EUROPEAN COMMISSION
Impact Assessment Board

Brussels,
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Opinion*

Title **An EU initiative on a revision of Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment**

(draft version of 21 May 2013)

(A) Context

The Commission is considering the revision of its Directive 89/686 on personal protective equipment (PPE). The Directive permits the free movement of PPE in Europe while ensuring a high level of protection for its users. It defines a PPE as "any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards." It envisages three different PPE categories with different regulatory requirements. Problems and policy responses already analysed in the impact assessment on the alignment package are out of the scope of the present report which only focusses on the specific problems affecting the PPE directive and not the horizontal issues addressed by the so-called "New Legislative Framework" (NLF).

(B) Overall opinion: POSITIVE

The report should be improved in a number of respects. First, it should acknowledge upfront the lack of detailed quantitative data while flagging the efforts undertaken to collect data. It should then strengthen the assessment of the problems and their relevance, for instance by making a more extensive use of available data, expert advice and stakeholders' examples. Second, it should clarify how the options under consideration are meant to achieve the objective of simplification. Third, it should strengthen the assessment of benefits and costs for all stakeholders (including SMEs) in order to throw more light on the trade-offs between protection and costs. In particular, the net benefit of extending the PPE Directive to protective gloves for private use should be better substantiated given that private consumers may not be willing to pay a higher price for what could be viewed as a marginal improvement in product safety. Finally, stronger monitoring and evaluation arrangements should be considered in light of the lack of formal evaluation results and detailed quantitative evidence to support the present revision.

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

(C) Main recommendations for improvements

(1) Strengthen the presentation of the problems. The report should acknowledge upfront the lack of detailed quantitative data while flagging the efforts undertaken for their collection. In any case, it should make a more extensive use of available data, expert working group advice and stakeholders' examples to underpin the assessment of the effectiveness and efficiency of the present Directive and the identification of the issues to be addressed. In this context, the report should better distinguish between the problems caused by products which are faulty, products which are non-compliant with existing standards and products which do not offer sufficient protection because of inadequate safety standards. The report should also clarify whether a high share of faulty or counterfeit products and internal market obstacles are considered relevant issues to be addressed. Finally, the report should strive to provide a broad order of magnitude for the selected problems.

(2) Clarify the content of the options. The report should clarify how the options under consideration are meant to achieve the objectives of simplification of conformity assessment procedures and technical file requirements. In so doing, it should show how extending the application of a (simpler) technical file to all categories of PPE and introducing simpler but mandatory renewals for EC type-examination certificates would be compatible with the objective of simplification. Finally, the report should clarify if the different options are considered as "stand-alone" and whether stakeholders suggested alternatives different from the options under explicit consideration.

(3) Strengthen the assessment of impacts and the comparison of the options. The report should provide a better assessment of the trade-offs between protection and costs. To this end, the assessment of impacts should rely more on quantification or, where this may not be possible due to insufficient data, a more evidence-based analysis for all stakeholders (including SMEs). This refers to expected social/health benefits, costs (including newly introduced administrative burdens), irritation factors and final price impacts. In this regard, the net benefit of extending the PPE Directive to protective gloves for private use should be better substantiated given that private consumers may not be willing to pay a higher price for what may be viewed as a marginal improvement in product safety. The report should also better distinguish between impacts on faulty and non–compliant products. The way in which the model developed in annex III is meant to support the analysis should also be clarified. Finally, the report should build upon the enhanced discussion of impacts to strengthen the comparison of options and provide a more conclusive argument on the superior efficiency, as opposed to effectiveness, of the legislative option (given the higher costs of the later). Options should also be systematically compared against the baseline scenario.

(4) Strengthen future monitoring and evaluation arrangements. Given the lack of detailed data and explicit evaluation results, the report should consider strengthening the monitoring framework in view of the objectives, or explain why this is not regarded as necessary. In this context, the role of a future PPE experts working group should be clarified. Similarly, the report should clarify when and how a formal evaluation would take place.

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 clarify the use of the terms "unsafe" and "faulty" products. The summary sheet and the executive summary should be amended as they need to reflect the changes suggested above.

(E) IAB scrutiny process	
Reference number	2011/ENTR/015
External expertise used	No
Date of IAB meeting	19 June 2013