Personal Protective Equipment

Impact Assessment (SWD (2014) 118, SWD (2014) 119 (summary)) of a Commission proposal for a Regulation of the European Parliament and of the Council on personal protective equipment (COM (2014) 186)

Background

This note seeks to provide an initial analysis of the strengths and weaknesses of the European Commission's Impact Assessment (IA) accompanying the above proposal, submitted on 27 March 2014. This is a proposal to revise Council Directive 89/686/EEC of December 1989 which aims to permit the free movement of personal protective equipment (PPE) in Europe while ensuring a high level of protection for its users against risks. PPE is defined as 'any device or appliance designed to be worn or held by any individual for protection against one or more safety hazards'[1]. It ensures protection against any type of hazards e.g. heat, flames, chemicals, flying particles, mechanical, that may occur in different environments, such as work, home, or leisure, and can protect any part of the human body.

This proposal seeks to align the current legislation with the **New Legislative Framework (NLF)**, which is a common framework for EU product harmonization legislation. It refers to provisions which are commonly used in EU product legislation (e.g. definitions, obligations of economic operators and notified bodies, safeguard mechanisms, etc.). New elements have been introduced (e.g. obligations of importers), as they are considered fundamental for improving the safety of products on the market. The alignment with the NLF is seen as a major step in simplifying the current legislation in the EU and providing a more structured and clear legal framework: the obligations of economic operators become clearer and modules for conformity assessment are harmonized with others applied in other EU legislation.[2].

The IA claims that, although the PPE Directive has never been subject to any formal evaluation, all stakeholders have recognized its success in leading to the harmonization of standards and regulations on PPE, in removing barriers to trade and in helping to develop a large European market in PPE[3].

Problem definition

The IA contains a problem tree[4] which clearly indicates the main problems to be:

- Insufficient level of health protection for EU citizens
- Uneven playing field for PPE economic operators
- Complex regulatory environment.

[1] IA, p. 6.
[2] IA, p. 16.
[3] IA, p. 10.
[4] IA, p. 26.

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These are caused by:

- Inadequate product coverage;
- Inconsistent list of products subject to the most stringent assessment procedures;
- Unclear and insufficiently detailed requirements regarding the technical file, validity and content of the certificate, declaration of conformity and basic health and safety requirements (BHSR).

The presentation of the problem definition in the text of the IA itself, however, is rather confused, notably in the way it mixes problems with problem drivers and possible solutions. This is compounded by the lack of consistency between the way it is presented in the main report, on the one hand, and in the Executive Summary, on the other - to the extent that the 'problems' listed in the latter do not always correspond to those identified in the former. In fact, the problems identified in the Executive Summary in particular appear to correspond rather to possible solutions (alignment of the PPE Directive with the NLF, extension of the product coverage; change of health and safety requirements etc.).

In spite of all these inconsistencies in the presentation of problem factors and in order to facilitate understanding, it would seem reasonable to conclude that they appear to be related to:

- the scope of the current PPE Directive (exclusion of certain products for private use which are not currently subject to the established safety and health requirements and conformity assessment procedures for PPE; inconsistencies in the list of products subject to the most stringent conformity assessment procedure (PPE of category III, e.g. PPE ensuring protection against mortal danger or danger that may seriously and irreversibly harm health) (e.g. life jackets);
- impractical or over-complex BHSR (for protection against mechanical vibration, the harmful effect of noise and non-ionizing radiation);
- ineffective or unclear requirements for the technical file, the validity and content of the EC-type examination certificate, and of the EC Declaration of Conformity which hampers the work of the market surveillance authorities and prevent a clear understanding of manufacturers' responsibilities.

Objectives of the legislative proposal

The IA presents a hierarchy of objectives. The *general* objectives of the Commission proposal are:

1. To better protect the health and safety of PPE users;
2. To create a level playing field for PPE economic operators;
3. To simplify the European regulatory environment in the field of PPE.

These general objectives are translated into *specific* and *operational* objectives.

Range of options considered

The Commission examines the potential impact of a limited range of three options, including the option of retention of the status quo.

Option 1 – Status quo, do nothing.

Option 2 - Soft law (non-legislative action). This would include voluntary measures, guidelines, and commonly agreed interpretations of the application of the PPE Directive.

