PPE Directive : A review of the proposed amendments

General application problems – Failings in the current PPE directive

The drafting group for the amendment of PPE Directive 89/686/EEC[1] set up by the European Commission concluded its work in September 2001. The draft was discussed in the last PPE Standing Committee in October and largely nodded through by the Member States. The new text aimed to improve the application of the Directive. The European Commission's initial suggestion that the amendment go through the SLIM process to produce a 'simplified' Directive was turned down by the Member States.

Looking at the Directive's implementation over the past ten years, it is clear that some problems were due to failings and loopholes in the text of the Directive as it is. Few of the Member States did much by way of market surveillance, so control of the workplace situation on PPE is poor and substandard products are mostly discovered after accidents. The PPE Directive's market surveillance provisions are weak, and Member States' obligations vague.

Manufacturers have problems classifying their products, and some even deliberately misinterpret the categories to downgrade the category they fall under. There is widespread abuse of the Directive's self-certification provisions. Notified Bodies doe not all follow identical certification procedures, so tests and periodic controls are of varying quality. In practice, the certification process for some products (e.g., multi risk PPEs, whose parts are frequently assigned to different categories requiring different certification procedures) is very difficult. The directive's classification categories are unclear. Also, the Category I certification requirements are weak and the list of category III [2] products is incomplete. This leaves categories wide open to interpretation.

Failings in technical information and instructions for use of products are to blame for the selection of inappropriate PPEs that leads to a number of accidents. Poor selection of PPE is often due to insufficient, over-general provisions on information for use in the Directive, insufficient marking for category identification and far too many classes of protection.

PPEs are also failing in use because real working conditions bear little resemblance to the laboratory testing environment. A Finnish[3] study tested a sample (21) of respiratory protective equipment for asbestos removal and found that only a small percentage of them (8) actually gave the protection claimed. Similar studies in the UK[4] and France identified performance problems with PPEs in different working conditions (e.g., wet and dry environments) and recognized the need to link equipment testing to work organization. The current directive's ergonomic requirements are poor and focus more on 'fitness for purpose' requirements than 'fitness for user' characteristics. The only comfort aspects addressed are anthropometric misfit and the physiological burden from the weight of PPE.

Finally, there is a migration of products for consumer use into workplaces. Products that are not regarded as PPE and have not undergone stringent examination procedures mislead workers about the protection offered. Again, the definitions for the different categories and exclusions are not clear enough.

Significantly, a large number of employers in Europe have flouted the directive's provisions and supplied workers with PPE as the first means of protection instead of taking collective prevention measures or making the pre-assessment required by work environment directive 89/656/EEC. This has led to workers rejecting the PPE, with the end result that they are little used, if at all.

Highlights of the draft amended text

The new text introduces some general amendments aiming at improving certification and official control procedures, and specific amendments to tackle technical issues arising out of the current text.

General amendments

Restructuring the Directive

The new draft is differently structured to the current directive. Definitions of terms used and a clear description of procedures to follow before placing PPE on the market have been added.

Setting up an independent PPE Standing Committee

The existing PPE Standing Committee of Member States' representatives that dealt with implementation and practical application of the Directive is unofficial (there is no provision in the current Directive) and operates as a subcommittee of the equivalent Machinery Committee. The new draft now puts the PPE Committee on an official footing with increased powers to bypass the regulatory procedure for amending the exclusive lists laid down in Annex I for PPE categories. This is intended to side-step time-consuming procedures for amending the legislation when practice shows that some products need reclassifying in a higher category.

General tightening-up of market surveillance

The draft amendment aims to tighten up market surveillance by adding new provisions to clarify Member States' obligations. It provides better control

[1] European Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment.
[2] There is a clear need to reclassify some category I products as category II, and category II products as category III.
[3] *Santé et Travail,* No. 32, p. 34.
[4] R. M. Howie *et al.*, "Workplace effectiveness of respiratory protective equipment for asbestos removal work", *HSE contract report,* No. 112, 1996.

of notified bodies by allowing authorities to withdraw approval from a body that repeatedly grants certificates which do not satisfy ESR. New provisions have also been added for administrative cooperation among Member States on the application, common interpretation of the Directive, and information on products that are unsafe or have been modified after a request from a Member State. Despite quite ambitious initial aims, however, the text ended up identical to the Machinery directive amendment which may slightly ease the work of Member States. Market surveillance of PPE is less easy than for other New Approach directives due to the wide variety of different products and categories. Also, the field of surveillance is wider because the end users are workers and consumers.

Limited validity for certificates
The validity of EC type-certificates is now limited to 5 years. Notified Bodies still have the same ongoing responsibility to ensure that the certificate remains valid, but manufacturers are now set a time in which they must apply for the certificate to be extended. The aim is to improve the Notified Bodies' control over manufacturers.

Clarification of categories
Definitions and explanations have been added for the three categories.

