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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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Commission legislative proposal for a revision of

Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment.

Disclaimer: This report 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.

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EXECUTIVE SUMMARY SHEET

Impact assessment on the revision of Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment (PPE Directive)

A. Need for action

Why? What is the problem being addressed?

All the identified deficiencies of the PPE Directive are of minor significance. Consequently, the Impact Assessment Report deals with the identified issues in a proportionate way. The areas of improvements called "problems" do not involve major changes; however, in light of the experience of the functioning of the Directive, the outcome of the Impact Assessment Study (2010) and the input to the Public Consultation (2011) the following issues will be addressed:

- the alignment of the PPE Directive with the New Legislative Framework (NLF) in line with the political commitment laid down in Article 2 of the NLF Decision No 768/2008/EC;
- 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.

What is this initiative expected to achieve?

The overall objectives of this initiative are to (1) better protect the health and safety of PPE users, (2) create a level playing field for PPE economic operators and (3) simplify the European regulatory environment in that field.

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

The alignment with the NLF Decision No 768/2008/EC is the major step on simplification as it will ensure that harmonised solutions can be applied across the sectors subject to EU product harmonisation legislation. The PPE Directive harmonizes the rules for the placing on the internal market of PPE. The proper and effective functioning of the internal market requires common rules for the design and placing on the market of personal protective equipment in order to ensure both the free movement within the Union and the health protection and safety of user. If actions are taken at national level to address the problems, they may create obstacles to the free movements of PPE. Therefore, any changes to the scope, procedures or requirements must be carried out at EU level in order to avoid distortions on the EU market.

B. Solutions

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

Three alternative policy options have been considered for each of the discussed problems, i.e. 1) the "do nothing" as a baseline option; 2) the "soft law" option as non-legislative alternative consisting of issuing commonly agreed interpretation on the application of the PPE Directive; and 3) as "legislative" options the amendment of the legal text.

Option No. 3) is the preferred choice since only it can appropriately respond to the "problems" identified.

Who supports which option?

In general all stakeholders expressed support for the initiative. Both authorities and industry support the need to simplify and clarify the PPE legislation. There is unanimity on the need to improve market surveillance and

the system for assessing and monitoring notified bodies. The revision of the PPE Directive has been several times subject to discussion at the Member States PPE Working Group that is chaired by the Commission and the Notified Bodies group meetings which have suggested many of the modifications. The majority of the respondents to the Public Consultation (2011) confirmed the envisaged approaches using the legislative option. Alternative proposals for the areas covered were not put forward by interested parties.

C. Impacts of the preferred option

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

All described problems are of regulatory nature. Therefore 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 proposed changes will bring about the following social benefits: the health and safety of the PPE users will increase because the level of protection provided by the PPE will increase and the number of products on the market that do not ensure an adequate level of protection will be reduced (expected percentage of reduction differs for affected PPE from 10% up to 50%). With the clarification also the work of the market surveillance authorities will be supported. Manufacturers will benefit from the higher legal certainty as well as from established level playing field.

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

The costs of the preferred option differ for the affected manufacturers. The extension of the product coverage will entail costs for relevant manufactures in the order of a few hundred euros per product series and will thus have a low impact on costs per unit. The change in the conformity assessment procedures will not entail high costs for the manufacturers that have already quality control systems in place. The changes of the basic health and safety requirements will lower the costs for manufacturers and Notified Bodies. The costs of implementing the changes to the technical file and the EC Declaration of Conformity will be marginal. In case of the changes to the EC type-examination certificate no values for the costs were available. But the proposal will provide for a procedure in order to limit the additional burden of the manufacturers.

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

The proposed changes will be applicable to all types of businesses. Exempting SMEs from the proposed changes in the Directive is not a viable option since a large percentage of PPE manufacturers are SMEs. An exemption would result in a much lower improvement of the health and safety of the users than intended by the revision. Since the PPE sector is part of the health and safety field such an outcome is undesirable.

Will there be significant impacts on national budgets and administrations?

The initiative will not have significant impacts on national budgets and administrations.

Will there be other significant impacts?

The changes to the PPE Directive improve its readability and clarity and are therefore not assumed to have any other significant impacts.

D. Follow up

When will the policy be reviewed?

No decision on the revision of the policy has been made. However it is a common practise to have an evaluation carried out five years after a revised legislation has become applicable.

1. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

1.1. Identification

Lead DG: DG ENTR

Other involved DGs: SG, SJ, DG EMPL, DG SANCO

Agenda Planning/WP Reference: 2011/ENTR/015

1.2. Organisation and timing

Work on the present Impact Assessment (IA) report started in 2010 with the launch of an external study. A steering group was created and met 3 times: on 15 March 2012, 30 August 2012 and 14 November 2012. Representatives of SG, SJ, DG EMPL and DG SANCO were invited. SG and DG SANCO participated in the meetings. DG EMPL sent written contributions.

1.3. Consultation and expertise

Stakeholders, including Member States, manufacturers' federations, notified bodies and representatives from standardisation, have been involved in the IA process from its beginning. The consultation included organising **of meetings for a selected group of experts** as well as **consultation of the Personal Protective Equipment (PPE) Working Group members**[1]. Among others, they were actively involved in the elaboration of the options.

Additionally **a public consultation** was launched and ran between April and June 2011.It collected views and opinions of relevant stakeholders and citizens on various issues that the revision of the PPE Directive (89/686/EEC) might address, such as the appropriateness of the scope of the Directive, the consistency of the conformity assessment procedures, the requirements on the EC type-examination certificate and technical documentation, the reasonability of the basic health and safety requirements and the alignment of the PPE Directive with the New Legislative Framework. Overall 77 responses were received, 74 from the 27 Member States (authorities, enterprises, notified bodies, trade associations, individual citizens), 2 from an EFTA country and 1 from overseas. The replies provided the Commission services with a broader view on the identified policy needs and as such confirmed the envisaged approaches[2]. The Commission's minimum consultation standards were fully met.

In general all stakeholders expressed support for the initiative. Both authorities and industry support the need to simplify and clarify the PPE legislation. There is unanimity on the need to improve market surveillance and the system for assessing and monitoring notified bodies.

The results of the consultation complemented the findings of **an external study** launched and completed in 2010[3]. The study provides an overview of the structure of the personal protective equipment market as well as it assesses the impacts of the proposed measures.

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1 The PPE Working group is chaired by the Commission with the participation of the Member States and European stakeholders (industrial associations, standardisation, Notified Bodies).

2 A report on the results is available at http://ec.europa.eu/enterprise/sectors/mechanical/files/ppe/pc-report_en.pdf

3 See http://ec.europa.eu/enterprise/sectors/mechanical/files/ppe/rev-study-assess-part1_en.pdf (part 1 on market assessment) and

In 2012 **another complementary study** was carried out. It focused on analysing the competitiveness impacts of the envisaged changes[4].

1.4. Scrutiny by the Commission Impact Assessment Board

The Impact Assessment Board of the European Commission assessed a draft version of the present impact assessment and issued its opinion on 19/06/2013. The Impact Assessment Board made several recommendations and, in the light of the latter, the final impact assessment report:

Clarifies

- how the options under consideration are meant to achieve the objective of simplification;
- that the different policy options proposed are generally independent one from the others and that no alternative proposals for the areas covered were suggested by interested parties;
- the measures to improve the monitoring and evaluation arrangements.

Describes

- the lack of detailed quantitative data while flagging the efforts undertaken to collect data;
- that the proposed improvements result from the experience of Member States authorities and other stakeholder and are not directly related to accidents.

The assessment of the problems and their relevance is strengthened as well as the assessment of benefits and costs in order to throw more light on the trade-offs between protection and costs.

2. CONTEXT

2.1. PPE Directive

This IA accompanies a proposal for a revision of the Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (PPE Directive). 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."[5] This definition distinguishes this directive from most of the other product directives (e.g. Machinery Directive 2006/42/EC[6] or Low Voltage Directive 2006/95/EC[7]). As the PPE sector is a safety sector, the most relevant feature of the products falling under it is to protect their users against risks. Therefore, safety requirements are not additional requirements. They are the purpose of the product.

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http://ec.europa.eu/enterprise/sectors/mechanical/files/ppe/rev-study-assess-part2_en.pdf (part2 on impact assessment)

4 See http://ec.europa.eu/enterprise/sectors/mechanical/files/ppe/rev-study-competitiveness_en.pdf

5 For guidelines on the application of Directive including explanations on the definition look at http://ec.europa.eu/enterprise/sectors/mechanical/files/ppe/ppe-guidelines_en.pdf

6 See http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:157:0024:0086:EN:PDF

7 See http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:374:0010:0019:EN:PDF

PPE covers equipment designed to protect against all kinds of hazards (e.g. heat, flames, chemicals, flying particles, mechanical) occurring in different environments – at home, at work (occupational health and safety risks), at leisure (sports) etc.[8] There is PPE for nearly every part of the human body: mostly for its outer parts but also for the inner parts (e.g. respiratory protection).

Examples of PPE include: head/ears/eyes protection (helmets, hearing protection, and glasses), respiratory protection (gas masks, filter masks), body protection (protective clothing against chemicals, motorcycle suits, and high visibility vests), arm/shoulder protection, hand protection (gloves), leg and foot protection (safety shoes, knee pads), and equipment to prevent drowning (life jackets) (see Figure 1).

Figure 1: Examples of personal protective equipment

The Directive applies to each individual item of PPE which is intended to be placed and/or put into service on the EU market for the first time. It sets out the basic health and safety requirements and establishes the conformity assessment procedure to be followed by manufacturers before a specific PPE is placed on the market. The procedure depends on the severity of the risk involved. There are three distinct groups of PPE and their corresponding conformity assessment procedures: "Simple design", commonly known as category I, "Complex design" (category III) and "neither of these" (category II):

- Category I ("simple design"): the PPE is defined by the exhaustive list in Article 8(3) of the PPE Directive.
  PPE of simple design is the one where the designer assumes the user can himself assess the level of protection provided against the minimal risk concerned, the effects of which can be safely identified by the user in good time.
  The manufacturer declares conformity by means of an EC declaration of conformity

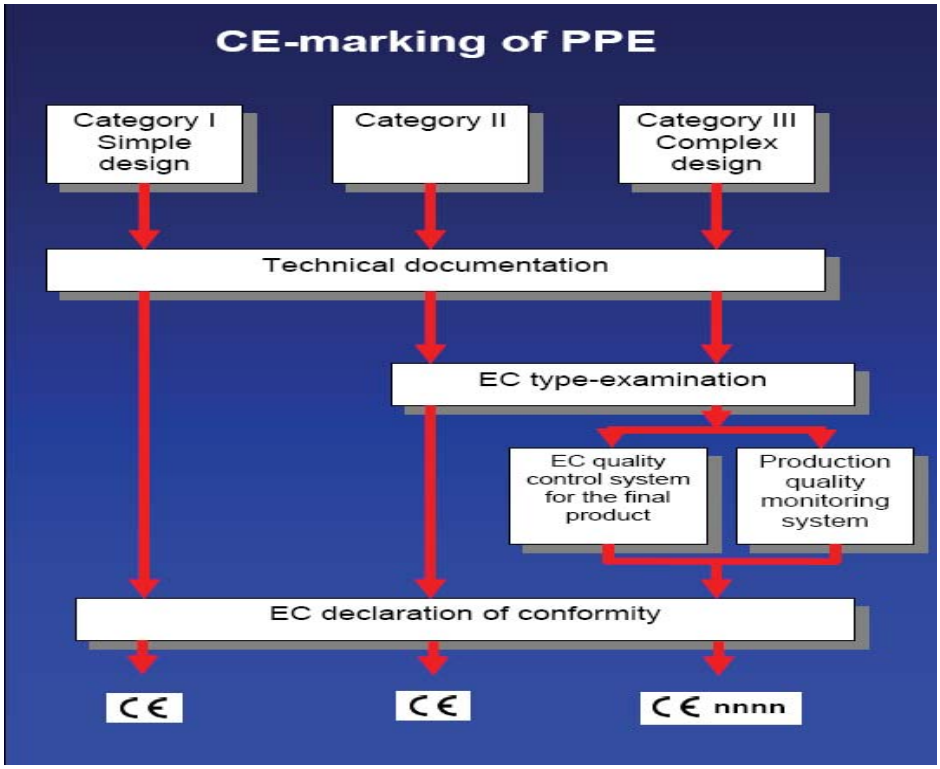
[8] Mäkinen, 'Protective clothing- nowadays and vision', article for the 3rd European Conference on Protective Clothing (ECPC) and NOKOBETEF 8, may 2006.

(see Fig. 2 below).
Examples: gardening gloves, sunglasses.

- Category II ("neither simple nor complex"): PPE not defined by Article 8(3) nor (4)(a) is subject to an EC type-examination by a Notified Body[9] after which an EC declaration of conformity is issued.
  Examples: safety helmets, football shin-guards.
- Category III ("complex design"): the PPE is defined by the exhaustive list in Article 8(4)(a).
  PPE of complex design is intended to protect against mortal danger or against dangers that may seriously and irreversibly harm the health, the immediate effects of which the designer assumes the user cannot identify in sufficient time.
  These PPE are subject both to EC type-examination and to two Quality Assurance procedures as described in Articles 11A and 11B (see Annex 1). An EC declaration of conformity is issued.
  Examples: dust masks, fall arresters.

Figure 2: Certification procedures for PPE

The CE marking for category III PPE shall be followed by the identification number (in the figure shown as nnnn) of the Notified Body which is involved in the quality assurance procedures.



[9] These bodies are conformity assessment bodies, which test, inspect and certify products. They are called "notified bodies" because they are notified by the Member States to the Commission.

The basic health and safety requirements are described in ANNEX II of the Directive[10]. There are three main chapters: General Requirements applicable to all PPE, Additional requirements common to several classes or types of PPE, Additional requirements specific to particular risks.

Annex III of the Directive lists the technical documentation that the manufacturer shall assemble before placing a PPE on the market. This so-called technical file shall be submitted to the competent authorities on request.

The PPE Directive is based on Article 114 of the Treaty on the functioning of the European Union and is a so-called "New Approach[11] Directive", i.e. the Directive is restricted to the definition of mandatory essential requirements (including appropriate conformity assessment procedures) necessary to protect the public goals of health and safety. Technical specifications agreed by stakeholders and experts in the field, usually harmonised European standards, support the Directive in "translating" the essential requirements into detailed requirements for certain types of products. The New Approach has recently been revised and integrated into the New Legislative Framework (NLF)[12].

PPE Actors and stakeholders

There are various actors and organisations involved in the management of the PPE Directive (i.e. adopting, implementing, applying and enforcing). There is the PPE Working group chaired by the Commission and made up of Member States and European stakeholders. The market surveillance representatives of the Member States are organised in the PPE AdCo group (Administrative Cooperation). The CEN/CENELEC consultants are key operators in the checking of harmonised European standards. There is also a close connection to the Coordination group for the Notified Bodies in the field of PPE. Figure 3 shows a scheme of the main actors in the management of the PPE Directive.

