Personal protective equipment

2014/0108(COD) - 27/03/2014 - Legislative proposal

PURPOSE: to lay down requirements for the design and manufacture of personal protective equipment (PPE) in order to ensure the health and safety protection of users and rules on its free movement in the Union.

PROPOSED ACT: Regulation of the European Parliament and the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: Directive 89/686/EEC on personal protective equipment was adopted on 21 December 1989 and became fully applicable as from 1 July 1995. It sets out basic requirements that PPE must comply with in order to be made available on the EU market.

The PPE Directive applies to PPE that is defined as “any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards”.

While the directive has successfully achieved its objectives in creating a single market and ensuring a high level of protection for users of PPE, **certain problems have been encountered** in its implementation. These concern products on the market that do not ensure an adequate level of protection, diverging approaches of the notified bodies, the effectiveness of the market surveillance as well as risks related to protective equipment which is currently not covered by the PPE Directive.

The proposal modifies and clarifies a number of the provisions of the existing Directive and **aligns it with the provisions of Decision No 768/2008/EC** establishing a common framework for the marketing of products (NLF Decision). The Commission has already proposed the alignment of nine Directives to the NLF Decision within an NLF implementation package adopted on 21 November 2011.

IMPACT ASSESSMENT: the preferred option consists of **amending the PPE Directive** as it: (i) lead to an improved level of protection of the health and safety of the users; (ii) ensures a more effective work of the market surveillance authorities and consequently reduces the non-compliant products; (iii) does not entail significant costs for economic operators and notified bodies.

CONTENT: this proposal intends to replace Directive 89/686/EEC on personal protective equipment by a Regulation. Its general objectives are to ensure a **high level of protection of human health and safety** whilst guaranteeing fair competition for economic operators on the Union market and simplifying the regulatory environment in this area.

The proposal also clarifies a number of provisions of the existing Directive and aligns it with those of the Decision No 768/2008/EC establishing a common framework for the marketing of products (decision on the new legislative framework).

Scope: the Commission proposes to enlarge the scope of the current PPE Directive by deleting the exclusions of **PPE designed and manufactured for private use against heat, damp and water**. The proposal keeps the other existing exclusions and clarifies that it does not apply to PPE for head, face or eye protection, subject to the relevant UNECE Regulation, of users of two- or three-wheeled motor vehicles.

Two PPE specific definitions have been added in order to clarify the applicable conformity assessment procedures: "**Individually adapted PPE**" and "**Made-to-measure PPE**".

Making available on the market, free movement, obligations of economic operators, CE marking: the proposal:

- contains the typical provisions for product-related Union harmonisation legislation and sets out the obligations of the relevant economic operators (manufacturers, authorised representatives, importers and distributors), in accordance with the NLF Decision;
- obliges the manufacturer of PPE to draw up a technical documentation and to ensure that the PPE is accompanied by a copy of the EU declaration of conformity or a simplified EU declaration of conformity.

Notified bodies: the proposal sets out requirements for national authorities responsible for conformity assessment bodies (notified bodies). It leaves the ultimate responsibility for designating and monitoring notified bodies with the individual Member State.

Categories and Conformity assessment: the proposal simplifies the definition of the categories of PPE. The category only depends on the risk against which the PPE is intended to protect. Provisions are set out for made-to-measure PPE. PPE intended to protect the user against drowning, cuts by hand-held chain-saws, high-pressure cutting, bullet wounds or knife stabs, and harmful noise are subject to the **most stringent conformity assessment procedure**.

Minor amendments have been made which change marginally three essential health and safety requirements (EHSR) in order to remove requirements shown to be impracticable or that create confusion.

Application: the proposed Regulation will become applicable **two years** after its entry into force to allow manufacturers, notified bodies and Member States time to adapt to the new requirements. However, the designation of notified bodies pursuant to the new requirements and process needs to start shortly after the entry into force of this Regulation.

Transitional provisions are foreseen for products manufactured and the certificates issued by notified bodies under Directive 89/686/EEC so as to allow stocks to be absorbed and ensure a smooth transition to the new requirements.

DELEGATED ACTS: this proposal contains provisions empowering the Commission to adopt delegated acts in accordance with Article 290 of the Treaty on the Functioning of the European Union.