on their own, and where the Union can do better?

Yes, the intended objectives can be better achieved at Union level. The proposed harmonised criteria for toy safety will ensure a high level of protection of children and the free movement of toys within the Union. They will also avoid the emergence of diverging national criteria on the EU's single market. The Regulation will set essential requirements for

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| which the technical specifications will be determined by harmonised standards. |
| (b) Is the form of Union action (choice of instrument) justified, as simple as possible, and coherent with the satisfactory achievement of, and ensuring compliance with the objectives pursued (e.g. choice between regulation, (framework) directive, recommendation, or alternative regulatory methods such as co-legislation, etc.)? |
| The proposal takes the form of a Regulation. The proposed change from a Directive to a Regulation takes into account the Commission's general objective to simplify the regulatory environment and the need to ensure a uniform implementation throughout the Union of the proposed legislation. In addition, the Toy Safety Directive is a already total harmonisation directive, which means that it establishes a high level of safety, and does not allow the Member States to impose different obligations but however requires Member States to transpose the Directive as well as the subsequent regular amendments into national legislation. A Regulation will ensure the consistent application of the toy safety rules as well as any futur amendment to it, and will lead to simplification for businesses and Member States. |
| (c) Does the Union action leave as much scope for national decision as possible while achieving satisfactorily the objectives set? (e.g. is it possible to limit the European action to minimum standards or use a less stringent policy instrument og approach?) |
| The proposed Union action does not exceed what it is needed to achieve the objectives followed. In order to ensure harmonisation with an equivalent level of protection of health and safety of children when playing with toys, as well as the free movement of toys in the Union, it is necessary to set common requirements for toys at EU level. Regulatory action at EU level should lay down EU-wide requirements for ensuring the health and safety of children when playing with toys, and allowing market enforcement at the national level. |
| (d) Does the initiative create financial or administrative cost for the Union, national governments, regional or local authorities, economic operators or citizens? Are these costs commensurate with the objective to be achieved? |
| There will not be significant impacts on national budgets and administrations caused by this Regulation, although Member States will face some adaptation costs to the product passport which is already foreseen in the Commission proposal for a Regulation on Ecodesign for Sustainable Products[4]. Similarly, adapting to the product passport will imply certain costs for businesses, in particular in the beginning, but it will also lead to savings in administrative burden, in particular when dealing with enforcement authorities. |
| (e) While respecting the Union law, have special circumstances applying in individual Member States been taken into account? |
| Not relevant. |

[4] Sustainable products initiative (europa.eu). 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.