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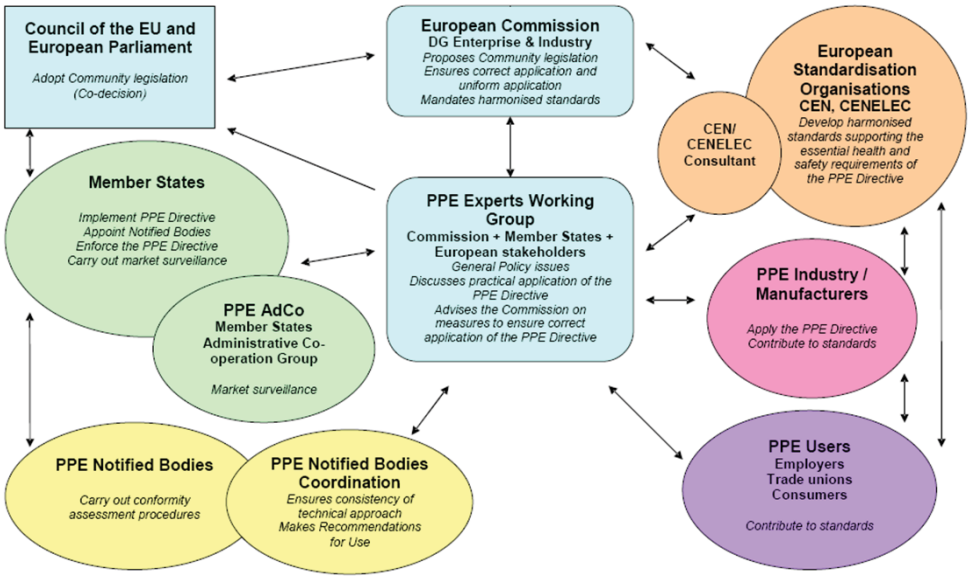
10 See Annex 2 of this document for the parts of ANNEX II of the PPE Directive that are relevant for this impact assessment.

11 New Approach, see http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-approach/index_en.htm

12 New Legislative Framework for marketing of products: see http://ec.europa.eu/enterprise/policies/single-market-goods/regulatory-policies-common-rules-for-products/new-legislative-framework/index_en.htm

Figure 3: Organisational scheme for the PPE 89/686/EEC Directive



The evaluation of the PPE Directive

The Directive has been in place since 1989. Although it has never been a subject to any formal evaluation, a regular feedback on its functioning is mainly received through the representatives of Member States responsible for the implementation of the Directive and relevant stakeholders who meet in the PPE Working Group.

The representatives of Member States in the PPE Working Group as well as the representatives of stakeholders have consistently over time expressed the opinion that the PPE Directive has provided an efficient and effective improvement of the safety of the users.

The success of the PPE Directive is recognised by all stakeholders. The implementation of the Directive across the EU has led to the **harmonisation of standards** and regulations on protective equipment, facilitating the **development of a large European market**[13]. In particular, the harmonisation of standards has removed barriers to trade related to the need to comply with the standards and regulations of different jurisdictions.

The harmonisation of standards also means that suppliers are exposed to more direct competition from producers across the EU, with the likelihood that prices and profit margins are reduced for them. European as well as foreign manufacturers are obliged to comply with quality standards, product liability, sizing, and packaging requirements set down by the Directive.

Thanks to the standardisation in this field, the European PPE sector has gained a major advance over all other regions of the world. Although voluntary, the harmonised standards are used by almost all PPE manufacturers and their application provides purchasers of PPE with objectively tested information on the level of protection provided by the equipment as well as precise instructions for use. Major 'success stories' for the PPE Directive include the European standards for sunglasses, cycling helmets and high-visibility clothing.

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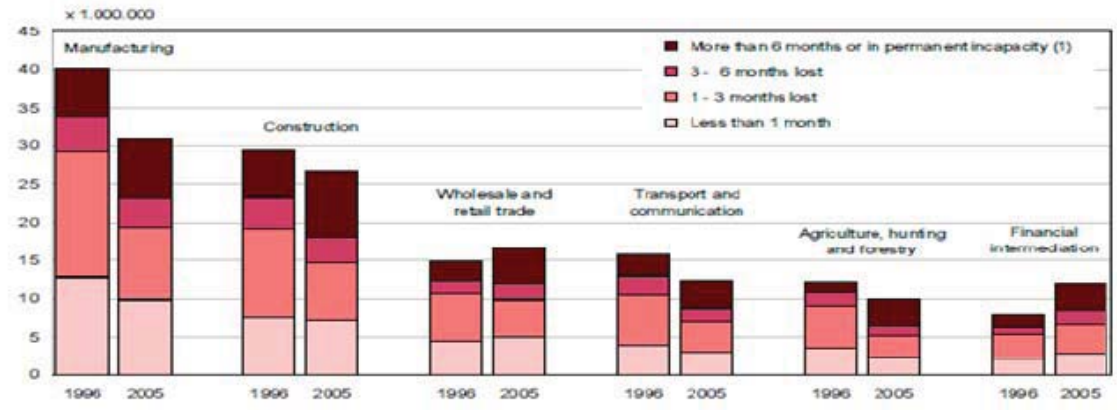
13 BizAcumen Inc. (2009), report "Personal protective equipment, A world market analysis", November 2009

A key benefit generated by the Directive is the **improvement of the safety of users** (workers and consumers). Thanks to the requirements ensuring high quality of products with high level of protective function, the number of injuries and thus of working days lost as a result of these injuries considerably decreased over the last 10 years. The figures below provide some indications about trends on accidents. Although it must be noted that available data are not disaggregated enough to be able to attribute trends in injuries directly to the PPE Directive, all stakeholders believe that the PPE Directive did play a role to a certain degree in improving the safety of users.

Per relevant sector, the total number of annual absence at work caused by an injury also decreased (see Fig. 4).

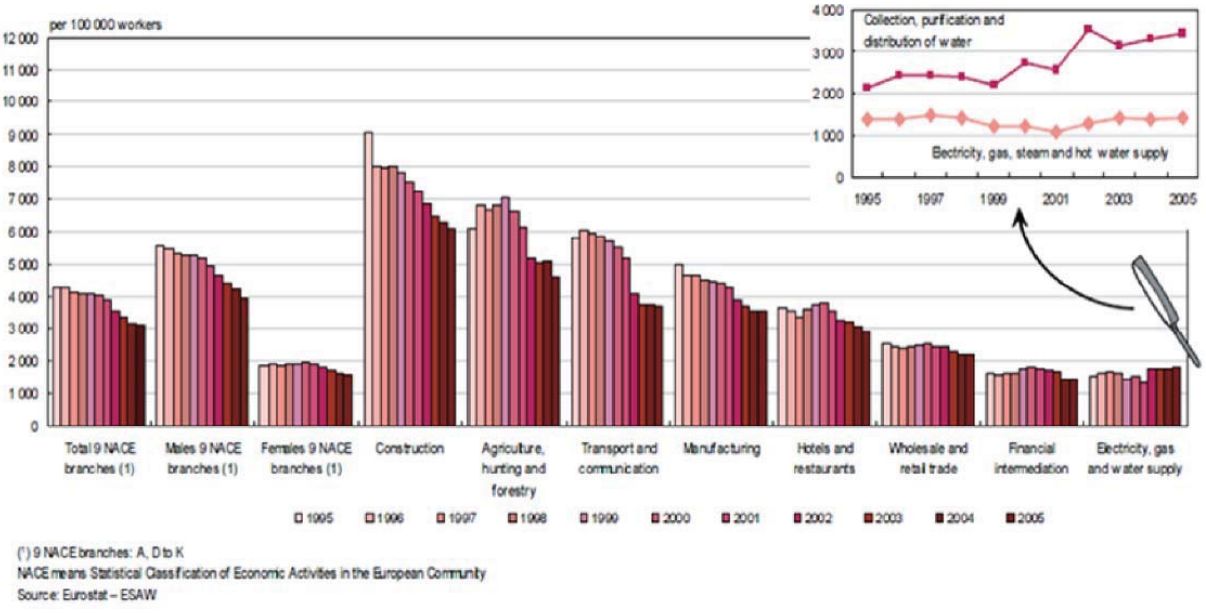
Figure 4: Total number of annual days of absence by sector of economic activity, EU-15, 1996-2005



*** EU-15 + Norway**
(1) 270 days were used for the class "more than 6 months of absence or in permanent incapacity"
Source: Eurostat - ESAW

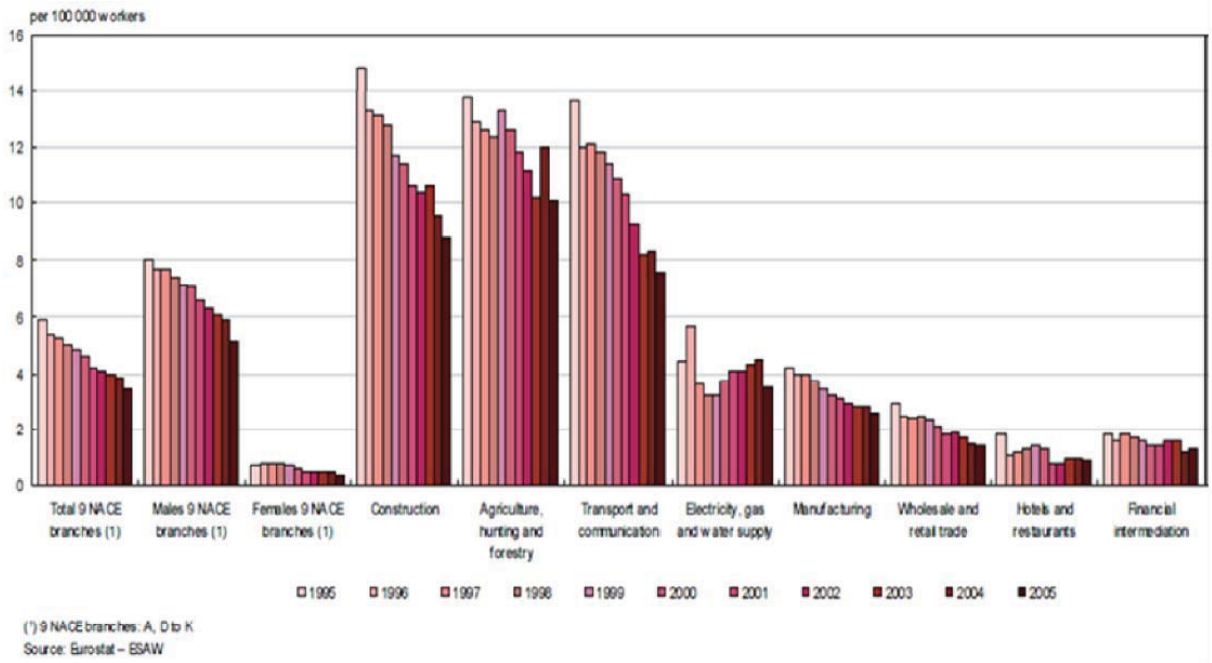
Between 1995 and 2005 both non-fatal and fatal accidents at work have also fallen in different relevant sectors (see Figures 5 and 6).

Figure 5: Incidence rate of non-fatal accidents at work, EU-15, 1995-2005



(') 9 NACE branches: A, D to K
NACE means Statistical Classification of Economic Activities in the European Community
Source: Eurostat – ESAW

Figure 6: Incidence rates of fatal accidents at work, EU-15, 1995-2005



2.2. Overview of the PPE market

The quantitative data available about PPE and the PPE market is not enough accurate and detailed to provide a clear picture about the PPE market and about the relationships between the different PPE products 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.

2.2.1. Volume of the European PPE market

The size of the European and global market for PPE is difficult to assess. Data are scarce and estimations show substantial differences. Matrix Insight for example, estimated the EU market for PPE to be approximately €5.9 billion in 2007 (at end-user prices), while the global market was estimated to be €19.2 billion[14]. Research by Ecorys in 2009 indicated that the size of the European PPE market might be over €10 billion[15,16]. This estimate is based on a previous calculation related to the Lead Market Initiative[17]. Of this total, Euratex estimates

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14 Matrix Insight Ltd, 'Amendment of the PPE Directive – study to support the European Commission's impact assessment; Part 1', December 2010, p. 13. This estimation is based on data from BizAcumen Inc., report 'Personal protective Equipment, a world market analysis', November 2009.

15 Ecorys, 'Competitiveness of the European security industry' (including PPE), study for the European Commission, November 2009.

16 Ecroys, Interview with Euratex and European Safety Federation (ESF) in autumn 2009.

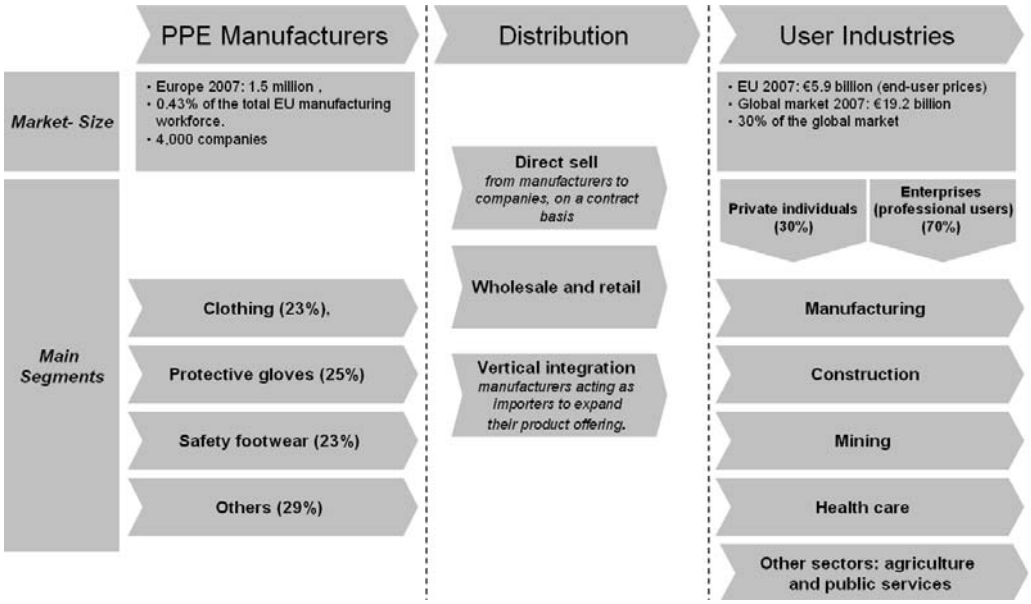
17 In the report of the 'Taskforce on protective textiles', composed in preparation of the Lead Market Communication, the size of the total European market for PPE (in relation to textiles) was estimated at € 8 billion, of which 85% is covered by the EU15. The Report uses a definition of PPE that covers 'clothing and other often textile-based systems and accessories whose main function it is to protect the user'. This definition is broader than the legal definition given in Article 1 of Directive 89/686/EEC.

that protective textiles represent 50-60% of total turnover, while footwear (partly textile-based) adds another 20%. Six areas represent 80% of the turnover, namely (i) foul weather clothing (mainly leisure and active wear), (ii) fire resistant clothing, (iii) medical (non-woven) protection, (iv) high-visibility, (v) ballistic & cut protection, and (vi) disposable chemical protection[18].

