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**COMMISSION STAFF WORKING DOCUMENT**

**EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT**

***Accompanying the document***

**Proposal for a**

**REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on personal protective equipment**

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**Disclaimer:** This executive summary commits only the Commission's services involved in its preparation and does not prejudge the final form of any decision to be taken by the Commission.

## 1. PROBLEM DEFINITION

Despite the successful functioning of PPE Directive 89/686/EEC, a broad consensus exists among the Member States and other stakeholders that it needs some improvements. This does not involve major changes; however, in light of the experience of the functioning of the Directive, the input to the Public Consultation (2011) and the outcome of the Impact Assessment Study (2010), the following issues will need to be addressed:

– The alignment of the PPE Directive with the New Legislative Framework (NLF);

– The extension of the product coverage of the PPE Directive;

– The addition of some types of PPE to the list of products subject to the most stringent conformity assessment procedure;

– The change of three basic health and safety requirements; and

– The change of the requirements to the technical file, the validity and content of the EC type-examination certificate, and the EC Declaration of Conformity.

Problem 1: Alignment of the PPE Directive with the NLF

Many of the general problems identified by the NLF have also been observed in the context of implementing the PPE Directive (PPE placed on the market that does not ensure an adequate level of protection, problems with the quality of the services delivered by some notified bodies, different practices in the Member States as regards the evaluation and monitoring of notified bodies). A number of manufacturers are also faced with the problem of the legal framework being complex and sometimes inconsistent.

The alignment of the PPE Directive with the NLF responds to the political commitment laid down in Article 2 of the NLF Decision No. 768/2008.

The Impact Assessment Report on the Alignment Package has already examined the different options to give effect to the NLF Decision. Since the options are exactly the same for the PPE Directive, this Impact Assessment Report will not examine these aspects.

Problem 2: The extension of the product coverage of the PPE Directive

There are products on the market that provide for a protective function to the user and fit the definition of the PPE Directive but are not covered by this Directive. Consequently these products are not subject to the safety and health requirements for PPE and, as a result, the level of protection offered by such products is not as high as for PPE. The consumer might believe that she/he is protected against a specific risk when in fact she/he is not. Products protecting against heat, damp and water *designed for private use* are explicitly excluded from the Directive. However these types of products intended *for professional use* are covered. Products that are outside the scope raise safety and health problems. One Member State has identified 150 000 cases of burn at home in the country per year. Half of these burns concern the hands.

The situation also causes problems for the market surveillance authorities. The distinction between professional and private use should not be relevant for placing (identical) products on the market. Market surveillance authorities regularly raise the need to overcome this situation.

Problem 3: The addition of some types of PPE to the list of products subject to the most stringent conformity assessment procedure

PPE is classified by the Directive into three categories that are subject to different conformity assessment procedures. The definitions of categories I and III are accompanied by lists that describe the PPE covered by these categories.

The experience has shown that the list of PPE subject to the most stringent conformity assessment procedure (i.e. PPE of category III) misses PPE that fits the definition of category III, i.e. PPE designed to protect against serious risks. As a consequence there are no regular audits of the production process for this PPE. Therefore in certain fields there is no check of the quality of the actual PPE produced and, by implication, not the same level of safety is provided by this PPE.

The affected types of PPE are: life jackets, bullet-resistant and knife stab-resistant PPE and PPE for protection against cutting by hand-held chain saws, for protection against high pressure cutting and for protection against noise.

Problem 4: The change of three basic health and safety requirements (BHSR)

Experiences in dealing with the BHSR have shown that there are three requirements that include impracticable or confusing elements:

BHSR 3.1.3: for protection against mechanical vibration;

BHSR 3.5: for protection against the harmful effects of noise;

BHSR 3.9.1: for protection against non-ionizing radiation.

For these points the Directive sets out requirements that are either not practicable or confusing for the user or it was shown that it is not possible to fulfil. The manufacturers are faced requirements that are known to be impracticable. The users are affected because the information connected with the PPE is partial, may be irrelevant and may be a potential source of confusion.

Problem 5: The change of the requirements to the technical file, the validity and content of the EC type-examination certificate, and the EC Declaration of Conformity

The market surveillance authorities have to deal with insufficient results of the requirements concerning the above mentioned documents. Their work is hindered due to unclear or ineffective requirements in the Directive for those documents even if their quality and completeness are crucial for the assessment of the compliance of the PPE. Also the manufacturers do not have a clear understanding of their responsibilities. Some requirements for the documents do not reflect the change of the harmonised standards with time and can follow to a potentially non-conformity of the PPE with the Directive. Furthermore the authorities claim that there are problems to collect documents necessary to assess the PPE.