Certification procedures
New voluntary modules[5] have been added in the PPE certification procedures for Category III products[6]. The Commission originally intended to provide the widest possible range of certification modules to manufacturers, including Module H, which does not involve third party quality testing of the product itself in the design and production stages. The module was opposed by most of the drafting group, however, and was eventually dropped.

Confidentiality
A new provision obliges Member States to ensure that information under the administrative cooperation between Member States is covered by professional secrecy.

Penalties
A new article lays down the Member States' obligations to define and ensure the implementation of the penalties adopted and notify the Commission accordingly.

Specific amendments

New exclusions from the scope of the Directive
One much-debated issue in the PPE Standing Committee and drafting group was whether *structural anchors* (parts permanently fixed in a wall or other structures) that are linked with the *anchor points* on the harness are PPEs for heights. In the current version, all connecting devices, including structural anchors and anchor points are considered as PPEs. Manufacturers are keen for the amendment to separate anchor points from structural anchors, which they say are not personal. It was also argued that structural anchors are very difficult to test, because their reliability depends on the building or other structure to which they are fixed. The upshot is that permanent anchors are not considered as part of PPE, but anchor points are. Even so, Member States like France, Belgium, the Netherlands and Spain have lingering doubts. They either object to anchors points being classed as PPE (France) or want the definition to make it clear that they cannot protect the user.

Protective cream and fluids and insulating tools are now excluded from the scope of the directive. This new exclusion limits the definition of PPEs, so Member States can no longer translate the expression "PPE" in national legislation as protective means in the way they do at present.

Custom-made equipment
A request from the UK authorities has led to new provision being made for single items of custom-made equipment taking into account an individual user's medical or bodily specification. These can now be exempted from the certification procedures, since destruction testing of a sample is not feasible for such products.

Specific measures on inadequate families of PPE
Member States are given the power to order the withdrawal of obsolete PPEs that do not meet ESRs or the current state of the art. For example: were latex gloves to prove hazardous to users because of their allergic effects, and gloves could be made from new safe materials, latex gloves would be considered as an inadequate family of PPE.

Annex I

The Category I and III lists of PPEs have been modified. Some PPEs – like sunglasses in highly-reflective environments – have been upgraded from Category I to Category II, while things like ear muffs and ear–plugs for noise protection, PPE against biological agents, PPE against drowning, bullet-proof jackets, jackets against knife attacks, dry suits for diving in cold water, gloves for high mechanical protection and eye protection against laser radiation and solar eclipse viewing, have gone from Category II to Category III.

Annex II

At the last PPE Standing Committee plenary, it was decided that the amendment should not change the essential safety requirements (ESRs) in Annex II as this would involve changes to the relevant harmonized standards. But not all essential requirements have relevant harmonized standards, and the ESRs addressed important issues that stand in need of improvement.

[5] See *Guide to the implementation of directives based on the New Approach and the Global Approach*, European Commission, 2000, pp. 31-35.
[6] PPEs that are intended to protect against mortal danger or against dangers that may cause serious and irreversible harm to health.

The Finish Ministry of Social Affairs and Health and the Finish Institute for Occupational Health hosted a seminar on the revision of the PPE Directive in Kittilä[7] (Finland) in December 2000 for subject-specialists representing different interest groups and national authorities across Europe. Specific remarks on Annex II produced by one of the workshops were submitted to the Commission to inform the amendment process.

Basically, they suggested:
- beefing up the current Directive's poor ergonomic provisions;
- requirements for information from manufacturers on PPE material allergies;
- enhanced information for use including selection guides and other warnings;
- a link to be made between end-user complaints and manufacturer (to be aligned with the provisions on the General Product Directive[8], article 5);
- product labelling to facilitate product selection and market surveillance;
- compatibility control of PPE components of the same or different manufacturers;
- improvements in wording to avoid misinterpretation of the Directive;
- introduction of a new ESR on reliability of PPE incorporating electronic circuits (new-generation PPEs are heavily dependent on electronic circuits and no relevant requirement was provided in the Directive).

All the suggestions were accepted apart from the obligations to label products and provide information on allergies, on which the members of the drafting group could not reach a consensus.

On the whole, the drafting group's document is good, but does not address all the application issues. Some Member States voiced concerns in the PPE Standing Committee about failings like the notified bodies' obligations being too weak, and the new text doing too little to strengthen market surveillance. The Commission stands too far apart from the process, and safeguard clauses remain bureaucratic procedures. Also conformity assessment of combined PPE is not detailed. A number of Member States also wanted the PPE amendment document more closely aligned with the General Product Directive.

The next stage is to launch a Business Impact Assessment for the new text which should be completed by the end of spring. Inter-service consultations will then take place, after which it will be put forward to the Council and Parliament. ■

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[7] 5th seminar on personal protective equipment in Europe, Kittilä, Finland, 4-6 December 2000: *Seminar report*, Jurvelius H. (Ed.), FIOH, Vantaa, 2001.
[8] European Parliament and Council Directive 2001/95/EC of 3 December 2001 on general product safety.