Textiles Intelligence estimated in 2009 that the *global* turnover for PPE is over €10 billion ($13 billion) per year. This turnover refers to four PPE-categories: (i) above-the-neck-protection (headwear, ear and eye protection), (ii) protective clothing, (iii) protective gloves, (iv) footwear[19,20]. Frost & Sullivan (2005)[21] indicated that the segments for protective clothing and gloves are the 'predominant textile-based sectors' of the PPE market in Western Europe. According to their estimates the turnover of protective textiles and gloves accounted for approximately 60% of the total PPE market in Western Europe.

An overview of the PPE industry and value chain is provided in Figure 7 below.

Figure 7: Overview of the PPE industry and value chain



Source: Matrix Insight Ltd. (2010).

Euratex indicated to the study team that, for example, medical clothing and clean room textiles were included in the report, while these do not fall under the PPE-Directive. Further the Taskforce Report estimated (based on Euratex and Eurostat data) that in 2006 the EU-25 market for textile industrial applications was approximately € 39.4 billion, of which protective textiles was one of the largest segments (20%). The Report also estimated that 200,000 jobs are directly or indirectly linked to the PPE industry. The service operations related to PPE (work wear and healthcare segments) account for € 1.5 – 2 billion turnover and 35.000- 40.000 employees.

18 European Commission, Report of the Taskforce on Protective Textiles: 'Accelerating the development of the protective textiles market in Europe', composed in preparation with COM (2007) 860 on 'A Lead Market Initiative for Europe'.

19 Textiles Intelligence, Editorial: Europe's Research Roadmap for new PPE, May 2009.

20 Ecorys, 'Competitiveness Proofing – Personal Protective Equipment (PPE) Industry, study for the European Commission, August 2012: Initial and partial assessment made by the study team would suggest that this figure underestimates the size of the sector.

21 Frost & Sullivan, 'Personal Protective Equipment in Western Europe provides Growth opportunities for technical textiles', press release June 2005.

2.2.2. Growth of the European PPE market

In nominal terms, the EU-27 PPE market grew by 2.1% annually (in terms of value) between 2003 and 2007 compared with GDP growth of 4.73%. PPE market growth was projected to accelerate to 2.67% annually between 2007 and 2015[22].

In terms of geographic distribution, growth is higher in Eastern and Central European countries.

Smaller PPE segments (like fall protection equipment and hearing protection equipment) had higher annual average growth rates than larger sectors (like protective clothing and safety footwear) between 2003 and 2007 (4.05% compared with 2.10%).

2.2.3. Demand for PPE in Europe

Consumers of PPE can be divided into enterprises (professional users) and private individuals. Professional use constitutes approximately 70% of the overall demand for PPE. The industry sectors with the highest intensity of demand for PPE are manufacturing, construction, mining and health care. Other sectors like agriculture and public services have been increasing their consumption of PPE in the recent past.

In terms of geographic distribution, the demand for PPE is concentrated in large Member States (Germany, UK, France, Italy and Spain). However, set against the number of workers, professional users in Northern European countries tend to spend more in terms of PPE equipment than in Central, Southern or Eastern European countries.

2.2.4. Production of PPE in Europe

Data estimates from different sources for total EU production of PPE show substantial differences. Production could be within a range of €2 to €6 billion. Production of PPE appears to have been declined at an annual average of 2 %. Production declines have been particularly marked in the UK, Spain and the Netherlands. According to an available study[23] manufacturers in the EU have partially re-located or subcontracted production to more labour intensive countries.

In terms of geographic distribution, production is concentrated in few Member States with Italy, Germany and the UK as market leaders in the three largest segments of PPE (protective footwear, protective gloves and protective clothing respectively).

Together Italy, Germany, France and the UK are responsible for more than the half of all PPE production in Europe. According to the data available, Italy was the leading manufacturer of PPE in the EU, followed by Germany and France.

As depicted in Fig. 7 the distribution of PPE takes primarily three forms:

- direct sell from manufacturers to companies, on a contract basis;
- wholesale and retail distribution; and
- vertical integration, with manufacturers acting as importers to expand their product offering.

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22 Source: International Monetary Fund 2010

23 See chapter 4.3 of http://ec.europa.eu/enterprise/sectors/mechanical/files/ppe/rev-study-assess-part1_en.pdf

Wholesalers and retailers play an increasingly important role, because they can supply "top-to-toe" PPE that has been characterised by high demand in the recent past. In contrast, most manufacturers tend to focus on one PPE segment only, though they increasingly also provide consultancy services to their clients.

In addition to its economic significance, the European PPE industry has a significant social and employment impact. It represents 0.43% of the total manufacturing workforce.

2.2.5. Main players in Europe

Approximately 4,000 companies in the EU are involved in manufacturing PPE. Most of these companies produce protective clothing and safety headgear; only very few companies are involved in the production of fall protection equipment.

A very large percentage of enterprises involved in the manufacturing of PPE are SMEs. The percentage of SMEs in the market is particularly high in the protective clothing industry.

There are few key players in the European PPE industry. Amongst these, Honeywell Safety Products is the global leader in eye protection equipment (20% market share); 3M (due to acquisition of Aearo) dominates the global market for hearing protection equipment (40% market share) and continues leadership for respiratory protection equipment (30%). The other PPE market segments are much less concentrated. Key players have managed to extend their market share primarily through mergers and acquisitions.

2.2.6. Competition and competitiveness

The introduction of binding regulation on safety in the workplace and on protective equipment, both in the EU and in the rest of the developed world, has led to the development of a mature, well established and very competitive PPE market. Whilst consumers are increasingly attracted by factors such as comfort, fashion and branding, price continues to play a crucial role on purchasing decisions[24].

Trade and exposure to competition from cheap exporting regions have reduced the profitability of the European PPE industry. In response, manufacturers have tried to expand their market share by targeting new products through mergers and acquisitions and to reduce production costs by relocating to countries with lower labour costs.

2.2.7. Research and innovation intensity

It is difficult to estimate the research and innovation intensity and performance accurately across the sector. In terms of innovation, it is apparent that there is a growing focus on a number of key areas with a view to countering the impact of cheap imports. The design and development of new products that provide a greater level of comfort and/or style have been a particular focus, as have products with increased lifetimes. However, the recent economic crisis might also have led to a reduction in innovation investments, which will slow down product innovation and lengthen product cycles, especially in Western European countries.

The research intensity can be considered in terms of R&D expenditures. Expenditures across the different PPE segments are relatively low if compared to the production value. The Safety footwear segment exhibits the lowest rate of investment, while the Eye protection segment exhibits the highest rates of investments across the PPE sector.

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[24] BizAcumen Inc. (2009), report “Personal protective equipment, A world market analysis”, November 2009

2.3. Alignment to the New Legislative Framework

The Alignment to the New Legislative Framework is the major step on simplification of the current legislation. With the Alignment, the obligations of economic operators become more clear and identical to those involving other pieces of New Approach legislation. At the same time, modules for conformity assessment are harmonised with those to be applied in other EU legislation. Manufacturers and notified bodies have very often to use different pieces of EU legislation to ensure compliance with legal requirements. The current proposal contributed to provide a more structured and a more clear legal framework.

As mentioned above the whole area of product legislation and in particular the "New Approach" has recently undergone a horizontal review that resulted in the adoption of the **New Legislative Framework (NLF)**[25]**.** The objective of the NLF is to remedy a number of shortcomings observed across various sectors, including the PPE sector, namely a significant number of products that do not ensure an adequate level of protection that reach the market, the unsatisfactory performance of certain notified bodies[26] and inconsistencies throughout the legislation making its application unnecessarily complicated for manufacturers and authorities.

The NLF consists of two instruments. Regulation (EC) No 765/2008 on accreditation and market surveillance[27] (NLF Regulation) has introduced rules on **accreditation**[28] and requirements for the organisation and performance of **market surveillance** and controls of products from third countries. It is complemented by Decision No 768/2008/EC establishing a common framework for the marketing of products[29] (NLF Decision) which is conceived as a **"toolbox"** for **future legislation** providing solutions that can work across all sectors. It contains model **provisions** to be **commonly used** in EU product legislation (e.g. definitions, obligations of economic operators, notified bodies, safeguard mechanisms, etc.). The three EU institutions involved in the legislative process, Council, Parliament and Commission have committed themselves to use the NLF Decision's provisions as much as possible in future legislation in order to bring about the maximum of coherence in the regulatory framework[30]. The NLF was accompanied by an impact assessment[31].

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25 http://ec.europa.eu/enterprise/policies/single-market-goods/documents/new-legislative-framework/index_en.htm

26 Laboratories and certification or inspection bodies delivering certificates which are notified to the Commission by Member States.

27 Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93, OJ L 218, 13.8.2008, p. 30;
See http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0030:0047:EN:PDF

28 Accreditation is a tool for the control of the competence of laboratories and certification/inspection bodies delivering certificates in the EU

29 Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC, OJ L218, 13.8.2008, p.82.
See http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:218:0082:0128:EN:PDF

30 Article 2 of Decision 768/2008 reads: "***Subject matter and scope***: This Decision sets out the common framework of general principles and reference provisions for the drawing up of Community legislation harmonising the conditions for the marketing of products ("Community harmonisation legislation"). Community harmonisation legislation shall have recourse to the general principles set out in this Decision and to the relevant reference provisions of Annexes I, II and III. However, Community legislation may depart from those general principles and reference provisions if that is appropriate on

The problems identified by the NLF have also been observed in the context of implementing the PPE directive, namely with regard to equipment placed on the market that does not ensure an adequate level of protection.

PPE that does not ensure an adequate level of protection can present serious risks to the health and safety of the user who can no longer rely on its protective function when exposed to the risk. This can cause injuries, burns, electric shocks, and sometimes can even lead to fatalities. Recent examples discussed at EU level[32] are:

– *Defective safety footwear:* which is supposed to ensure protection against mechanical penetration. However it was observed that the metallic anti-penetration inserts of the footwear could become fully oxidised in which case they no longer offer protection against injuries.

– *Defective protecting clothing against liquid chemicals:* the protective clothing prevented permeation by liquid chemicals only for a very short time (only a few minutes instead of hours as claimed in the product description).

– *Defective PPE against falls from a height:* the fall arrest system either failed to arrest the fall within the required distance or failed to arrest the fall altogether when tested in a "fall back" situation – which is a foreseeable condition of use.

There have been also problems with the quality of the services delivered by some notified bodies. In its reports to the PPE Working Group the notified body group frequently expressed regret that many notified bodies do not participate in the coordination meetings and do not apply the Recommendation for Use Sheets[33]. Furthermore the group frequently pointed out different practices in the MS as regards the evaluation and monitoring of notified bodies, for example with regard to sub-contracting testing to other notified bodies or laboratories.

A number of PPE manufacturers are also faced with the problem of a complex and sometimes inconsistent legal framework: Certain PPE also has to comply with other directives[34], e.g. the pressure equipment directive (for breathing devices), the electromagnetic compatibility directive and the Radio and telecommunication terminal equipment directive (for PPE that incorporates electrical or telecommunication devices).

In order to address the problems described above and in line with the political commitment laid down in Article 2 of the NLF Decision[35] to use the solutions offered by the Decision as consistently as possible, the PPE Directive needs to be aligned to the NLF.

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account of the specificities of the sector concerned, especially if comprehensive legal systems are already in place".

31 See SEC 2007(173) http://ec.europa.eu/governance/impact/ia_carried_out/docs/ia_2007/sec_2007_0173_en.pdf

32 These products have either been subject of safeguard clause notifications from Member States to the Commission or formal objections against harmonised standards.

33 These "Technical sheets for coordination" report the common position of the Notified Bodies. The topics range from the interpretation of provisions of the Directive to practical problems as encountered by NB. It is expected that all NBs stick to the common positions as published.

34 See Guide to application of the directive 89/686/EEC on Personal Protective Equipment, Chapter I, point 1.1.5 available at http://ec.europa.eu/enterprise/sectors/mechanical/documents/guidance/personal-protective-equipment/chapter1/index_en.htm

35 See footnote 30

In addition to these horizontal problems a number of other issues specific to the PPE sector have been identified that will be described in chapter 3. Those PPE specific shortcomings were the reason why the PPE Directive had not been included in the package of Directives which underwent a pure alignment with the New Legislative Framework (NLF) Decision in 2011.

The Impact Assessment Report on the Alignment Package[36] has already examined in depth the different options to give effect to the NLF Decision. These options are exactly the same for the PPE Directive. The report also provided an analysis of the impacts resulting from the measures set out by the NLF Decision. In view of the structural similarities of the sectors examined in that report with the PPE sector and the horizontal nature of these measures the impacts are expected to be the same in the PPE sector. For this reason this report will not examine these aspects. It will focus on PPE specific problems and the ways to address them.

3. PROBLEM DEFINITION

Despite a successful functioning of the Directive (see chapter 2.1 "The evaluation of the PPE Directive"), there is also a broad consensus that there is room to achieve some improvements that can contribute to an even more effective protection of the health of the users and to a more efficient functioning of the PPE legislation. Most of the proposed improvements result from the experience of Member States authorities and other stakeholders with the enforcement and implementation of the PPE legislation and are not directly related to accidents. With the transposition of the Directive into national law and with the experience of daily work with that legislation the below described problems and inconsistencies were identified. The identified issues are the output of communication with Member States and stakeholders:

- product coverage
- the application of the conformity assessment procedures
- basic health and safety requirements
- market surveillance

As it will be explained in more detail in chapters 3.1-3.3, these problems lead to insufficient protection of EU citizens, uneven level playing field for the economic operators and complex regulatory environment for PPE. The quantitative data available are not enough detailed to enable to provide an order of magnitude for the selected issues.

3.1. Product coverage

3.1.1. Problem that requires action and its underlying drivers

There are products on the market that provide for a protective function to the user and fit the definition of personal protective equipment of the PPE Directive but are not covered by this Directive. That means in particular that these products are not subject to the established safety and health requirements and conformity assessment procedures for PPE. As a result, the level of protection offered by such products is not as high as for PPE which explicitly fall under the Directive's requirements. Therefore, when wearing them, the user is potentially more exposed to injuries than in the case of a PPE compliant product. The consumer might believe that she/he is protected against a specific risk when in fact she/he may not be. For example

[36] See SEC 2007(173) http://ec.europa.eu/governance/impact/ia_carried_out/docs/ia_2007/sec_2007_0173_en.pdf

products protecting against heat *designed for private use* (such as oven gloves) are explicitly excluded from the Directive. So are the products against damp and water *for private use* (e.g. dish-washing gloves). However, the same type of products when they are intended *for professional use* is subject to the PPE Directive. The majority of the replies to the public consultation pointed out that the risk in the case of the oven gloves was the same in all kinds of environments (be it professional or private). The members of the PPE Working Group mentioned at several occasions that these products that are outside the scope raise safety and health problems. Dish-washing gloves for instance could also be used by consumers to protect against relatively mild cleaning materials used in a domestic setting. While e.g. housekeeping gloves, intended to protect against the latter risk, are covered by the Directive the dish-washing gloves themselves are not. The current situation creates confusion between those different usages.