Option 3 - Legislative measures - changing the legal text, (e.g. enlarge the scope of the PPE legislation; extend the list of products subject to the most stringent conformity assessment procedure; delete the unnecessary BHSR requirement; modify the requirements for the technical file; time limit the validity of and improve the requirements for the content of EC-type examination certificate, and require EC Declaration of Conformity for every PPE placed on the market).

The way the Commission presents the policy options (examining all three options for each problem) suggests that combinations of options (e.g. do nothing on one problem, propose voluntary measures for another and adopt legislative measures for others) might be a possibility, although the IA claims that this is not the intention. It would have been clearer if the IA had presented the analysis of impacts for every option, this being the more comprehensible and usual approach adopted, instead of considering all options for every problem individually. Finally, far greater attention is given to the analysis of the likely impact of the preferred option than to the other two.

The preferred option is option 3.

Scope of the Impact Assessment

The IA presents what the Commission considers to be the most relevant social and economic impacts. It does not make any reference to environmental impacts. Social impacts are considered as benefits to health and safety of PPE users. Economic impacts are seen as costs entailed to manufacturers and market surveillance authorities. The costs for manufacturers are considered as both fixed and variable costs.

The IA claims that the assessment of each proposed change is based on a cost-benefit analysis. Benefits refer to health gains and improvements in legal certainty. The Commission explains its methodology and approach in assessing the impacts, clarifying that 'an estimate of the degree of certainty of health effects of the amendments was derived from the number of interviews undertaken and the degree of consistency across responses. Where quantitative estimates were not possible, a qualitative assessment of the likely effect was made based on the interviews'[5]. Despite this description of the methodology, the IA is not transparent on how this has been applied throughout the analysis of impacts. Figures are rarely provided when calculating costs, and when this is the case no explanation is given in the IA itself or its annexes on how these figures were obtained. There is no explanation as to the calculations behind the figures provided.

Costs of the change to manufacturers were compared against the perceived improvements in health. 'Thus, researcher judgement was used to compare the certainty of the health effect against the impact on manufacturer costs, with greater certainty of that effect being given more weight'[6]. When it was not possible to conclude about the value of the intervention based on health effects and costs, the impact of the amendments on legal certainty was also taken into consideration. The situations when this is the case are presented in the IA. None of these steps of the methodology seems to take account of the costs for market surveillance authorities.

Subsidiarity / proportionality

The proposal is based on Article 114 of the TFEU and refers to the proper functioning of the internal market for PPE. It is suggested that actions that could be taken at national level to address the problems might infringe the free movement of PPE. The IA concludes that 'any changes to the scope, procedures or requirements must be carried out at the EU level to avoid distortions in the EU market'[7].

The Explanatory Memorandum of the legislative proposal argues that the proposed changes are proportional and do not go beyond what is necessary. It mentions also that these changes do not bring unnecesary burdens and costs to industry (especially SMEs) and administrations, and that where these 'modification have been identified to have negative impacts, the analysis of the impacts of the option serves to provide the most proportionate response to the problems identified'[8].

No reasoned opinions were received from national parliaments.

[5] IA, p. 31.
[6] IA, p. 31.
[7] IA, p. 24.
[8] Explanatory Memorandum of the proposal, p. 9.

Budgetary or public finance implications

The Explanatory Memorandum of the proposal indicates that there are no implications for the EU budget. The executive summary sheet of the IA states out that this initiative will not have important impacts on national budgets and administrations.

SME test / Competitiveness

The IA, and in particular its cost-benefit analysis, include the impact on SMEs. In the in-depth analysis part of the IA, for the proposed changes dealing with product coverage, the impact on SMEs is systematically considered, together with the impact on cost competitiveness. For example, the impact on SMEs producing oven gloves might not be negligible, but as requirements for this type of PPE (category I) are not demanding, additional costs nevertheless tend to remain relatively low[9]. However, the IA does not indicate precisely the percentage of SMEs producing this or any other type of PPE that might be adversely affected, concluding simply at one point, with regard to bullet and knife resistant PPE producers, that the number of SMEs affected is unclear 'but [that] stakeholders expect that it is only a limited number'[10].

For most of the products that are added to the list of products subject to the most stringent conformity assessment procedure, the IA presents impacts on cost competitiveness, on the capacity to innovate and on international competitiveness as part of economic impacts. Concerning PPE to protect against drowning (life jackets), it seems that additional annual costs for monitoring by Notified Bodies could compete with research budgets and that EC-type certification could cause delay in product development[11]. However, it is argued that for most SMEs in Europe, the annual monitoring costs are still relatively low when compared to the number of lifejackets sold[12].

