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#### COVER NOTE

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From: Secretary-General of the European Commission,  
signed by Mr Jordi AYET PUIGARNAU, Director

date of receipt: 9 September 2016

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of  
the European Union

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Subject: COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY  
OF THE IMPACT ASSESSMENT Accompanying the document Proposal  
for a Council Directive amending, for the purpose of adapting to technical  
progress, Annex II to Directive 2009/48/EC of the European Parliament  
and of the Council on the safety of toys, as regards lead

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Delegations will find attached document SWD(2016) 289 final.

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Encl.: SWD(2016) 289 final



Brussels, 9.9.2016  
SWD(2016) 289 final

**COMMISSION STAFF WORKING DOCUMENT**  
**EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT**

*Accompanying the document*

**Proposal for a Council Directive amending, for the purpose of adapting to technical progress, Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards lead**

{COM(2016) 560 final}  
{SWD(2016) 290 final}

## Executive Summary Sheet

Impact assessment accompanying the document Proposal for a Council Directive amending, for the purpose of adapting to technical progress, Annex II to Directive 2009/48/EC of the European Parliament and of the Council on the safety of toys, as regards lead

### A. Need for action

#### Why? What is the problem being addressed?

Lead is particularly toxic. According to the European Food Safety Authority (EFSA) in 2010, lead has no safe threshold in humans. The 3 limits for lead in toys, of 2009 (Toy Safety Directive 2009/48/EC; TSD), therefore have to be strengthened.

Market monitoring studies in 2010 and 2011 in Germany (almost 2 500 samples) showed that most toys already complied with strengthened limits, except finger paints, colour pencil leads and water paint tablets, possibly due to contaminated raw material. These results were confirmed by Sweden.

#### What is this initiative expected to achieve?

This initiative will adapt the lead limits in the TSD to latest scientific knowledge. It will thus maintain

- the high level of protection of children regarding a possible presence of lead in toys: All children in the EU under 14 years of age (73 million), but primarily children under 3 (16 million) who are most vulnerable and who particularly mouth toys and ingest toy material.
- the Single Market for toys, since the TSD applies throughout the EU.

#### What is the value added of action at the EU level?

This initiative will maintain a high level of protection, block possible action of single Member States (MS) to establish national limits, and eliminate the existing diverging limit in Germany.

### B. Solutions

#### What legislative and non-legislative policy options have been considered? Is there a preferred choice or not? Why?

Baseline option: No strengthening of the 3 limits in the TSD. Other options: Voluntary agreements with(in) industry to reduce lead in toys, labelling of contaminated toys, strengthening all 3 limits, strengthening with exemptions for certain toys or (certain parts of) industry. **Preferred option:** strengthening all 3 limits: In agreement with science, best protection of children, equal treatment of economic operators.

#### Who supports which option?

Strengthening all 3 limits was supported by 17 MS, 9 MS favoured strengthening but with less strict limits (2 MS not represented), as did industry. - Options with exemptions were discarded because of the health risks for children and unequal treatment of economic operators.

### C. Impacts of the preferred option

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

Health benefits of the preferred option: EUR 836 million for avoiding behavioural and attention problems (ADHD) and EUR 1 176 million for avoiding reduced intelligence in children. (No adding up!)

Economic benefits can be anticipated for test laboratories: More testing of toys and toy raw materials.

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

The preferred option could lead to 662 lost jobs, equivalent to EUR 8,5 million, and to a loss of EUR 89 million of production value: Thus total up to EUR 97,5 million.

#### How will businesses, SMEs and micro-enterprises be affected?

Only the industry producing toys with contaminated raw materials could be affected (6,5 % of all toy sales in the EU). The EU toy industry consists of over 99 % SMEs.

#### Will there be significant impacts on national budgets and administrations?

No.

#### Will there be other significant impacts?

No.

<b>D. Follow up</b>
<b>When will the policy be reviewed?</b>
Upon new scientific knowledge.