For products intended for private use that are not covered by the PPE Directive the General Product Safety Directive 2001/95/EC (GPSD)[37] will be applied. This legislation is intended to ensure a product safety for consumer products that are not covered by specific sector legislation. It provides a generic definition of a safe product. Nevertheless it does not set specific safety requirements for products. In order to comply with the GPSD and to check whether a product is safe or not, manufacturers as well as public authorities have to develop technical specifications of the product to ensure safety. However, when personal protective equipment is involved, a specific European legislation is available, namely the PPE Directive, which provides the requirements needed for this kind of products, even if limited so far to products for professional use. From a legal certainty point of view, it is more appropriate to apply similar requirements to similar products.

The situation described above cause problems, for instance, for the market surveillance authorities. The product coverage of the PPE Directive for some types of protective equipment depends on the circumstances of the intended usage, i.e. whether it is used in work places or for private activities. It has been argued that 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.

The problem described is of regulatory nature. This failure has repercussions for the market, on the level of health and safety protection of users and creates confusion for the market surveillance authorities.

3.1.2. Who is affected, in what ways and to what extent?

It is mainly the users of these products that are affected as well as the market surveillance authorities. The users might not get the optimum level of protection when using products with a protective function. The market surveillance authorities have to assess identical products according to their intended use.

3.1.3. Evolution of the problem

As the source of the problem stems from the legislation itself, it will persist. The situation for market surveillance authorities and manufacturers will not change either.

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[37] GPSD, see http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:011:0004:0017:EN:PDF

For some types of protective equipment the applicable legislation will depend on the nature of the intended use. If it is intended to be used at work places it is subject to the PPE Directive, if it is intended to be used for private activities it is subject to the GPSD.

In the case of products that have a protective function but which remain outside of the scope of the Directive there will be examples on the market of those with sufficient level of protection but also of those with insufficient or no protection at all. Oven gloves for private use are an illustrative example of such a risk: oven gloves are supposed to provide protection even if intended for private use, but oven gloves carrying solely fashionable properties are available on the market.

One Member State has identified 150 000 cases of burn at home in the country per year. Half of these burns concern the hands.

Detailed data, in particular data related to gloves that do not ensure an adequate level of protection and associated accidents, are not available. Just to provide a broad indication to be interpreted with caution, we have used below statistics about accidents at work.

Burns, scalds and frostbites, i.e. the type of injuries which could be prevented by the use of oven/dishwashing gloves, account on average for roughly 2% of the total number of accidents at work. The overall number of these types of injuries was around 85 000 in 2011. A conservative estimate of the costs due to this type of injuries (considering only the costs of slight injuries as those are deemed to be the most often occurring) was in the range of 1.5 billion Euros in 2011. It means that in the period 2002-2011 this type of injuries could have cost society around 14.4 billion Euros.

3.2. Conformity assessment

3.2.1. Problem that requires action and its underlying drivers

As described in chapter 2.1 PPE is classified by the Directive into three categories that are subject to different conformity assessment procedures (see Fig. 2). The definitions of categories I and III are accompanied by lists that describe exclusively and exhaustively the PPE covered by these categories.

The experience with the application of the Directive has shown that the list of products subject to the most stringent conformity assessment procedure[38] (i.e. PPE of category III) misses products that fit the definition of category III, i.e. PPE designed to protect against mortal danger or danger that may seriously and irreversibly harm health. As a consequence there are no regular audits of the production process for these types of PPE in contrast to the listed types. 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 those PPE.

For instance a life jacket is intended to protect against drowning and that risk does indeed fit the above mentioned definition of category III. There have been cases reported by the European Parliament and Member States where accidents and fatalities happened due to improper functioning of life jackets. Nevertheless PPE to prevent drowning is not listed as category III. As category II PPE the conformity of life jackets is currently tested by an independent body only once during the EC type-examination before serial production starts. But there is no obligation for independent tests of the quality of the life-jackets actual

[38] See Annex 3 for the relevant text of the current PPE Directive.

produced thereafter. So, there is no guarantee of a constant quality and consequently of a constant level of safety for these types of PPE.

Other involved products are 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. For the last of these it may not be immediately obvious that it fits the definition of category III but it is an established fact that damage to hearing is irreversible. The actual damage may not be perceived as an irreversible development because the effect of the damage will be perceptible only in the medium or long term.

Again the described problem is a regulatory failure because both the definition and the list are integral parts of the Directive.

3.2.2. Who is affected, in what ways and to what extent?

The users of those products intended to protect against serious risks are affected. Because there is no obligation to test the items actually produced, the PPE in use might not have the same level of protection as the type-tested specimen. Due to variability in the production process the quality of the product can be subject to fluctuations. Changes in product design, that might have impacts on the safety level, will not be picked up by the Notified Body in contrast to what would happen with regular audits. Manufacturers using a quality management system for the production process on a voluntary basis will experience commercial disadvantages.

3.2.3. Evolution of the problem

Questions on categorisation of particular types of PPE are often discussed by Member States and the stakeholders. However, discussions need to follow what is prescribed in the current text of the PPE Directive. Inconsistent categorisation will persist unless changes to the exclusive and exhaustive lists in the Directive are made. Taking into account that more and more manufacturers apply quality management in their production process one can expect some progress in the future. Nevertheless this process does not involve technical competent third bodies who will *ensure* independent assessment of the quality of the production process. As long as a stable high quality level of the products mentioned above over the entire production process cannot be guaranteed, there will be repercussions on the health and safety of the users of these critical kinds of PPE.

Statistically, the accidents which theoretically can be prevented by **life jackets** (drowning) accounted for around 2200 fatalities during the period 2002-2011 and represented a total societal loss of 570 million Euros. The potential benefit of a -0.5% decline in these types of injuries for the period 2012-25 would bring about a social benefit of around 2.9 million Euros. Taking into account the same reduction, the estimated cost for society for the period 2012-25 would be of 630 million Euros.

3.3. Requirements

3.3.1. Problem that requires action and its underlying drivers

Technical file[39]

[39] The technical file must comprise all relevant data on the means used by the manufacturer to ensure that a PPE complies with the basic requirements relating to it.

Market surveillance authorities claim that their work is hindered in some cases due to unclear or insufficiently detailed requirements in the Directive for the technical file. Authorities report that manufacturers of category I PPE are reluctant to work together with the authorities when they are required to hand over documents on internal production control, saying this information in the technical file is not required for category I PPE. On the other hand stakeholders do not have a clear understanding of their responsibilities with respect to the content of the technical file due to the current structure of the requirement for the technical file. The quality and the completeness of the technical file are indisputably crucial for the assessment of the compliance of the product by the authorities.

Validity and content of EC type-examination certificate

Regularly manufacturers, as well as market surveillance authorities, report on problems with the EC type-examination certificate. Due to the possibly unlimited validity of the certificate products that were EC type-examined in the past on the basis of versions of harmonised standards that have been subsequently withdrawn may be placed on the market. Such products have to be considered as potentially not in conformity with the Directive. In addition, this situation has a negative impact on competition and on competitiveness. In fact, the manufacturers who have adapted their products to the requirements of the more recent, and legally in force, harmonised standard have to support the compliance costs while those manufacturers who have not do escape those costs. The Notified Bodies have set up a voluntary agreement to limit the validity of certificates to five years. However not all of the Notified Bodies are observing that agreement. Discussions with representatives of the Member States and of stakeholders have shown that the clarification of this situation is widely supported.

Additionally the work of the market surveillance authorities is hindered by the fact that the certificates issued by various bodies differ in layout and content. There is no requirement in the Directive to harmonise the certificate. In particular the authorities have problems due to different languages and difficulties in identifying products.

EC Declaration of conformity (DoC)

The EC Declaration of Conformity is a legal statement by the manufacturer attesting that the product concerned complies with all relevant provisions of the Directive. It contains a description and identification of the product that enables both the user and the market surveillance authorities to identify the product covered by the declaration without ambiguity. The DoC is a crucial document for the market surveillance authorities to check the compliance of the product. However, market surveillance authorities report that it is hard to obtain the DoC from the manufacturer, especially if the manufacturer is located outside Europe. The PPE Directive does not require that every product is accompanied by a DoC as is the case for other single market directives.

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.

For protection against mechanical vibration the Directive requires that the PPE does not transmit vibrations to the user that exceed the established limit values recommended in the light of the maximum foreseeable daily exposure. Such a general requirement applicable for any PPE of this type is not practicable: At different workplaces, using different working tools, the worker is exposed to different levels of vibration. A better solution would be to have the choice between different classes of PPE providing different attenuation levels of vibration.

The worker would be able to select a PPE providing him an optimum for both protection and usability for the actual working situation.

For hearing protectors the Directive requires the product to be labelled with a value of the "comfort index" provided by the PPE. This index should include aspects such as the pressure of the protector against the head, the weight, and the type of material. In the light of discussions on this “comfort index” it was concluded that it is not possible to measure and establish such an index. Comfort is seen and felt very differently by individual persons as it could be described for all persons using a universal index. The manufacturer is not able to fulfil the related requirement.

For protection against non-ionizing radiation the manufacturer is obliged to include the transmission curve[40] of the used filters in the instructions. This should make it possible to select the most appropriate PPE. Nevertheless, the selection on the basis of the transmission curve cannot be done straightforward; it requires additional calculation involving expert knowledge. The selection using the transmission curve has proven to be a source of confusion to the user who at the end does not take advantage of such information. There is other information available, like the transmission factor that could serve much better the same aim of the user selecting the appropriate PPE.

The described problems above are regulatory in nature because the requirements are an integral part of the Directive.

3.3.2. Who is affected, in what ways and to what extent?

Market surveillance authorities, manufacturers and users are affected. The authorities have to deal with the insufficient results of the requirements resulting in some cases in an ineffective work. The manufacturers of certain types of PPE are faced with trying to fulfil requirements that are known to be impracticable. The users of PPE are affected to the extent that the information they receive connected with the product is partial and, on that basis, may be irrelevant and may be a potential source of confusion.

3.3.3. Evolution of the problem

The identified problems will persist unless changes to the requirements are made. Without sufficient and appropriate information provided by the manufacturer the compliance of a product with the applicable requirements is difficult or impossible to assess. Further to potential negative effects on the protection of users, the work of the Member States market surveillance authorities cannot be satisfactorily performed. There is a need to clearly state the obligation of manufacturers to assemble the necessary technical documentation.

With respect to the validity of EC type-examination certificates, the voluntary agreement of the Notified Bodies to limit this validity to 5 years may reduce the intensity of this problem. Nevertheless the agreement being voluntary and thus not applied by all Notified Bodies, the problem is not likely to disappear in the foreseeable future. In addition, it is not likely that the current confusion caused by the different layouts of the certificates will disappear either.

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[40] The transmission curve is the mathematical function or graph that describes the transmission fraction of an optical or electronic filter as a function of frequency or wavelength. It is a figure for the properties of the used filter.

The difficulties raised by the impracticable or unclear provisions on protection against mechanical vibration, hearing protectors and protection against non-ionizing radiation will remain.

3.4. EU right to act

This initiative concerns the proper functioning of the internal market for products in the field of PPE. 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 89/686/EEC. This legislation does not however address the identified problems as effectively as desirable. If actions are taken at national level to address the problems, they may create obstacles to the free movement of the PPE goods. Therefore, any changes to the scope, procedures or requirements must be carried out at EU level in order to avoid distortions in the EU market.

4. OBJECTIVES

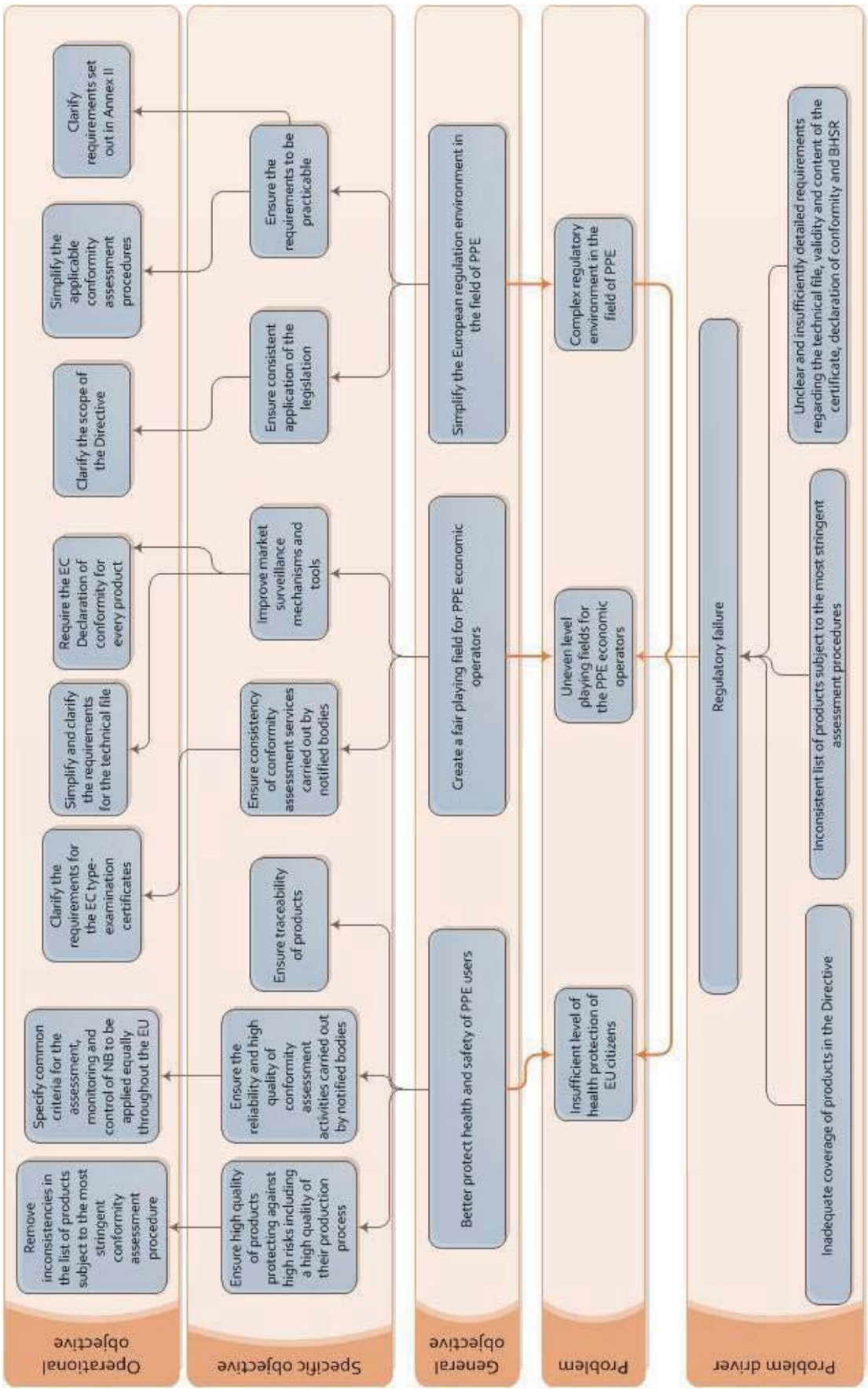
4.1. General policy objectives

The overall objectives of this initiative are to (1) better protect the health and safety of PPE users, (2) create a level playing field for PPE economic operators and (3) simplify the European regulatory environment in the field of Personal Protective Equipment (PPE). For the problem tree see Figure 8.

