Personal protective equipment

2014/0108(COD) - 30/04/2015 - Committee report tabled for plenary, 1st reading/single reading

The Committee on the Internal Market and Consumer Protection adopted the report by Vicky FORD (ECR, UK) on the proposal for a regulation of the European Parliament and of the Council on personal protective equipment.

The committee recommended that Parliament's position adopted at first reading following the ordinary legislative procedure should amend the Commission proposal as follows:

Purpose and scope: the Regulation lays down requirements for the design and manufacture of personal protective equipment (PPE) which is being made available on the market in order to ensure the protection of users and rules on its free movement in the Union.

Amendments aiming to **include in the scope of the Regulation** equipment to protect against oxygen deficiency (e.g. diving equipment), chemicals, biological agents and radiation/radioactive contamination, laser radiation and radioactive contamination, and explosive fragments are now inserted into Annex I, Category III.

Excluded from the scope of the legislation are PPE:

- designed to be used for self-defence, with the exception of **PPE intended for sporting activities;**
- intended for **private use** to protect against: (i) damp and water not of an extreme nature; (ii) heat, for which the economic operator does not explicitly describe and market the products as having a protective function;
- in the form of clothing intended for private use, with reflective or fluorescent garments which are exclusively included for reasons of design or decoration, and for which the economic operator does not describe and market the products as having a protective function;
- designed and placed on the market as artisanal products which are decorative in nature.

Definitions: Members wanted to see more specific technical provisions, regarding:

- **connection systems** as items essential to the PPE's function;
- adding a definition of 'demonstration' and **'field test'** and permitting field testing to take place. Field tests should not be designed to test the protection performance of the PPE but to evaluate other non-protective aspects such as comfort, ergonomics and design.

Obligations of economic operators (manufacturers, importers, distributors):

Manufacturers should:

- keep the technical documentation and the EU declaration of conformity for at least **five years** after the PPE has been placed on the market (rather than 10 years as proposed by the Commission);
- ensure that **instructions**, as well as any labelling, are clear, understandable and intelligible;
- ensure that **performance** as recorded during relevant technical tests to check the levels of classes of protection provided by the PPE is available electronically or upon request.

Manufacturers should include with the EPP either the simplified EU declaration of conformity or include in the instructions or information leaflet the web site address where the EU declaration of conformity might be seen.

Importers should:

- indicate, on the PPE their contact details in the **official language** or languages of the Member State (s) in which the PPE is to be marketed;
- ensure that PPE is accompanied by the **instructions and safety information** in a language which can be easily understood by consumers;
- with regard to the risks presented by PPE, carry out sample testing of PPE made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls, and shall keep distributors informed of any such monitoring.

Members stressed that importers and distributors should immediately **inform the manufacturer and the competent national authorities** if they have reason to believe that PPE that they have placed on the market is not in conformity with the Regulation.

Examination certificate: the PPE should be examined on the basis of the latest scientific evidence. The maximum period of validity of the EU type-examination certificate should be five years and a process for reviewing the certificate should be provided. Following a positive review, a renewed certificate may continue to be valid for further periods, each of which should be for a maximum of five years.

Presumption of conformity: unless otherwise provided for by Union harmonisation legislation, the **withdrawal of a harmonised standard** shall not invalidate existing certificates issued by notified bodies. Products produced in accordance with the existing certificate shall still benefit from continuing conformity with the essential requirements and may continue to be placed on the market until the end of the validity of the relevant certificates issued by notified bodies.

CE marking: the CE marking and, where applicable, the identification number of the notified body may be accompanied by a pictogram or other marking indicating the risk against which the PPE is intended to protect. Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.

Notification of conformity assessment bodies: accreditation should be the general rule for notified bodies. Members also stipulated that:

- Member States must notify manufacturers if a notified body has ceased activity;
- any appeal procedure must be transparent and accessible.

Market surveillance: noting that the existing PPE legislation is in need of updating in line with the New Legislative Framework (NLF) on regulation of goods, Members introduced a new Chapter that will take into account: the requirements of the market surveillance regulation when the latter has been finalised; Union market surveillance and control of products entering the Union market; procedure applicable to PPE presenting a risk at national level, safeguard measures, etc.

Requirements for employers: Members clarified the requirements for employers who provide PPE to their employees. Accordingly, employers shall provide PPE that complies with the relevant Union provisions on design and manufacture with respect to safety and health.