Necessity for public intervention

The EU action in this area is based on Article 114 of the TFEU. The aspects addressed in this context are already regulated by the PPE Directive. This legislation does not however address the identified problems effectively. The study carried out and the conclusions on the options examined have shown that the problems will remain if the Directive is not revised.

## 2. ANALYSIS OF SUBSIDIARITY

The proper and effective functioning of the internal market requires common rules for the design and placing on the market of PPE in order to ensure both the free movement and the health protection and safety of the user.

Actions taken at national level to address the problems may create obstacles to the free movement of PPE. Any changes to the scope, procedures or requirements must be carried out at EU level in order to avoid distortions on the EU market.

In view of the increasing internationalisation of trade, the number of cross-border cases is constantly rising. Coordinated action at EU level can much better achieve the objectives set, and will in particular render market surveillance more effective. Hence it is more appropriate to take action at EU level.

## 3. OBJECTIVES

The overall objectives of this initiative are to better protect the health and safety of PPE users, create a fair level playing field for PPE economic operators and simplify the European regulatory environment in the field of PPE.

The more specific and operational policy objectives are presented in Table 1 below.

**Table 1: Specific and operational policy objectives**

| GENERAL | SPECIFIC | OPERATIONAL |
|---|---|---|
| Better protect the health and safety of PPE users | Ensure high quality of products protecting against high risks including a high quality of their production process | Remove inconsistencies in the list of products subject to the most stringent conformity assessment procedure |
| | Ensure the reliability and high quality of conformity assessment activities carried out by notified bodies | Specify common criteria for the assessment, monitoring and control of NBs to be applied equally throughout the EU |
| | Ensure traceability of products | |
| Create a level playing field for PPE economic operators | Ensure consistency of conformity assessment services carried out by notified bodies | Clarify the requirements for EC type-examination certificates |
| | Improve market surveillance mechanisms and tools | Simplify and clarify the requirements for the technical file |
| | | Require the EC Declaration of conformity to accompany every product |
| Simplify the European regulatory environment in the field of PPE | Ensure consistent application of the legislation | Clarify the scope of the Directive |
| | Ensure the requirements are practicable | Simplify the applicable conformity assessment procedures |
| | | Clarify the requirements set out in ANNEX II |

## 4. POLICY OPTIONS

Three alternative policy options have been considered for each respective problem, i.e.

– the “do nothing” as baseline option;

– the “soft law” option as non-legislative alternative consisting of issuing commonly agreed interpretation on the application of the PPE Directive; and

– the “legislative” option included the change of the legal text.

The analysis of impacts of the above policy options was separately carried out for each of the identified areas of improvement.

## 5. ASSESSMENT OF IMPACTS

The qualitative analysis demonstrated that for all the problem areas the legislative option is the preferred one. As all the described problems are of regulatory nature only the legislative option will result in clarification and legal certainty. Despite the fact that the costs for the legislative option are higher compared to the soft law option the legislative option results in higher benefits as well as in higher legal certainty.

The quantitative data available about PPE and the PPE market is not enough accurate and detailed to provide a clear picture about the market and about the relationship between the different PPE and the legislative provisions. The European Commission services have commissioned two studies and have gathered other information to provide quantitative information as complete as possible.

The assessment of each proposed change is based on its costs and benefits, where the latter includes health benefits, as well as improvements in legal certainty. In the following section the outcome of the in-depth analysis of the legislative option for each problem is presented.

**Product coverage**

The amendment will have a positive impact on the fairness of competition, because self-certification will become mandatory.

Social impact: One advantage of the amendment is that the product labelling and user information will result in more clarity on the purpose of use of the PPE and the content of materials used. The general level of information provided will be improved. Manufacturers as well as market surveillance authorities expect a reduction of products that do not ensure an adequate level of protection between 20% and 50%. No data was available to assess the impact of including oven gloves as PPE. One Member State has identified 150 000 cases of burn at home in the country per year. Half of these burns concern the hands.