4.2. 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
		Simplify the applicable conformity assessment procedures
	Ensure the requirements are practicable	Clarify the requirements set out in ANNEX II

Figure 8: Problem tree depicting the links between problems, their drivers and the objectives.



4.3. Consistency with other policies and objectives

This initiative is in line with the Council Directive on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace[41] as well as with the Commission's policy on the Single Market (Single Market Act)[42] and Better Regulation policy.

5. POLICY OPTIONS

The policy options proposed are generally independent one from the others. They proposed taking into account the contributions of representatives of Member States and of stakeholders as well as the results of the studies commissioned by the Commission services. Alternative proposals for the areas covered were not put forward by interested parties.

5.1. Product coverage

1. Do nothing.

   Option 1 is to leave the existing situation unchanged. The product coverage of the Directive would not be changed. Products that are covered have to fulfil the requirements, products that are not covered do not have to fulfil the requirements. The described problems will persist.

2. Further clarify the product coverage in the Guidelines (Soft law).

   Option 2 is a soft law option. The Directive is not changed but the Guidelines on the application of the PPE Directive are used to explain, in a more detailed way than currently, the product coverage of the Directive. This would follow in a clarification of the situation on the product coverage for some types of PPE. Clarification could be added that products have to be assessed for every kind of protection provided, even if it is not the intended use.

3. Amend the exhaustive list of PPE not covered by the Directive.

   Option 3 uses legislative measures, i.e. the PPE Directive will be changed. Annex I with its exhaustive list of PPE classes not covered by the Directive will be changed in order to solve the described problems. The exclusions of PPE designed and manufactured for private use against damp and water and against heat will be deleted.

5.2. Conformity assessment

1. Do nothing.

   Option 1 is to leave the existing situation unchanged. The exclusive and exhaustive list for category III[43] products will not be changed. Consequently those types of PPE described in section 3.2.1 (life jackets, bullet-resistant vests etc.) will not be subject to the most stringent conformity assessment procedure even if they fit the definition of category III. There will not be an obligation to let the production process be monitored by an independent third body.

2. Voluntary agreement on application of production control (Soft law).

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41 See http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:1989:393:0018:0028:EN:PDF

42 See http://ec.europa.eu/internal_market/strategy/index_en.htm

43 See Annex 3 for the relevant text of the current PPE Directive.

Option 2 consists of non-regulatory instruments that encourage the voluntary application of the third body control of the production process for the described types of PPE. The manufacturers should agree to apply the most stringent conformity assessment procedure even if the PPE is not listed as category III. The agreement should also include the (fee-based) involvement of Notified Bodies.

3. Modify the list of products subject to the most stringent conformity assessment procedure.

   Option 3 uses legislative measures. The exclusive and exhaustive list for category III products will be changed. Some types of PPE will be added. The intended consequence will be the obligation that the production of this PPE shall be subject to a procedure to monitor the production process involving an independent third body.

5.3. Requirements

Technical file

1. Do nothing.

   Option 1 is to leave the existing situation unchanged. The current structure of the requirements for the technical file will remain and the requirements for products of category I will continue not to be as detailed as for products of the other categories. This affects in particular the description of the product and details on the means used by the manufacturer to ensure the compliance of the product with the applicable basic requirements.

2. Further clarify the issue in the PPE guidelines (Soft law).

   Option 2 is a soft law option. The Directive is not changed but the Guidelines on the application of the PPE Directive are used to explain the content of the technical file and its importance for both the manufacturer and the authorities. The manufacturer of category I products can be encouraged to draw up voluntarily a detailed technical file as is explicitly required for the other categories.

3. Modify the requirements on the technical file.

   Option 3 uses legislative measures. Annex III of the Directive will be changed. The requirements will be applied to all categories of PPE. Additionally the structure and the wording will be simplified in order to provide more clarity.

Validity and content of the EC type-examination certificate

1. Do nothing.

   Option 1 is to leave the existing situation unchanged. The validity of the EC type-examination certificate will continue not to be limited by legislative means. In addition the requirements in respect of its content are insufficient in particular to clearly identify the product.

2. Notified Bodies to agree on limited validity and minimum content of certificates (Soft law).

   Option 2 consists of non-regulatory instruments that encourage a voluntary agreement of the Notified Bodies to limit the life-time of the certificates as well as on a minimum content.

3. Time limit the validity of certificates and improve the requirements for the content of certificates.

   Option 3 uses legislative measures. The validity of the EC type-examination certificate will be limited. The existing requirements for the content of the certificate will be redrafted to ensure that all necessary information is provided such that a clear identification of the product is ensured.

EC Declaration of conformity (DoC)

1. Do nothing.

   Option 1 is to leave the existing situation unchanged. The manufacturer is obliged to draw up a DoC that should be made available to market surveillance authorities immediately on demand.

2. Further clarify in the Guidelines the need for detailed information on conformity of the product and about the manufacturer (Soft law).

   Option 2 is a soft law option. The Directive is not changed but the Guidelines on the application of the PPE Directive are used to explain the importance of both detailed information on the product and the possibility that this information is available for the authorities. The detailed information must sufficiently describe the compliance of the product with the Directive.

3. Create a requirement for the DoC to be supplied with every product.

   Option 3 will introduce a requirement into the legislative text that every single product placed on the market shall be accompanied by the DoC.

Basic Health and Safety Requirements (BHSR)

1. Do nothing.

   Option 1 is to leave the existing situation unchanged. The described problems will persist. In particular, concerning the requirement to label PPE protecting against the harmful effects of noise with a "comfort index", the manufacturers have to deal with an obligation that cannot be fulfilled.

2. Further clarify the application of BHSR in the Guidelines (Soft law).

   Option 2 is a soft law option. The Directive is not changed but the Guidelines on the application of the PPE Directive are used to further clarify the application of the BHSR. In particular they can be used to explain how, in practice, the problematic requirements described in 3.3.1 can be addressed.

3. Delete requirements from the BHSR on:

   - Mechanical vibrations (BHSR 3.1.3).
     – Delete in BHSH 3.1.3 the requirement that *under no circumstances must the effective value of the accelerations transmitted to the user by those vibrations exceed the limit values recommended in the light of the maximum foreseeable daily exposure of the part of the body at risk.*
   - Protection against harmful effects of noise (BHSR 3.5).

– Delete in BHSR 3.5 the requirement to label the PPE with the value of the comfort index provided by the PPE.

- Protection against radiation, non-ionising radiation (BHSR 3.9.1).
  – Delete in BHSR 3.9.1 the requirement that the instructions for use supplied by the manufacturer must indicate the transmission curves.

6. ANALYSIS OF IMPACTS

6.1. General remark

The analysis of impacts will be presented in two steps. First all the policy options will be assessed qualitatively and preferred options (chapter 6.3) will be selected. Then an in-depth analysis of these options will follow (chapter 6.4). Following its outcome, mitigating measures for the most affected parties will be considered (chapter 6.5).

6.2. Overview of the relevant impacts and the methodology for their assessment

The following impacts are deemed the most relevant and therefore have been considered:

Social impact: The social impact consists mainly of benefits to the health and safety of the users of PPE. The proposed changes are designed to reduce the number of illnesses and injuries through the following three mechanisms

- ***Proportion of products on the market that do not ensure an adequate level of protection:*** the proposed changes are likely to decrease the number of such products on the market and thus reduce the probability that the use of such a product results in an injury.
- ***Usage of PPE:*** some amendments would improve and extend the usage of PPE. An increased usage of PPE might reduce the number of injuries especially in those sectors where usage of PPE is more common.
- ***Safety level prescribed by proposed policy changes:*** some amendments (e.g. reclassifying products from category II to category III) would result in an increased level of safety associated with the use of PPE and thus reduce the likelihood of accidents/injuries.

Economic impacts: Implementation of the proposed changes will entail costs to both manufacturers and market surveillance authorities. Firstly, extended coverage and stricter requirements will cause additional work for market surveillance authorities. In addition, manufacturers will incur the following compliance costs:

- ***Fixed costs:*** Manufacturers of PPE that was previously excluded from the Directive will need to invest in product design, testing and document generation to ensure conformity. Manufacturers of PPE that is moved from Category II to Category III PPE, or classified as Category II PPE when previously excluded from the Directive, will need to invest in testing and document generation, production controls and monitoring systems, as well as paying higher fees to notified bodies for monitoring the quality of products.
- ***Variable costs:*** Manufacturers of PPE that is moved from Category II to Category III PPE, or classified as Category II PPE when previously excluded from the Directive,

will need to invest in annual quality assurance by notified bodies. Requirement changes will entail manufacturers having to invest in the production of the declaration of conformity.

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. Interviews with representatives of manufacturers, notified bodies, and market surveillance bodies were used[44]. An estimate of the degree of certainty of the 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.

The first step of the options appraisal was to compare the cost of the changes to manufacturers against the perceived likelihood of their generating improvements in health. It is important to note that health effects were not monetised to facilitate comparison with costs, when:

- a review of the existing evidence revealed insufficient robust data on the improvements in health being generated by the evidence; and

- the output from the interviews was certainty about the existence of a health effect, rather than the degree of that effect.

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. It was not always possible to conclude about the value of the intervention based on health effects and costs alone. The impact of the amendments on legal certainty was also considered in the following situations:

- Where health effects and costs were considered marginal.

- Where health effects and costs were considered similar.

- Where there was insufficient data to determine the health effects and/or costs.

6.3. Qualitative analysis

6.3.1. Product coverage

1. Do nothing.

   No impact. For the baseline scenario see the description in chapter 3.1.3.

2. Further clarify the product coverage in the Guidelines (Soft law).

   With a further explanation of the product coverage of the Directive in the Guidelines only a slight reduction of the products that do not ensure an adequate level of protection can be expected. Some manufacturers who already have products for professional use in their portfolio (dish-washing or oven gloves) will follow the Guidelines and will also fulfil the Directive's requirements for the gloves for private use. Nevertheless, due to the fact that it is a voluntary measure, it is expected that not all manufacturers will follow this explanation. The manufacturers who currently have no knowledge about the PPE

[44] See chapter 2.4.2 on p.18 of http://ec.europa.eu/enterprise/sectors/mechanical/files/ppe/rev-study-assess-part2_en.pdf and chapter 1.2 on p.12 of http://ec.europa.eu/enterprise/sectors/mechanical/files/ppe/rev-study-competitiveness_en.pdf

Directive because they only produce products for private use that are currently excluded from the Directive will hardly be reached by this option. This option will not lead to a clear legal situation because the exclusions in the Directive will remain. Those manufacturers who will apply the changes will incur higher costs due to the process of making the products compliant to the Directive, which may result in a cost disadvantage with respect to those not complying.

3. Amend exhaustive list of PPE not covered by the Directive.

With a change of the legislation a clear legal situation will be established. All manufacturers of the relevant product will be reached. Consequently, the possible reduction of products that do not ensure an adequate level of protection will be maximised. For all manufacturers there will be costs due to the process of making the products compliant to the legislation. The legislative option will provide for an effective compliance with higher safety requirements for those products that today do not ensure an adequate level of protection. A more effective protection of consumers will be ensured and a contribution for the reduction of accidents is therefore to be expected.

	Effectiveness	Efficiency		Coherence
		Costs	Benefits	
Do nothing	0	0	0	0
Soft law	+/-	-	+	+
Legislative measure	++	--	++	++

6.3.2. Conformity assessment

1. Do nothing.

No impact. For the baseline scenario see the description in chapter 3.2.3.

2. Voluntary agreement on application of production control (Soft law).

Using this option some reduction of products that do not ensure an adequate level of protection can be expected, as it can be expected that some manufacturers would adhere to stricter production control provisions. In order to have the maximum effect all involved manufacturers should agree. However, the research carried out suggests that this prospect is not realistic.

3. Modify the list of products subject to the most stringent conformity assessment procedure.

Modification along these lines will lead to greater legal certainty. All manufacturers of the relevant PPE must apply the most stringent conformity assessment procedure. It is expected that this will lead to a higher general quality of the products, i.e. to a reduction of the products on the market that do not ensure an adequate level of protection because the quality of the production process is regularly monitored. Overall costs for this option will be higher than for option 2 because all manufacturers are obliged to apply the changes.

However, an effective, consistent and reliable high quality of conformity assessment activities will be ensured.

	Effectiveness	Efficiency		Coherence
		Costs	Benefits	
Do nothing	0	0	0	0
Soft law	+	-	+	+
Legislative measure	++	--	++	++

6.3.3. Requirements

Technical file

1. Do nothing.

No impact. For the baseline scenario see the description in chapter 3.3.3.

2. Further clarify the issue in the PPE guidelines (Soft law).

The efficiency of the market surveillance authorities will be increased in the case where manufacturers follow the Guidelines and draw up a full technical file for category I products. The reduction of products that do not ensure an adequate level of protection that can be reached will depend on the percentage of manufacturers voluntarily following the Guidelines. The authorities will have the same problems as of now if the manufacturer does not provide a full technical file. Costs will arise for those manufacturers who will voluntarily draw up a full technical file.

3. Modify requirements on the technical file.

This will be the best solution in terms of clarity. The market surveillance authorities will be able to demand the technical file from all manufacturers because it will be a legal requirement. This option will increase the efficiency of the work of the authorities to the greatest degree. It is also reasonable to expect that the number of products that do not ensure an adequate level of protection will subsequently be reduced. Overall costs for this option will be higher than for option 2 because all manufacturers are obliged to draw up a full technical file. On the other hand, manufacturers would have a clearer legal framework in this respect. However, the legislative option will ensure that market surveillance authorities can effectively verify whether or not compliance with essential requirements is effectively achieved.

	Effectiveness	Efficiency		Coherence
		Costs	Benefits	
Do nothing	0	0	0	0
Soft law	+/-	-	+	+

Legislative measure	++	--	++	++

Validity and content of the EC type-examination certificate

1. Do nothing.

No impact. For the baseline scenario see description in chapter 3.3.3.

2. Notified Bodies to agree on limited validity and minimum content of certificates (Soft law).

In order to reach the best possible effect all Notified Bodies should follow such an agreement. As described in chapter 3.3.1 experiences have shown that not all Notified Bodies take part in the coordination group nor do they apply all agreed procedures. So the expected reduction of products on the market that do not ensure an adequate level of protection due to this change will be limited. The market surveillance authorities, who will be assisted to a degree by this proposal, will still be confronted with unclear certificates that, in addition, might be based on obsolete standards.

3. Time limit the validity of certificates and improve the requirements for the content of certificates.

This option will deliver the maximum effect. The legal requirement of a time-limitation of certificates will lead to a regular assessment of the compliance of the product with the legislation. All manufacturers and Notified Bodies will be bound by this. A reduction of the products on the market that do not ensure an adequate level of protection is to be expected. Because this option will be mandatory to all manufacturers the costs will be higher compared with option 2.

	Effectiveness	Efficiency		Coherence
		Costs	Benefits	
Do nothing	0	0	0	0
Soft law	+/-	-	+	+
Legislative measure	++	--	++	++

EC Declaration of conformity (DoC)

1. Do nothing.

No impact. For the baseline scenario see description in chapter 3.3.3.

