



EUROPEAN COMMISSION
Impact Assessment Board

Brussels,
D(2013)

Opinion

Title **DG ENTR - Impact Assessment on Commission directive amending, for the purposes of adaptation to technical progress, part III of Annex II to Directive 2009/48/EC relating to toy safety (draft version of 12 December 2012)***

(A) Context

The Toy safety Directive 2009/48/EC (TSD) modernised the legal framework for toy safety in the EU. Applicable as of 20 July 2011 (for the chemical requirements a longer transition period has been foreseen, namely 20 July 2013) the TSD will increase the level of safety for toys while ensuring their free movement on the market. However, these limits, adopted in 2009, have been recently invalidated by new scientific evidence. In 2010, the European Food safety Agency (EFSA) concluded that for lead, as a toxic metal, there is no threshold below which exposure to lead has no critical health effects. In non-human primate models, even low-level exposure to lead has caused neurotoxicity (i.e. damage to the nervous system and/or brain), in particular learning deficits. In light of these findings, it is necessary to revise the limit values of lead in toys.

(B) Overall opinion: POSITIVE

The report should be improved in several respects. Firstly, it should describe the regulatory framework more comprehensively and should better explain the systematic process in place at EU level to review the scientific evidence in relation to the health impact of exposure to lead (or other heavy metals). The report should then strengthen the baseline scenario by providing a more robust outlook of the likely evolution of the exposure of children to lead, differentiating toys from other (natural) sources. It should also better explain the risk of market fragmentation. Secondly, the report should present a more complete set of alternative options and strengthen the arguments and evidence provided to justify discarding some of the options at an early stage. Thirdly, the report should ensure that all feasible options are comprehensively assessed and that their underlying calculations are provided. In particular, it should better assess the impacts on SMEs, on competition and on employment on the relevant markets. The report should better compare the performance of options against all the objectives. Finally, the report should provide all relevant stakeholders' views particularly when they are divergent or conflicting. In these instances, the report should explain how their concerns have been taken into account.

In their written communication with the Board DG ENTR accepted to amend the report along the lines of these recommendations.

* Note that this opinion concerns a draft impact assessment report which may differ from the one adopted

(C) Main recommendations for improvements

(1) Better describe the policy context and strengthen the baseline scenario. The report should describe the regulatory framework more comprehensively including: what were the allowed limits before the Toy safety Directive in 2009; coherence with other policies dealing with the use of chemicals (such as REACH); how existing limits in the EU compare internationally. In this regard reference should be made to cases of incidents due to infringement and/or circumvention of existing limits. The report should better explain if there is a systematic process in place at EU level to review the scientific evidence in relation to the health impact of exposure to lead on a regular basis. On that basis the report should enhance the baseline scenario by providing historical trends in lead exposure and a more robust outlook of the likely evolution of the exposure of children to lead, differentiating toys from other (natural) sources taking into account all existing policies in this area and technological developments. It should better explain, and provide relevant examples of the market fragmentation problems that might arise from initiatives being envisaged by Member States. It should also clarify the figures in tables 7 and 10 regarding baseline health costs. Finally, it should modify the problem tree by including the problem consequences and better linking the drivers, problems and consequences to the objectives.

(2) Better design policy options. The report should present a more complete set of alternative options. This may include combining non-legislative elements (e.g. Labelling or soft-law/self-regulation) with legislative options, for instance with respect to particular issues that cannot be addressed via legislative measures (e.g. traditional pens). The report should strengthen the arguments and evidence provided to justify discarding some of the options at an early stage. Particularly, in relation to Options 3a (I) and 3c, given the potentially significant negative impact on the arts & crafts industry and the concerns raised by the industry.

(3) Strengthen analysis of impacts and comparison of options. The report should ensure that all feasible options are assessed in a comprehensive and balanced way and the underlying calculations are transparently presented. Given the uncertainty of the calculations, the report should provide a summary table of the economic and social impacts that also include the worse-case scenario for all options. It should clarify whether production methods that can provide alternatives to lead may have negative impacts on the environment. The report should enhance the assessment of impacts on SMEs, on competition and on employment (e.g. types of jobs, regional distribution) by ensuring conclusions are underpinned and consistent with evidence. Finally, the report should better compare the performance of options against all the objectives.

(4) Better present stakeholders' views. The report should provide all relevant stakeholders' views throughout the report in relation to all key elements of the report, particularly when their views are divergent or conflicting, such as those of the industry. In these instances, the report should explain how their concerns have been taken into account.

Some more technical comments have been transmitted directly to the author DG and are expected to be incorporated in the final version of the impact assessment report

(D) Procedure and presentation

The report should name or label the options presented in a consistent way both in the main text and annexes. It should include a glossary of most commonly used technical terms. It should avoid repetitions and duplication of paragraphs in annexes and main text.

(E) IAB scrutiny process

Reference number	2012/ENTR/017
External expertise used	No
Date of IAB meeting	16 January 2013