The changes in the legislative proposal will impact on all manufacturers, including SMEs. The IA argues that excluding SMEs from the proposed changes is not feasible since a large proportion of PPE manufacturers are SMEs. Such an exemption would bring about a much lower improvement of the health and safety of PPE users than intended. Since the PPE sector is part of the health and safety field, this outcome is undesirable. It also argues that an exemption for SMEs could produce a boomerang effect: if PPE put on the market by SMEs were perceived to have a lower level of safety compared to products sold by big producers, this could result in SMEs being excluded from the market.

The IA argues that 'as most of the burdens to SMEs will originate from enhanced conformity assessment procedures, these burdens could be reduced to a reasonable dimension'[13]. It suggests that mitigation measures could be introduced for SMEs when using the services of a Notified Body, such as obligations for Notified Bodies to carry out the conformity assessment in a proportionate manner, adapting their services to the size and structure of the manufacturers.

Simplification and other regulatory implications

The IA claims that the change to a regulation is in line with the Commission's general objective to simplify the regulatory environment and the need for a uniform implementation throughout the Union of the proposed legislation. The alignment to the New Legislative Framework is said to be a major step towards simplification of legislation as harmonized solutions can be applied across the sector. In addition, some of the proposed changes concern the improvement of clarity of the existing Directive.

The Commission proposes to change the legal instrument from the current Directive to a Regulation. It argues that a Regulation does not conflict with the subsidiarity principle and that the PPE Directive 89/686/EEC itself is a total harmonization directive. In the words of the IA, 'Member States are not allowed

[9] IA, p. 37.
[10] IA, p. 43.
[11] IA, p. 39.
[12] IA, p. 40.
[13] IA, p. 47.

to impose more stringent or additional requirements in their national legislation for the placing on the market of PPE. [....] Given this level of harmonisation, which is necessary to avoid obstacles to the free movement of PPE, Member States have almost no flexibility in transposing the Directive into their national law and its content is in many cases reproduced word for word in the national transposition legislation'[14]. In addition, the IA argues that the change to a Regulation will not bring any changes in the regulatory approach. Moreover, it claims that this approach seems to be preferred by stakeholders in order to avoid the risk of 'gold plating' and that it also 'allows manfacturers to work directly with the Regulation text instead of needing to identify and examine 28 transposition laws'[15].

Not all Member States seem to share the view about the change in the legal instrument. While some do see benefits from saving transposition costs, others indicate that, despite direct applicability of a regulation, some national implementation measures and modifications of national legislation would still be necessary. The IA nevertheless concludes that a regulation is the best solution for the sector (even if no other solution seems to have been considered) as it saves trasposition costs for the Member States, allows a more rapid and coherent application and establishes a clearer regulatory environment for economic operators. Neither the IA generally, nor its presentation of the public consultation, indicate any difficulties for economic operators regarding the trasposition laws in the Member States.

Quality of data, research and analysis

Two external studies were carried out, one in 2010, providing an overview of the PPE market and assessing the impacts of the measures proposed, and the other one in 2012, analysing the impacts of the proposed changes on competitiveness. The analysis contained in the IA is mostly qualitative and the application of the methodology for assessing the impacts rather unclear, as explained above.

The IA report could have benefited from a more consistent presentation of the problems and possibly a better description of the root causes which could be logically linked to the objectives and the presented options. With regard to assessment of impacts, the analysis is not always entirely clear, for example, in relation to costs for various stakeholders. In its opinion on the IA, the Impact Assessment Board (IAB) demanded a clearer assessment for costs and benefits, in particular the net benefit of extending the Directive to protective gloves for private use. The IAB argued that private users of PPE might not want to pay a higher price for what they could see as a marginal improvement in safety. This point does not appear to have been addressed convincingly by the IA.

As mentioned above, social impacts are always considered to be linked to benefits of health and safety for consumers, while economic impacts refer to costs entailed to manufacturers. The IA does not assess how consumers might be affected by the rise in PPE prices as a result of increased financial costs for manufacturers.

An in-depth analysis of the impacts for every option, instead of considering all options for every problem individually, would have facilitated comparison and understanding.