2. Further clarify in the Guidelines the need for detailed information on conformity of the product and about the manufacturer (Soft law).

The change is proposed in order to support the work of the market surveillance authorities. It can be expected that some manufacturers will follow the recommendation of the Guidelines and voluntarily accompany their products with a DoC. This will lead to a more

efficient work of the authorities and subsequently to a reduction of the percentage of the products on the market that do not ensure an adequate level of protection. However, this option does not oblige the manufacturers to supply the DoC with the product. The market surveillance authorities will still be faced with the problem of only partial information being available.

3. Create requirement for the DoC to be supplied with every product.

This option will lead to a clear legal situation. Market surveillance authorities will benefit from the DoC now being supplied with every product. Their work will be more efficient than it has been previously been. Consequently the number of products that do not ensure an adequate level of protection will decrease. All manufacturers will be faced with the costs of printing the DoC for each item of PPE sold.

	Effectiveness	Efficiency		Coherence
		Costs	Benefits	
Do nothing	0	0	0	0
Soft law	+	-	+	+
Legislative measure	++	--	++	++

Basic Health and Safety Requirements (BHSR)

1. Do nothing.

No impact. For the baseline scenario see description in chapter 3.3.3.

2. Further clarify the application of BHSR in the Guidelines (Soft law).

This option will lead to a better understanding of the requirements by the manufacturers. Nevertheless the unclear legal situation will remain as there will be requirements in the legislation that either cannot be fulfilled in principle (comfort index in BHSR 3.5) or will lead to confusion of the user (transmission curve in BHSR 3.9.1). There are no additional costs expected with this proposed change.

3. Delete requirements from the basic requirements on:

- Mechanical vibrations (BHSR 3.1.3).
- Protection against harmful effects of noise (BHSR 3.5).
- Protection against radiation, non-ionising radiation (BHSR 3.9.1).

This option will solve practical problems for the manufacturers. In the case of BHSR 3.5 the manufacturer is in principle not able to present the comfort index with the product as described in chapter 3.3.1. The proposed changes will lead to a clarification and simplification of the legal situation without any effects, which could reasonably be expected, on the safety level of the products. No additional costs are expected.

	Effectiveness	Efficiency		Coherence
		Costs	Benefits	
Do nothing	0	0	0	0
Soft law	+/-	0	0	+
Legislative measure	++	0	0	++

6.4. In depth analysis

6.4.1. Product coverage

6.4.1.1. General remarks

The amendment proposes to include in the Directive products designed to protect against damp, water and heat and manufactured for private use (e.g. dish-washing and oven gloves). One of the reasons behind is that gloves for professional use are already included in the PPE Directive. Confusion in the market will be reduced and a more level playing field created by including gloves for private use as well. The amendment will have a positive impact on the fairness of competition, because self-certification will become mandatory. The public consultation showed support for this amendment as two third of the respondents agreed with it; the expected impact on costs was considered to be minimal.

6.4.1.2. Social impact

In interviews with the European Safety Federation[45], with one manufacturer and with representatives of Notified Bodies, some further reasons were offered. 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 gloves and the content of materials used. Inclusion in the PPE legislation will improve the general level and standard of information provided, including information for users on potentially allergenic materials used in rubber and coloured textile gloves. Consumers will thus be able to make a more informed choice when purchasing a given type of glove.

Manufacturers and market surveillance authorities agree that the inclusion of dish-washing gloves in the PPE legislation will have a positive effect on the proportion of products that do not ensure an adequate level of protection. Manufacturers expect a strong reduction of such products of 50% or more, whereas market surveillance authorities see room for a more modest reduction of 10-20%. Little data was available on the effect of updating the products included as PPE insofar as it would affect the probability that people will use such products. No data was available to assess the impact of including oven gloves as PPE.

As already stated, one Member State has identified 150 000 cases of burn at home in the country per year. Half of these burns concern the hands.

[45] ESF – an European association of manufacturers in the field of PPE

6.4.1.3. Economic impact

Impact on cost competitiveness

The effect of the amendment in terms of compliance and administrative costs per product is small. Self-certification implies that some technical documentation is needed on product composition and fulfilment of the basic requirements. These costs can be estimated to be in the order of a few hundred euros per product series and will thus have a low impact on costs per unit. The costs of labelling and of compiling and inserting user information are small as well, particularly in the case of firms that already produce certified oven gloves for professional use. However, according to one of the companies interviewed, consistent compliance with the basic requirements would entail a more costly production process (e.g. washing of latex and leather gloves so that they meet the requirements on protein and chromium, respectively). 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. Because the gloves are not yet covered by the PPE Directive, information for tracing the manufacturer is not yet required. Therefore, 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. The amendment implies that such information should be traceable in the future. Provided market surveillance is effective, this will improve the conditions for fair and transparent competition.

Impact on SMEs

Awareness among SME about the basic requirements for protective gloves may be at a lower level, if they do not produce PPE gloves. If production processes need to be upgraded to ensure compliance, the cost impact could be relatively large. The extent to which EU-based SMEs would fail to comply with the basic requirements is unclear, but information from the trade association ESF, one of the Notified Bodies and also from the consultation report does not suggest many difficulties in this respect. Compared to dishwashing gloves, the market for oven gloves features quite a number of small operators that produce in the EU. The overall size of the market is relatively small. Branding and design of textile gloves for small retailers is a substantial niche market, where smaller volumes are produced. The fixed costs related to this amendment will affect these SME producers more. Previous awareness of the PPE Directive is also smaller among these types of firms, because they are typically not involved in the production of PPE products. The initial up-front costs will be higher as a consequence. Even so, as the requirements for Category I PPE are not especially demanding, additional costs are likely to remain relatively low. On the other hand manufacturers will benefit from increased competitiveness because self-certification to the basic PPE requirements improves transparency and helps to tackle import of products that do not ensure an adequate level of protection by more effective market surveillance and more awareness of the requirements by distributors that sell for example private labels.

6.4.2. Conformity assessment

6.4.2.1. General remarks

The proposal is to move certain types of PPE from category II to category III products. The proposed change has the consequence that these products will be subjected to the most stringent conformity assessment procedure (Article 11 of the PPE Directive[46]). It requires that the production process is subject to an additional quality control procedure on manufactured goods. The manufacturer has the option to choose between (i) an EC quality control system for final products (Article 11 A), or (ii) a system for ensuring EC quality of production by means of monitoring (Article 11 B). In both cases a Notified Body carries out the check on the final product or monitors the production process at least once a year.

The assessment is done separately for the different types of PPE.

PPE to protect against drowning (life jackets)

A prospective amendment to move life jackets into category III received support in several interviews on the grounds that they protect against a danger of fatality. The public consultation showed support for this reclassification, too.

6.4.2.2. Social impact

Interviews with the EU-based manufacturers revealed that such an amendment could help to improve compliance by introducing annual monitoring. With such an amendment product quality would be checked more consistently. The proportion of life jackets with inadequate level of protection will be reduced although there was disagreement as to the extent of the effect. Whereas market surveillance authorities would not expect to see a perceptible effect here, manufacturers envisage a small reduction and Notified Bodies expect reductions of products that do not ensure an adequate level of protection in the order of 10 %.

6.4.2.3. Economic impact

Impact on cost competitiveness

The public consultation indicates that about half of the respondents expect either very modest compliance and administrative costs or none at all. Even so a quarter would expect higher costs. The main impact of the amendment would be the need for annual monitoring of the production process under Article 11 of the PPE Directive. According to one Notified Body, some adjustment may be needed to an existing general quality assurance system to focus the system on the specific (families of) products that are produced (under the choice for monitoring according to Article 11 B).

If a quality control system equivalent to ISO 9001 has already been implemented but does not have a product-specific implementation, the costs of adjusting the system for PPE category III audits would be a one-off. It may involve one or two consultant audits (each in the order of a few thousand Euros), and the internal costs of setting up detailed quality assurance manuals.

Most firms based in the EU already have an ISO 9001 quality assurance system, or equivalent, in place. Those that produce under the SOLAS[47] regulation are also audited

[46] See Annex 1.

[47] SOLAS is the International Convention for the **S**afety **o**f **L**ife **a**t **S**ea, an international maritime safety treaty. Life jackets intended to be used on sea-going vessels are excluded from the PPE Directive.

annually in respect of quality assurance. For these manufacturers, additional costs would be low to negligible. In addition annual recurring audit costs are low for these manufacturers. A Notified Body indicated that quality assurance audit reports under SOLAS can be used as a basis for PPE audits as well. For firms that have to implement a quality control system from scratch, costs are highest.

Impact on the capacity to innovate

The sector has shown rapid innovation in characteristics such as in the operation of life jackets, and in their wearing comfort and weight over the past 20 years. An important driver has been the development of European and international product standards, most recently EN ISO 12402. These standards are the benchmark for EC-type certification, and also require quality control and the use of certified materials. The amendment therefore can be expected to have limited effects on innovation by EU manufacturers. Innovation and product quality are already seen as drivers of their competitive strategies. The amendment will not affect their choice and use of materials and their internal testing, because this is already part of the relevant EN ISO product standards. For manufacturers based outside of the EU, the lower end manufacturers will have to focus more on product quality, because annual monitoring will require consistent quality levels that meet the industry standards.

It was also pointed out by stakeholders that additional costs related to the annual checks by Notified Bodies could come at the expense of research budgets. Moreover, EC-type certification of new or changed products may cause delay in product development. This could reduce the capacity to innovate. However the rules of EC type certification also require examination under Category II. The extra impact of Category III is very limited or even absent with regard to EC type-examination. Annual production process audits can easily include additional products at limited costs.

Impact on international competitiveness

The impact on international competitiveness of EU-based manufacturers is seen as mostly positive. Most of the larger manufacturers do not produce in the EU. Some production by small to medium sized manufacturers takes place in Europe. Most of these manufacturers adhere to international standards and have quality control systems. Offshoring of production will probably not increase as a consequence of the amendment, as annual monitoring makes quality assurance even more important than before. Costs of site visits outside of the EU are likely to be higher, and without large scale production, it would be difficult to finance resources to assuring the quality of products and monitoring systems across various production sites, and even more so if they are offshore facilities. Some manufacturers deliberately choose to produce in the EU to better guarantee the quality of production.

The amendment is likely to improve the competitiveness of EU industry as a whole. This improvement of the competitive position of EU-based firms in both domestic and international markets would reflect their pre-existing focus on standards and quality assurance. Manufacturers outside the EU that want to sell into the EU market will have to install quality control systems that meet the EU standards, and invest in the proper documentation for annual monitoring. Compliance in the market will increase due to annual monitoring. This would help to prevent any forms of price competition that were simply at the

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Nevertheless there can be manufacturers that have life jackets for the use on sea-going vessels and for use as PPE in their portfolio.

expense of maintaining quality standards. EU-based manufacturers already commit themselves to EN ISO standards and related quality control. Ultimately, products that do not ensure an adequate level of protection may still reach the market, depending on the effectiveness of the market surveillance function and the policies of distributors, but this phenomenon is likely to decrease.

Impact on SMEs

Annual monitoring creates costs that are more difficult to bear at a lower scale of production. Budgets for research may compete with fixed annual costs of monitoring, although the costs per product series probably will not exceed a few thousand Euros annually once the quality assurance mechanism has been implemented. Most SMEs in Europe have already endorsed ISO standards and additional costs per product of annual monitoring are still relatively limited, when compared to the volume of lifejackets sold.

Hearing protection (ear plugs, ear muffs)

The move of hearing protection equipment from category II to category III is not endorsed unanimously by stakeholders. Opinions differ as to its justification on the basis of protection against serious irreversible harm. Others are not aware of user health and safety problems that are related to malfunctioning of certified products. The interviews carried out confirm the mixed opinions. The public consultation shows that about twice as many stakeholders disagreed with the amendment; those in agreement state that the impact in terms of compliance and administrative burdens would be minimal.

The prevalence of products on the market that do not ensure an adequate level of protection is often considered to be an especially acute problem for ear muffs and ear plugs manufacturers. Even if they have been certified in the past, current production may not comply with the PPE certified model products. The change to category III would provide extra safeguards for product quality. Annual testing better ensures product and production homogeneity and compliance to basic PPE requirements and relevant product standards. Another advantage of re-categorization would be quality differentiation with respect to products that do not ensure an adequate level of protection.

6.4.2.4. Social impact

The proposed move to category III would have a medium cost for manufacturers but also result in a medium reduction in the proportion of products on the market that do not ensure an adequate level of protection. Manufacturers expect a small reduction whereas Notified Bodies expect a significant reduction of such products in the order of 25-50 %.

6.4.2.5. Economic impact

Impact on cost competiveness

Basic ear plugs and basic ear muffs are homogeneous products. Production is typically in large volumes, and part of the production has been offshored to the Far East. Often quality control systems are in place. A move to category III would therefore not entail high costs. The annual product or production process control costs would have to be borne. The costs of EC type-examination (for new products) and annual product testing by Notified Bodies could be relatively low for ear plugs and basic ear muffs as these products are not so complex to test (a few thousand Euros per product series). Moreover, the costs can be split over a large volume of production, such that per unit costs would not increase much. Whilst the additional costs per product series may be in the order of a few hundred to a few thousand euros annually at

maximum for manufacturers with established quality control systems, the costs of starting from zero in terms of setting up quality control systems could be a factor of ten higher.

Complex ear muffs or plugs are integrated solutions for combinations of head, breathing, and hearing protection. In addition electronic communication devices are often integrated. These products involve more complex technology and are typically produced in smaller quantities, or can even be customized to a considerable degree. The market for such products is developing relatively fast. The cost structure is different for these products, as it is driven more by innovation and high-skilled labour costs. Although the production scale of individual items is smaller most firms in this segment of the market are still large manufacturers. The extra costs of annual audits would be small relative to the production value. Quality control systems in large firms can be expected to be in place, especially if basic ear muffs are also produced.

Price increases to compensate for the cost effect of the amendment are not expected, at least not in the short run. For large EU manufacturers, the cost increase per unit is expected to be (very) small. Smaller firms may face relatively higher initial costs to set up quality control systems. Price setting by the dominant firms in the market determines pricing of the smaller players. The amendment may result in cost increases due to annual conformity assessment for these products, which would, in turn, reduce the variations in product quality and prices.

Impact on the capacity to innovate

The impact on innovation differs somewhat across the market segments of hearing protection products that are affected. Ear plugs are less complex products than ear muffs, and involve less innovation. No substantial impact on innovation is expected for ear plugs, ear plug technology has not changed much over time. The large volumes of production imply that additional costs of category III type approval and quality assurance for new products only result in a small expected unit cost increase for any new or improved products.

The development of product quality standards has been a spur to innovation in the EU in various sectors of PPE. In ear muffs, a more consistent monitoring of quality under Category III can create a further focus on innovation. Innovation is a key to competitiveness for this segment. Production monitoring by the Notified Body via annual production site visits does not pose additional annual costs for new products.

Impact on international competitiveness

The impact on international competitiveness entails some positive and some negative aspects. Positive effects include the incentive to attain consistent levels of product quality and homogeneity in the production process, for which EU manufacturers are better positioned. Annual checks by Notified Bodies already help to increase compliance. The cost and possibly price increases resulting from the change in PPE category imply, however, that the need to keep products that do not ensure an adequate level of protection off the market becomes even more important to ensure fair competition.

