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**COMMISSION STAFF WORKING DOCUMENT**  
**EXECUTIVE SUMMARY OF THE EVALUATION**

**of Directive 2009/48/EC of the European Parliament and of the Council on the safety of  
toys**

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## Executive summary

Toys have to be safe when children play with them. The **Toy Safety Directive** (Directive 2009/48/EC) therefore lays down rules to make toys safe, including when they are exposed to children's sometimes 'unforeseeable' behaviour.

At the same time, the Directive ensures the successful functioning of the internal market for toys, worth almost EUR 20 billion a year. The toy industry is dynamic and innovative: around one third of the toys on the market each year have new features or are newly developed.

The Toy Safety Directive has been adapted 12 times since its adoption, resulting most often in strict(er) limit values for hazardous chemicals that might be present in toys, such as for chromium VI, lead, phenol and bisphenol A. There is a focus on chemicals because knowledge about their toxicity evolves more often than knowledge about other hazards in toys; chemicals are more often recognised to be more hazardous than previously known.

This evaluation of the Toy Safety Directive assesses the functioning of the Directive since its entry into force. It is based on the following sources:

- a 2015 external study evaluating the Directive;
- online questionnaires addressed to Member States and stakeholders (a public consultation and a specific consultation of economic operators on the costs caused by the Directive);
- the Member States' reports on the application of the Directive in their national territory; these are due every 5 years, covering 2009–2013 and 2014–2018;
- a study on the Directive's costs and benefits, supplied by the Commission's Joint Research Centre (JRC); and
- several Commission fitness checks and related studies on chemicals legislation, insofar as they refer to toys;
- a 2013 external report on the toy industry prepared on behalf of the Commission;
- knowledge and experience acquired in the Directive's day-to-day management, including from discussions with Member States and stakeholders.

The **effectiveness** of the Toy Safety Directive appears to have improved over that of its predecessor Directive from 1988. This is due in particular to the clarified definition of 'toy', but also to the much larger number of particular safety requirements, notably on chemicals restricted for use in toys.

Despite this, the Directive's effectiveness is deficient in several points, in particular on chemicals. Although specific limit values can be set for any chemicals in toys, these limit values only apply to toys for children under the age of 36 months, and to toys intended to be put in the mouth. Since a chemical's toxicity does not vanish when a child reaches the age of 36 months or just because a toy is not intended to be put in the mouth, the Directive's effectiveness is limited in this regard. Furthermore, the prohibition in principle of chemicals that are carcinogenic, mutagenic or toxic for reproduction (CMR) has a derogation that tolerates their presence in concentrations too high to ensure effective protection according to current scientific knowledge. Similarly, the limit values for nitrosamines, which are often carcinogenic, and for nitrosatable substances, which may generate nitrosamines, are too high. Finally, the tailor-made labelling requirements for specific allergenic fragrances in certain

experimental toy sets cannot be easily updated when the lists of allergenic fragrances are amended.

The Directive's safety requirements for hazards other than chemical hazards have not led to any major discussion with Member States or stakeholders about their effectiveness, so it seems that they can be readily applied in practice. Only the applicability of the requirements for toys for children under 36 months, which manufacturers find indeed challenging, is under almost permanent discussion. Classifying a toy as being for older children avoids the costs for the 'extra slice of safety' that children under 36 months deserve. Market surveillance authorities, however, quite swiftly find consensus, if not agreement, on disputed classifications.

Toy safety standards that the Commission has referenced in the Official Journal appear to have been effective in supporting children's safety. There have been no major incidents involving toys complying with such standards. Also, only very rarely did Member States object to a standard as insufficient.

The Directive's effectiveness with regard to the internal market was highly rated by all stakeholders, although some differences in interpretation and national deviations are still to be resolved. In practice, the market has flourished since the Directive started to apply fully in mid-2013, as demonstrated by the remarkable 60% increase in intra-EU exports of toys since 2012/2013.

In contrast, the effectiveness of market surveillance under the Directive, which lays down just a general obligation to carry out surveillance, is limited. Market surveillance authorities inspect just a few tens of thousands of toys every year, even though the market might consist of billions. Moreover, when authorities select toy samples for inspection, they find approximately one in every three samples as non-compliant with the Directive. However, an improvement in market surveillance can be expected from the Regulation on Market Surveillance and Compliance of Products, applicable as of 2021, with its binding, detailed EU-wide rules.

In terms of **efficiency**, the Toy Safety Directive is generally considered to provide an appropriate balance between costs and benefits. The Directive, which is stricter than its predecessor, imposed one-off costs on manufacturers in particular to adapt to the new manufacturing, testing and documentation requirements. These costs amounted to about 2% of annual turnover, and are recovered over 3 years or less on average. The Directive also generates higher costs at cruising speed due to its higher number of requirements (about 7% higher than in the predecessor Directive) and its regular adaptations (about 1% of annual turnover). Despite the higher costs, the number of toy companies in the EU increased by some 10% within 5 years from mid-2013, when all the requirements of the new Toy Safety Directive became applicable in the Member States.

Quantifying the benefits of the Directive is very challenging. On the one hand, this is due to the non-availability of data for key indicators such as the reduction of accidents and injuries involving toys, but it is also due to many confounding factors, such as manufacturers' decisions to automate production processes or to move to low-wage countries to save costs, which might lead to lower toy prices (or higher profits for manufacturers). Qualitatively

speaking, benefits have been identified in particular in ensuring legal certainty and a level playing field in the internal market, and are considered to outweigh the costs.

The Toy Safety Directive's **relevance** is generally recognised with regard to the safety of toys, in particular given that dangerous toys continue to appear on the market; however, technical and scientific developments are not taken up sufficiently quickly. With regard to trade across the EU, the Directive is acknowledged as successfully enabling the free movement of toys. As the Directive is focused on the protection of (physical) health and safety, it does not cover internet-connected toys, which may also harm children's privacy and security. Specific action on internet-connected devices, including toys, is being taken instead under the Radio Equipment Directive.

The Toy Safety Directive provides for only a general reporting obligation for Member States. It does not identify the indicators and related data needs for future monitoring and evaluation that could help draw a detailed picture of the Directive's effects or identify impediments to its functioning. As a consequence, the available data are often incomplete or not representative and, therefore, not always comparable. Future data collection and monitoring on toy safety could thus be better harmonised to ensure consistency in the Member States' reports and to enable meaningful comparisons between the data collected.

The **coherence** of the Directive with other EU or national legislation appears to be ensured, with the exception of the stricter limit values for the (carcinogenic) nitrosamines and nitrosatable substances in one Member State, which the Commission has however acknowledged as being justified.

Finally, the **EU added value** of the Toy Safety Directive, stemming from it being a 'maximum harmonisation' directive, is clearly acknowledged. This EU added value is visible in particular in its harmonising effect on health and safety requirements for toys and the large, seamless market for toys that it creates throughout the EU.