As mentioned above, despite direct applicability of a regulation, some national implementation measures and modifications of national legislation would still be necessary. However, the Commission has not examined, either qualitatively or quantitatively, the costs entailed by these changes.

Stakeholder consultation

The IA identifies the PPE actors and stakeholders. One meeting for a selected group of experts and another one of the PPE Working Group members were organized. The public consultation took place between April and June 2011 and 77 responses were received. The IA states that generally all stakeholders support this legislative proposal, with both industry and authorities supporting the clarification and simplification of PPE legislation.

[14] IA, p. 51.
[15] IA, p. 52.

The presentation of stakeholders' views throughout the IA on the different options proposed is a positive aspect of this document.

Monitoring and evaluation

The IA openly recognises that there has been no formal ex post evaluation of the operation of the existing directive and does not seem to explain why. However, the IA states that in order to improve the monitoring and evaluation of this legislative initiative, a systematic reporting on accidents is required within various cooperation mechanisms already established. A standing agenda item will be established in all PPE groups in order for Member States, Notified Bodies and other stakeholders to report on PPE that do not provide an adequate level of protection and on related accidents. Indicators are identified to monitor the reduction of products which do not ensure an adequate level of protection. Complaints addressed to the Commission will also show non-compliance. With the feedback obtained from these mechanisms and according to its smart regulation policy, the Commission will evaluate the effectiveness of this PPE legislation after five to ten years after the date of its application.

Commission Impact Assessment Board

The Commission's Impact Assessment Board (IAB) delivered a positive opinion on a draft version of the IA on 21 June 2013. In its opinion, the IAB highlighted several shortcomings for improvement. These major points included calls for:

- better clarification of the assessment of the problems at stake and their relevance;
- a clearer analysis of how the options presented are meant to achieve the objective of simplification; clarification as to whether the different policy options proposed are considered as 'stand-alone' and are therefore independent one from the other;
- strengthening the assessment of impacts and the comparison of the options;
- stronger monitoring and evaluation mechanisms because of the lack of formal evaluation results and detailed quantitative evidence to support the current revision.

Even if the IA mentions clearly that these recommendations of the IAB have been taken in consideration[16], a number of these points still figure among those made by this initial appraisal, and do not therefore appear to have been fully addressed by the Commission.

Coherence between the Commission's legislative proposal and IA

The legislative proposal of the Commission seems to follow the recommendations expressed in the IA and does not appear to contain substantive elements that have not been addressed by the IA. Some of the monitoring and evaluation indicators referred to in the IA do not seem to appear in the proposal, but are apparently part of the proposed Product Safety and Market Surveillance Package. Moreover, the declared intention in the IA to review the effectiveness of the proposed PPE Regulation after five to ten years of application does not seem to be mentioned.

Conclusions

Overall, the impression is that the IA has made a reasonable attempt to present the issues and to consider likely impacts of the various options. The explanation of the need to align the legislation with the NLF is clear and there is a transparent presentation of stakeholder views throughout. Specific examples are presented in a clearly understandable way. The IA nevertheless has a number of shortcomings. The presentation of the problem definition is confusing and does not provide a clear overview. Nor is it always clear how the described methodology for assessing the impacts has actually been applied in practice. Some of the conclusions reached on the basis of the evidence referred to are not entirely convincing. The IA does not always provide sufficient explanation as to the assumptions made and how impacts were calculated,

[16] IA, p. 6.

particularly in the light of the acknowledged absence of adequate data. While some of the information may well be found in the background studies supporting the IA, some more direct references to these would have been helpful. The arguments presented in favour of the change from a directive to a regulation could have been strengthened. Finally, given the recognition of the lack of a formal ex-post evaluation of the implementation of the current directive, and of the lack of data, the monitoring and evaluation assessment aspect, within the IA and particularly within the legislative proposal itself, might have merited more detailed attention.

This note, prepared by the Ex-Ante Impact Assessment Unit for the Committee on Internal Market and Consumer Protection (IMCO) of the European Parliament, analyses whether the principal criteria laid down in the Commission's own Impact Assessment Guidelines, as well as additional factors identified by the Parliament in its Impact Assessment Handbook, appear to be met by the IA. It does not attempt to deal with the substance of the proposal. It is drafted for informational and background purposes to assist the relevant parliamentary committee(s) and Members more widely in their work.

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This document is also available on the internet at: www.europarl.europa.eu/committees/en/studies.html

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