Most of the production of ear plugs and basic ear muffs has been offshored to the Far East (e.g. China). The main reasons for offshoring are labour costs and materials costs. EC type-examination and annual monitoring are in general more expensive if production sites are located outside the EU, due to travel costs and the availability of testing houses. If anything, the consequence would be that offshoring becomes somewhat less attractive. As long as products are relatively basic, and large volumes of production are needed, quality of production can be sufficiently assured in offshore production sites. The larger firms have centralized testing facilities to check product quality across production sites. The more complex and customized products are still manufactured in Europe, and, relatively more

often, by smaller companies that serve a more local market. It involves more high-skilled labour inputs per unit produced. For all of these reasons offshoring has not been such an attractive option so far in this segment.

A shift to category III would imply more costs for manufacturers that do not have an EU-base where superior levels of knowledge of the procedures and requirements of annual sample testing or monitoring of production might reasonably be anticipated.

Impact on SMEs

Where quality control systems are not in place, their establishments involve fixed costs. The studies available do not provide data about the share of SMEs having created or not quality control systems. The impact on total costs and unit costs of creating such systems can be more substantial for this group of companies. SMEs are more common in the segment of complex, integrated hearing protection products, especially for highly specialized communication muffs. More complex products will be more likely to follow product standards that have a focus on product quality aspects. However, this does not necessarily mean that all or a majority of SMEs have created already quality control systems.

Bullet-resistant and knife stab-resistant PPE

Overall for these products the results of consultations indicate that the move from category II to category III is seen as a good, logical and important step. Related to this the European Safety Federation for example stated in its position paper that it agreed that these types of PPE should be classified as category III as these clearly provide protection against the risk of fatalities. This was backed up by the interviews carried out.

6.4.2.6. Social impact

The move to category III will have only a minor effect on the proportion of products on the market that do not ensure an adequate level of protection. The main reason for this is the already existing high quality of these products on the market. Nevertheless Notified Bodies expect a reduction of products that do not ensure an adequate level of protection in the order of 10 %.

6.4.2.7. Economic impact

Impact on cost competiveness

The amendment is expected to have a limited impact on the cost competitiveness of the EU companies. The cost structure of the vests is not entirely clear, but the high-tech fibres and fabrics and the specialised garment making form the main inputs for these capital intensive products. Furthermore most of the manufacturers of these vests already have a system in place which fulfils the category III requirements or they can fulfil the requirements with limited extra efforts. The most important clients (50%-60% of market sales) are the defence industry and public servants involved in the maintenance of law and order. These clients often work with tender procedures where quality is an important element. Although PPE designed and manufactured specifically for use by the armed forces or in the maintenance of law and order are not covered by the PPE Directive, these products have to satisfy very strict product quality and safety norms. Many producers, therefore, have quality assurance procedures in place or are certified for specific standards (e.g. ISO 9001) which then become the starting point for the annual quality assurance monitoring by Notified Bodies for those products that are subject to the PPE Directive. Their products and production processes satisfy category III-equivalent levels of requirements (i.e. the basic infrastructure and knowledge is already there). As a result, it is expected that the effect on the costs (including compliance costs) and prices of the

products is very limited. Exceptions to this general assessment are those (usually small) enterprises which do not have a proper quality system in place yet.

Impact on the capacity to innovate

The proposed move to category III has a very limited effect on the capacity to innovate for companies in this segment. For these types of PPE, the innovation mainly results from investments in research and development (R&D), public procurement procedures (with specific requirements) and existing standards. The additional quality control process will not hinder and/or encourage these innovation processes (e.g. in terms of market launch delay, lack of incentives, etc.). In very many of public procurement procedures these kinds of quality control processes are already required (and, indeed, already in place).

Impact on international competitiveness

The expected impact of the amendment on international competitiveness is considered neutral and/or limited. The amendment is expected to have practically no impact on the EU as a production base or on the relocation of production. This type of PPE requires high-tech inputs and a capital intensive production process (fibres, fabrics, garments). Production is mainly based in the EU and is expected to remain there. High quality fibres, fabrics and garments are essential for the level of protection and to maintain the trust of the main clients. Assembling work (e.g. stitching) is already done in Romania, Bulgaria or outside the EU (North-Africa, Turkey, etc.). This situation will not be influenced by the prospective amendments to the PPE legislation.

The amendment is expected to have a limited effect on the competitiveness of EU companies in international or domestic markets. The biggest markets, the US and EU, are already distinctly separate in nature and it is often difficult to access alternative markets, either for regulatory (lack of harmonised standards, specific US Army regulations) or for practical reasons (e.g. scattered presence of end-users, the place of the zip, etc.). The move from category II to category III will not influence this situation.

Impact on SMEs

As indicated above the amendment will have limited impact on manufacturers which already have a quality control system in place. Within this segment the leading manufacturers are often medium sized enterprises. Micro sized (< 10 employees) or small sized enterprises (< 50 employees) will tend, especially, to be confronted with additional costs as they are not always already (e.g. ISO 9001) certified. It is unclear how many (small sized) enterprises will be affected by this but stakeholders expect that it is only a limited number.

Protection against cutting by hand-held chain saws

The overall opinion of the stakeholders indicates that the move from category II to category III for this type of PPE is seen as a logical step. It is established beyond doubt that this type of PPE provides protection against irreversible harm to the health of the user or worse. The proposed move to category III was backed by a large majority in the public consultation (49 replies in favour against 5 not in favour).

6.4.2.8. Social impact

Manufacturers and Notified Bodies estimate that between 5 % and 20 % of the products on the market do not ensure an adequate level of protection. Whereas manufacturers would not expect a change in this proportion, Notified Bodies expect a large reduction of such products in the order of 50 %. Taking an average of these it can be said that the move to category III

will have a small effect on the proportion of products on the market that do not ensure an adequate level of protection.

6.4.2.9. Economic impact

The interviews point towards a low impact on manufacturer costs from a reclassification of equipment to protect against cutting by hand-held chain saws. A majority of those who responded to the public consultation thought that very modest or no additional costs would occur with the proposed modification.

Protection against high pressure cutting

There also seems to be a logical case for moving PPE protecting against high pressure cutting into category III. As with PPE protecting against cutting by hand held chain saws this PPE protects against irreversible harm to the health of the user. Consequently a majority of replies to the public consultation agreed with the proposed modification (31 replies in favour with 10 against).

6.4.2.10. Social impact

The Notified Bodies expect a significant reduction (in the order of 25-50 %) of products on the market that do not ensure an adequate level of protection. On the other hand market surveillance authorities as well as manufacturers, do not expect a perceptible effect. Taking an average of these it can be said that the move to category III will have a small effect.

6.4.2.11. Economic impact

The public consultation indicated a large majority estimating either very modest or no additional costs at all for the manufacturers from the proposed modification. This estimate was confirmed through the interviews that also foresaw only marginal additional costs for the manufacturers.

6.4.3. Requirements

The results of the interviews and consultations suggest that the proposed requirement changes will lead to marginal incremental costs for producers. These costs are offset by a variety of effects on health (either through reduced likelihood that a product does not ensure an adequate level of protection or through greater use of the product). Table 1 summarises the costs and benefits of the proposed changes.

Table 1: Summary of costs and benefits of the proposed changes to the requirements of the PPE legislation

Requirement change	**Cost to current manufacturers**	**Certainty of health impact**
Technical file	Marginal	Insufficient data
Validity of EC type-examination certificate	Insufficient data	Medium
EC Declaration of conformity	Marginal	Medium

In all interviews the importance of efficient market surveillance was stressed. The following proposed changes that are being assessed support the work of the market surveillance authorities and are seen by the stakeholders as an important tool to increase their efficiency.

Technical file

6.4.3.1. Social impact

In particular the market surveillance authorities see an advantage with the proposed change to require the technical file for category I PPE. This will facilitate the first assessment of these products and will increase the efficiency of the work of the authorities. The public consultation supports this option. A majority of 37 respondents agreed that the proposed change would facilitate market surveillance whereas only 10 respondents disagreed. The interviewees could not offer firm figures but the public consultation envisages, as a consequence, a reduction of the proportion of products on the market that do not ensure an adequate level of protection in the order of 1-10 %. Apart from this the proposed change will help to improve legal certainty.

6.4.3.2. Economic impact

The interviews suggest that the cost of implementing this change will be marginal as manufacturers already have internal production control in place and could easily provide this technical documentation. This is supported by the result of the public consultation that expects either very modest or no additional costs and/or administrative burdens for the manufacturers.

Validity and content of the EC type-examination certificate

6.4.3.3. Social impact

There was support from all types of interviewees, as well as from the majority of the responders of the public consultation, for the proposed time-limitation of the validity of the certificate to five years. That would reduce the number of products that do not ensure an adequate level of protection by ensuring that older products were assessed more regularly. The market surveillance authorities as well as the Notified Bodies expect a reduction in the order of 10-25 %.

The proposed change to introduce requirements for a minimum content of the EC type-examination certificates will support market surveillance authorities in identifying and acting upon the relevant information in the certificate. The results of the public consultation support this change with a huge majority (71 in favour, 2 against). Direct benefits to health and safety are probably more marginal and limited to an increase in the efficiency and effectiveness of the market surveillance function.

This proposed change on the EC type-examination certificate would indisputably enhance legal certainty.

6.4.3.4. Economic impact

The interviews did not give values for the cost connected to any time-limitation of the certificates. In order to limit the additional burden of the manufacturers for re-certification of their product after the expiry of the certificate the proposal will provide for a "light" procedure. Thus, where neither the product nor the relevant harmonised standard has

undergone a substantial change the applied procedure to gaining a new certificate will be reduced compared to a new request for EC type-examination.

The cost of a mandatory minimum content will be negligible as the Notified Bodies, although having to use a different format for their examination certificates, should be dealing with roughly the same content. Provided that the change is only enacted for new certificates, the costs would mainly be concentrated on the drafting process of the common format

EC Declaration of Conformity (DoC)

6.4.3.5. Social impact

The proposed requirement to supply the Declaration of Conformity with the PPE has the aim to support the work of the market surveillance authorities. With easier access to the data of the manufacturer their work will be more efficient. The resulted reduction of products on the market that do not ensure an adequate level of protection is expected to be in the order of 10-25 % by the authorities and in the order of 25-50 % by the Notified Bodies. The public consultation saw precisely as many replies in favour as against this proposal. A majority of those respondents who were in favour expected a reduction in the order of 5-15 %.

6.4.3.6. Economic impact

Both the interviews and the public consultation point towards very modest or no additional costs and administrative burdens for the manufacturers as the result of the proposed change. One manufacturer of PPE to protect against high pressure cutting felt that the mandatory supply of the Declaration of conformity would actually save money as his clients often require this document to be sent to them. Some manufacturers have raised objections against this change. In their opinion this will lead to extra costs for the manufacturers and extra burden for the environment. But they welcomed the Commission proposal to provide for a simplified Declaration of Conformity. A simplified DoC consists only of one sentence in the printed user information supplied with the PPE, which declares the compliance with the PPE legislation. It shall be immediately followed by the exact internet or E-mail address where the full EC Declaration of Conformity can be obtained. This solution will reach both aims to support the authorities and to minimise the additional burden of the manufacturers.

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. Either:

– the requirement is not deemed to be reasonable[48] (BHSR 3.1.3, limit values in case of mechanical vibration) or

– the manufacturer in principle cannot fulfil the requirement (BHSR 3.5, comfort index that is not established and consequently cannot be measured) or

– the consequences of the requirement are deemed to be confusing for the user of the PPE (BHSR 3.9.1, indicating a transmission curve in case of PPE against non-ionizing radiation).

[48] See explanation to BHSR in chapter 3.3.1.

Overall the impact of all the above 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. Those who responded to the public consultation confirm all three proposals with a large majority and in particular do not expect any substantial increase in prices of PPE due to the replacing of the requirement for information on the "transmission curve" with that on the "protection factor" in case of BHSR 3.9.1.

6.5. Mitigation measures

The in depth analysis has revealed that costs related to the annual monitoring of the production process will result in an additional burden especially for SMEs. In order to alleviate those, different mitigating measures have been analysed.

Exempting SMEs from the proposed changes in the PPE legislation is not a viable option for the following reasons. As mentioned in chapter 2.2.5 a large percentage of PPE manufacturers are SMEs. An exemption would result in a much lower improvement of the health and safety of the users than intended by the revision of the legislation. Only limited number of products placed on the market by larger companies would be improved. Since the PPE sector is part of the health and safety field such an outcome is undesirable. Furthermore it is likely that an exemption for SMEs could create a boomerang effect: the products placed on the market by SMEs would have a lower level of safety compared to the products sold by large manufactures. This being known to the consumers could have impact on their purchase choices and preference for products providing higher level of protection, i.e. those sold by large manufacturers.

However, as most of the burdens to SMEs will originate from enhanced conformity assessment procedures, these burdens can be reduced to a reasonable dimension. The revised legislation could provide for mitigating measures for SMEs when making use of the service of a Notified Bodies. There could be obligations for Notified Bodies to carry out the conformity assessment in a proportionate manner. The NBs have to adapt their activities to the size and structure of the manufacturer in order to reduce unnecessary burdens.

7. COMPARING THE OPTIONS

On the basis of the qualitative and in depth assessment done in chapter 6 the following conclusions are made for comparing the options (see Table 2). The magnitude of each impact is assessed according to the following scale:

++ significant positive impact

+ minor positive impact

0 no impact / baseline

- minor negative impact

-- significant negative impact

The preferred options for each proposed change are highlighted in grey colour.

