Personal protective equipment

2014/0108(COD) - 20/01/2016 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 577 votes to 48, with 86 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on personal protective equipment.

Parliament's position, adopted at first reading following the ordinary legislative procedure, amended 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 to be made available on the market, in order to **ensure protection of the health and safety of users**.

Amendments aiming to **include in the scope of the Regulation** equipment to protect against cleaning materials of weak action or prolonged contact with water. Other substances and mixtures which are hazardous to health include atmospheres with oxygen deficiency and harmful biological agents which are now inserted into Annex I, Category III which includes exclusively the risks that may cause very serious consequences such as death or irreversible damage to health.

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;
- designed for private use to protect against atmospheric conditions that are not of an extreme nature and damp and water during dishwashing;
- for exclusive use on seagoing vessels or aircraft that are subject to the relevant international treaties applicable in Member States;
- for head, face or eye protection of users, that is covered by Regulation No 22 of the United Nations Economic Commission for Europe on uniform provisions concerning the approval of protective helmets and their visors for drivers and passengers of motor cycles and mopeds.

Definitions: PPE should also mean:

- equipment designed and manufactured to be worn or held by a person for protection against one or more risks to that person's health or safety;
- connexion systems for equipment that are not held or worn by a person, that are designed to connect that equipment to an external device or to a reliable anchorage point, that are not designed to be permanently fixed and that do not require fastening works before use.

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

Manufacturers and importers shall, when deemed appropriate 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.

Manufacturers shall:

- ensure that the PPE is accompanied by the instructions and information, as well as any labelling, shall be clear, understandable, intelligible and legible;

- either provide the **EU declaration of conformity** with the PPE or include in the instructions and information the internet address at which the EU declaration of conformity can be accessed;
- further to a reasoned request from a competent national authority, provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the PPE with this Regulation.

CE marking: the CE marking shall be **affixed before the PPE is placed on the market**. The CE marking and, where applicable, the identification number of the notified body may be followed 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.

Accreditation system: in the recitals, it is stipulated that the system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008.

Transparent accreditation ensuring the necessary level of confidence in certificates of conformity, should be considered by the national public authorities throughout the Union as the preferred means of demonstrating the technical competence of conformity assessment bodies.

However, national authorities may consider that they possess the appropriate means of carrying out that evaluation themselves. In such cases, in order to ensure the appropriate level of credibility of evaluations carried out by other national authorities, they should provide the Commission and the other Member States with the necessary documentary evidence demonstrating the compliance of the conformity assessment bodies evaluated with the relevant regulatory requirements

Appeal against decisions of notified bodies: notified bodies shall ensure that a transparent and accessible appeal procedure against their decisions is available.

Market surveillance: in line with the New Legislative Framework (NLF) on regulation of goods and in order to ensure legal certainty, Parliament proposed to clarify that rules on Union market surveillance and control of products entering the Union market provided for in Regulation (EC) No 765/2008 apply to PPE covered by this Regulation. Members also introduced provisions relating to the procedure at national level for dealing with PPE presenting a risk, Union safeguard procedure as well as PPE presenting a risk for the health and safety of persons.