Economic impact: The effect in terms of compliance and administrative costs per product is small. These costs can be estimated to be in the order of a few hundred euros per PPE series and will thus have a low impact on costs per unit. Bringing production standards to the highest level in terms of the basic protection of health and safety can entail 10 % to 20% higher production costs for some of the segments of the overall glove market. This cost increase would mostly affect those manufacturers that do not meet the basic requirements at the moment. Products that do not ensure an adequate level of protection can currently reach the market without a clear indication of their quality, and the level playing field is thereby impaired. With the amendment such information should be traceable in the future which will improve the conditions for fair and transparent competition.

**Conformity assessment**

Social impact: The amendment could help to improve compliance of the above mentioned types of PPE by introducing annual monitoring. It provides for extra safeguards for product quality. Annual testing better ensures product and production homogeneity and compliance to basic PPE requirements and relevant product standards. The proportion of PPE with inadequate level of protection will be reduced. The proportion of the reduction depends on the type of PPE and differs from 10 % up to 50 %.

Economic impact: A majority of respondents to the public consultation expect either very modest compliance and administrative costs or none at all. Some respondents expect higher

costs. The main impact would be the need for annual monitoring of the production process. If a quality control system has already been implemented, the costs of adjusting the system for PPE category III audits would be a one-off. Moreover, for most of the affected PPE the costs can be split over a large volume of production, such that per unit costs would not increase much. Positive effects on international competitiveness include the incentive to attain consistent levels of product quality and homogeneity in the production process, for which EU manufacturers are better positioned.

**Basic health and safety requirements (BHSR)**

The objective of all three changes to the BHSR is to remove aspects from the Directive that do not contribute to health and safety. Overall the impact of these changes should be positive as no negative health and safety impacts can be expected given that non-compliance with these requirements cannot be proven at present and, in addition, their removal will lower the costs of producers and Notified Bodies who have hitherto been required to prove that they fulfil them.

**Technical file, EC type-examination certificate, EC Declaration of Conformity**

Social impact: The stakeholders see an advantage with the proposed change as it will either facilitate the assessment of this PPE and will increase the effectiveness of their work or reduce the number of PPE that does not ensure an adequate level of protection by ensuring that older PPE was assessed more regularly. Depending on the type of PPE the stakeholders envisage a reduction of products that do not ensure an adequate level of protection in the order of 1-25 %. The proposed change will improve legal certainty.

Economic impact: The cost of implementing the changes will be marginal for the technical file as manufacturers already have internal production control in place and could easily provide this document. The same applies for the change concerning the Declaration of Conformity. For the time-limitation of the certificates the interviews did not give values for the connected costs. In order to limit the additional burden of the manufacturers for re-certification of their PPE the proposal will provide for a "light" procedure. The cost of a mandatory minimum content of the certificate will be negligible as the Notified Bodies should be dealing with roughly the same content.

## 6. COMPARISON OF OPTIONS

The comparison of the options based on the outcome of the assessment of the options lead to the result that for all problems the legislative measure delivers the most positive impact. For the legislative option the specific objectives are fully met in providing for improvement of the health and safety, legal certainty, consistency in the requirements and the best improvement of the market surveillance work.

## 7. MONITORING AND EVALUATION

In order to improve the basis for monitoring and evaluation of the effectiveness of the PPE legislation, a systematic reporting on accidents with PPE involved will be required within the various cooperation mechanisms already established. In all of the groups on PPE with Commission participation a standing agenda item will be established for reporting on PPE that do not ensure an adequate level of protection and related accidents and Member States, Notified Bodies as well as other stakeholder will be asked to report.

Additional feedback will be obtained from the new or expanded cooperation and information exchange mechanisms provided for by NLF Regulation 765/2008.

Non-compliance will also be detectable through complaints addressed to the Commission.

## 8. CHOICE OF THE LEGAL INSTRUMENT

In line with the Commission policy to simplify the regulatory environment, it is proposed to change the Directive into a Regulation.

The use of a Regulation does not conflict with the subsidiarity principle. This legislation is based on Article 114 TFEU with the objective of ensuring the proper functioning of the internal market for PPE. To achieve this objective, the PPE Directive 89/686/EEC is a total harmonisation directive. Member States are not allowed to impose more stringent or additional requirements in their national legislation for the placing on the market of PPE.

The use of Regulations in the area of internal market legislation, allows, in accordance also with the preference expressed by stakeholders, to avoid the risk of 'gold plating'. It also allows manufacturers to work directly with the Regulation text instead of needing to identify and examine 28 transposition laws.

On this basis, it is considered that the choice of a Regulation is the most appropriate solution for all involved parties as it will allow a more rapid and coherent application of the proposed legislation and will establish a clearer regulatory environment for economic operators.