Table 2: Comparing the options for the proposed change, the preferred options are highlighted in grey colour

	Effectiveness	**Efficiency**		**Coherence**
		Costs	**Benefits**	
Product coverage				
Do nothing	**0**	**0**	**0**	**0**
Soft law	+/- Specific objectives partly met (health and safety improved so to some extent; but unclear legal situation remains)	- costs for making products compliant (assuming that not 100% of manufacturers will comply if they do not need to do so)	+ Slight reduction of non-compliant products (not all manufacturers will be reached)	+ Will partly contribute to better regulation and Single Market Act; but unclear legal situation
Legislative measure	++ Specific objectives fully met (improvement of health and safety; clear legal situation). The legislative option will allow that products that today do not ensure an adequate level of protection will need to comply with higher safety requirements and therefore become reliable to consumers and contribute to reduce the number of accidents. A more effective consumer protection will be ensured.	-- costs for making products compliant (all manufacturers obliged to comply)	++ The highest reduction of non-compliant products (all manufacturers will be obliged to comply)	++ Will optimally contribute to better regulation and Single Market Act; clear legal situation
Conformity assessment				
Do nothing	**0**	**0**	**0**	**0**
Soft law	+ Specific objectives partly met (consistency of conformity assessment procedures not fully reached; some improvement of the quality of the relevant products)	- costs for establishing production control (assuming that not 100% of manufacturers will comply if they do not need to do so)	+ Some reduction of non-compliant products (only voluntary measure)	+ Will contribute to better regulation and Single Market Act; but unclear legal situation
Legislative measure	++ Specific objectives fully met (consistency of conformity assessment procedures; most increment of the quality of the relevant products; clear legal situation). The legislative option is the one that can ensure a consistent high quality of conformity assessment activities and the resulting reliability.	-- costs for establishing production control (all manufacturers obliged to comply)	++ The highest reduction of non-compliant products (all manufacturers will be obliged)	++ Will optimally contribute to better regulation and Single Market Act; clear legal situation

Technical file				
Do nothing	**0**	**0**	**0**	**0**
Soft law	+/- Specific objectives partly met (partial improvement of market surveillance work; but unclear legal situation)	- costs related to drawing up the technical file (for those applying voluntary schemes)	+ Some reduction of non-compliant products (only voluntary)	+ Will contribute to better regulation; but unclear legal situation
Legislative measure	++ Specific objectives fully met (best improvement of market surveillance work; clear legal situation). The effectiveness of ensuring compliance with legal requirements will be enhanced.	-- costs drawing up the technical file (for all)	++ The highest reduction of non-compliant products (all manufacturers will be obliged)	++ Will optimally contribute to better regulation; clear legal situation
Validity and content of EC type-examination certificate				
Do nothing	**0**	**0**	**0**	**0**
Soft law	+/- Specific objectives partly met (consistency of conformity assessment procedures not fully reached; partial improvement of market surveillance work; but unclear legal situation)	- costs for re-certification (for those applying voluntary schemes)	+ Some reduction of non-compliant products (only voluntary)	+ Will contribute to better regulation; but unclear legal situation
Legislative measure	++ Specific objectives fully met (consistency of conformity assessment procedures; best improvement of market surveillance work; clear legal situation)	-- costs for re-certification (for all)	++ The highest reduction of non-compliant products (all manufacturers will be obliged)	++ Will optimally contribute to better regulation; requirement is coherent to other New Approach directives; clear legal situation
EC Declaration of Conformity (DoC)				
Do nothing	**0**	**0**	**0**	**0**
Soft law	+ Specific objectives partly met (partial improvement of market surveillance work; but unclear legal situation)	- costs for printing the DoC for each item sold (for those applying voluntary schemes)	+ Some reduction of non-compliant products (only voluntary)	+ Will contribute to better regulation; but unclear legal situation
Legislative measure	++ Specific objectives fully met (best improvement of market surveillance work; clear legal situation)	-- costs for printing the DoC for each item sold (for all)	++ The highest reduction of non-compliant products (all manufacturers will be obliged)	++ Will optimally contribute to better regulation; requirement is coherent to other New Approach directives; clear legal situation
Basic Health and Safety Requirements (BHSR)				
Do nothing	**0**	**0**	**0**	**0**

Soft law	+/- Specific objectives partly met (simplification only through Guidance; unclear legal situation)	**0** no costs due to the deletion of parts of the BHSR	**0** No effective change of the health and safety level due to the deletion of parts of the BHSR	+ Will contribute to simplification of regulation; but unclear legal situation
Legislative measure	++ Specific objectives fully met (simplification of the legislation; practicable Directive's requirements; clear legal situation)	**0** no costs due to the deletion of parts of the BHSR	**0** No effective change of the health and safety level due to the deletion of parts of the BHSR	++ Will optimally contribute to simplification of regulation; clear legal situation

8. 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. Those involve in particular the following established groups:

– PPE Working group;

– PPE Administrative Cooperation group (AdCo);

– Horizontal Coordination of the Notified Bodies in the field of PPE.

In all of these groups a standing agenda item will be established for reporting on products 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.

The monitoring of the reduction of products that do not ensure an adequate level of protection will be possible via the following indicators:

– Number of products checked;

– Number of products that do not ensure an adequate level of protection among those checked;

– Type of problems found.

These enforcement indicators will be based on information provided by the market surveillance authorities via

– the RAPEX[49] system;

– a general database established under Article 23 of the NLF Regulation 765/2008 for the exchange of information among the Member States on market surveillance activities and products that do not ensure an adequate level of protection (ICSMS);

– the safeguard clause notification procedures.

[49] RAPEX is the EU rapid alert system for all dangerous consumer and non-consumer harmonised products (see http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm).

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

In line with its "Smart regulation" policy[50] the Commission will evaluate the effectiveness of the revised PPE legislation within a period of five up to a maximum of 10 years after the date of application of the revised legislation, basing itself on the feedback obtained from the mechanisms set out above. Should specific circumstance so require, the Commission will ask for an external evaluation.

9. 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. As outlined in chapter 3.4, this legislation is based on Article 114 TFEU with the objective of ensuring the proper functioning of the internal market for personal protective equipment. To achieve this objective, the PPE directive 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. In particular, the mandatory essential health and safety requirements for products and the conformity assessment procedures to be followed by manufacturers must be identical in all of the Member States. 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.

The same applies to the new provisions that will be integrated into the text following the alignment to the NLF Decision No 768/2008/EC. These provisions lay down requirements, obligations and procedures for the manufacturers, importers and distributors of PPE and for the notified bodies that carry out the conformity assessment procedures. All of these provisions are clear and sufficiently precise to be applied directly by the actors concerned.

The obligations set by the legislation for the Member States, such as the obligation to assess, appoint and notify the conformity assessment bodies are, in any case, not transposed as such into national law but implemented by the Member States by means of the necessary regulatory and administrative arrangements. This will not change when the obligations concerned are set out in a Regulation.

The change from a Directive to a Regulation will not lead to any change in the regulatory approach. The characteristics of the New Approach will be fully preserved, in particular the flexibility given to manufacturers in the choice of the means employed to comply with the essential requirements (harmonised standards or other technical specifications) and in the choice of the procedure used to demonstrate compliance from among the available conformity assessment procedures. The existing mechanisms supporting the implementation of the legislation (standardisation process, working groups, market surveillance, administrative cooperation (ADCO), the development of guidance documents…) will not be affected by the nature of the legal instrument and will continue to operate in the same manner under the Regulation as they currently do under the Directive.

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50 http://ec.europa.eu/enterprise/policies/smart-regulation/index_en.htm

Stakeholder views:

On a general level, industry associations[51] have expressed their preference for using Regulations in the area of internal market legislation, for two reasons: first, the risk of 'gold plating' is avoided and second, it allows manufacturers to work directly with the Regulation text instead of needing to identify and examine 28 transposition laws.

There is no uniform position of Member States on this issue. While some see benefits in terms of saving transposition costs, other point out that, despite the direct applicability of a Regulation, certain national implementation measures (e.g. relating to enforcement) and modifications of existing national legislation are necessary.

Summing up, it is considered that the use of a Regulation will be beneficial for the sector. It will avoid the costs for the Member States associated with the transposition of a Directive. It will allow for a more rapid application of the new legislation and will help economic operators to conduct their business as they will have to deal with a single regulatory instrument rather than with 28 national laws transposing a Directive.

[51] E.g. ORGALIME Position paper on the reform of the internal market for goods , 16 April 2013, http://www.orgalime.org/sites/default/files/position-papers/PP_Internal_Market_for_Industrial_Products_April13.pdf

ANNEX 1: ARTICLE 11 OF THE PPE DIRECTIVE

Article 11

A. 'EC' quality control system for the final product

1. A manufacturer shall take all steps necessary to ensure that the manufacturing process, including the final inspection of PPE and tests, ensures the homogeneity of production and the conformity of PPE with the type described in the EC type-approval certificate and with the relevant basic requirements of this Directive.

2. A body of which notification has been given, chosen by a manufacturer, shall carry out the necessary checks. Those checks shall be carried out at random, normally at intervals of at least one year.

3. An adequate sample of PPE taken by the body of which notification has been given shall be examined and appropriate tests defined in the harmonized standards or necessary to show conformity to the basic requirements of this Directive shall be carried out to check the conformity of PPE.

4. Where a body is not the body that issued the relevant EC type-approval certificate it shall contact the body of which notification has been given in the event of difficulties in connection with the assessment of the conformity of samples.

5. The body of which notification has been given shall provide the manufacturer with a test report. If the report concludes that production is not homogeneous or that the PPE examined do not conform to the type described in the EC type-approval certificate or the relevant basic requirements, the body shall take measures appropriate to the nature of the fault or faults recorded and inform the Member State which gave notification thereof accordingly.

6. The manufacturer must be able to present, on request, the report of the body of which notification has been given.

B. System for ensuring EC quality of production by means of monitoring

1. *The system*

(a) Under this procedure the manufacturer submits an application for the approval of his quality-control system to a body of which notification has been given, of his choice.

That application shall include:

– all the information relating to the category of PPE concerned, including, where appropriate, documentation relating to the model approved,

– documentation on the quality-control system,

– the undertaking to maintain the obligations arising from the quality-control system and to maintain its adequacy and efficiency.

(b) Under the quality-control system, each PPE shall be examined and the appropriate tests referred to in Section A paragraph 3 shall be carried out to check their conformity to the relevant basic requirements of this Directive.

The documentation on the quality-control system shall in particular include an adequate description of:

– the quality objectives, the organization chart, the responsibilities of executives and their powers in respect of product quality,

– the checks and tests which must be carried out after manufacture,

– the means to be employed to check the efficient operation of the quality-control system.

(c) The body shall assess the quality-control system to determine whether it satisfies the provisions referred to in paragraph 1 (b). It shall assume that quality-control systems applying the relevant harmonized standard satisfy those provisions.

The body carrying out audits shall make all necessary objective evaluations of the components of the quality-control system and shall check in particular whether the system ensures conformity of PPE manufactured with the approved model.

The decision shall be communicated to the manufacturer. It shall include the conclusions of the check and the reasoned assessment decision.

(d) The manufacturer shall inform the body which approved the quality-control system of any plan to alter the quality-control system.

The body shall examine the proposed changes and decide whether the altered quality-control system satisfies the relevant provisions. It shall communicate its decision to the manufacturer. The communication shall include the conclusions of the check and the reasoned assessment decision.

2. *Supervision*

(e) The purpose of supervision is to ensure that a manufacturer correctly fulfils the obligations arising from the approved quality-control system.

(f) The manufacturer shall authorize the body to have access, for purposes of inspection, to PPE inspection, testing and storage sites and shall provide the body with all requisite information, in particular:

– documentation on the quality-control system,

– technical documentation,

– quality control manuals.

(g) The body shall periodically carry out audits to ensure that the manufacturer is maintaining and applying the approved quality-control system and shall provide the manufacturer with a copy of the audit report.

(h) In addition, the body may make unannounced visits to the manufacturer. In the course of such visits the body shall provide the manufacturer with a report of the visit and, if appropriate, with an audit report.

The manufacturer must be able to present, on request, the report of the body of which notification has been given.

ANNEX 2: RELEVANT PARTS FROM THE ANNEX II OF THE PPE DIRECTIVE

ANNEX II (of 89/686/EEC)

BASIC HEALTH AND SAFETY REQUIREMENTS

1. GENERAL REQUIREMENTS APPLICABLE TO ALL PPE

PPE must provide adequate protection against all risks encountered.

…

1.4. Information supplied by the manufacturer

In addition to the name and address of the manufacturer and/or his authorized representative established in the Community, the notes that must be drawn up by the former and supplied when PPE is placed on the market must contain all relevant information on:

(i) storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions;

(j) performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in question;

(k) suitable PPE accessories and the characteristics of appropriate spare parts;

(l) the classes of protection appropriate to different levels of risk and the corresponding limits of use;

(m) the obsolescence deadline or period of obsolescence of PPE or certain of its components;

(n) the type of packaging suitable for transport;

(o) the significance of any markings (see 2.12).

(p) where appropriate, the references of the Directives applied in accordance with Article 5 (6) (b);

(q) the name, address and identification number of the notified body involved in the design stage of the PPE.

These notes, which must be precise and comprehensible, must be provided at least in the official language(s) of the Member State of destination.

…

3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

3.1. **Protection against mechanical impact**

…

3.1.3. *Mechanical vibration*

PPE designed to prevent the effects of mechanical vibrations must be capable of ensuring adequate attenuation of harmful vibration components for the part of the body at risk.

Under no circumstances must the effective value of the accelerations transmitted to the user by those vibrations exceed the limit values recommended in the light of the maximum foreseeable daily exposure of the part of the body at risk.

…

3.5. *Protection against the harmful effects of noise*

PPE designed to prevent the harmful effects of noise must be capable of attenuating the latter to such an extent that the equivalent sound levels perceived by the user do not under any circumstances exceed the daily limit values laid down by Council Directive 86/188/EEC of 12 May 1986 on the protection of workers from the risks related to exposure to noise at work (OJ No L 137, 24.5.1986, p. 28).

All PPE must bear labelling indicating the noise attenuation level and the value of the comfort index provided by the PPE; should this not be possible, the labelling must be fixed to the packaging.

…

3.9. **Radiation protection**

3.9.1. *Non-ionizing radiation*

PPE designed to prevent acute or chronic eye-damage from sources of non-ionizing radiation must be capable of absorbing or reflecting the majority of the energy radiated in the harmful wavelengths without unduly affecting the transmission of the innocuous part of the visible spectrum, the perception of contrasts and the ability to distinguish colours where required by the foreseeable conditions of use.

To this end, protective glasses must be so designed and manufactured as to possess, for each harmful wave, a spectral transmission factor such that the radiant-energy illumination density capable of reaching the user's eye through the filter is minimized and, under no circumstances, exceeds the maximum permissible exposure value.

Furthermore, the glasses must not deteriorate or lose their properties as a result of the effects of radiation emitted under the foreseeable conditions of use and all marketed specimens must bear the protection-factor number corresponding to the spectral distribution curve of their transmission factor.

Glasses suitable for radiation sources of the same type must be classified in the ascending order of their protection factors and the manufacturer's notes must indicate, in particular, the transmission curves which make it possible to select the most appropriate PPE bearing in mind such inherent factors of the effective conditions of use as distance to source and the spectral distribution of the energy radiated at that distance.

The relevant protection-factor number must be marked on all specimens of filtering glasses by the manufacturer.

ANNEX 3: DEFINITION OF PPE OF CATEGORY III (EXCLUSIVE AND EXHAUSTIVE LIST OF PPE COVERED BY THIS CATEGORY)

Article 8

…

4. Production of PPE shall be subject:

(a) according to the manufacturer's choice, to one of the two procedures referred to in Article 11 in the case of PPE of complex design intended to protect against mortal danger or against dangers that may seriously and irreversibly harm the health, the immediate effects of which the designer assumes the user cannot identify in sufficient time. This category shall cover exclusively:

– filtering respiratory devices for protection against solid and liquid aerosols or irritant, dangerous, toxic or radiotoxic gases,

– respiratory protection devices providing full insulation from the atmosphere, including those for use in diving,

– PPE providing only limited protection against chemical attack or against ionizing radiation,

– emergency equipment for use in high-temperature environments the effects of which are comparable to those of an air temperature of 100 °C or more and which may or may not be characterized by the presence of infra-red radiation, flames or the projection of large amounts of molten material,

– emergency equipment for use in low-temperature environments the effects of which are comparable to those of an air temperature of -50 °C or less,

– PPE to protect against falls from a height,

– PPE against electrical risks and dangerous voltages or that used as insulation in high-tension work,