Personal protective equipment

2014/0108(COD) - 09/03/2016 - Final act

PURPOSE: to update internal market rules for personal protective equipment, in order to enhance consumer safety and ensure fair competition between companies.

LEGISLATIVE ACT: Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment and repealing Council Directive 89/686/EEC.

CONTENT: the new Regulation updates the existing rules in directive 89/686/EEC. It 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 and establish rules on the free movement of PPE in the Union.

Scope: personal protective equipment offers protection against all kinds of hazards (e.g. heat, flames, chemicals, flying particles, mechanical shocks, etc.) in a range of different environments, whether it be the home, at work or on the sports field.

Examples include: head/ear/eye protection, breathing protection, body protection, and hand/leg/foot protection. Products intended for private use to protect against atmospheric conditions that are not of an extreme nature or to protect against damp and water, including dishwashing gloves, fall outside of the scope of the Regulation.

This Regulation **covers PPE which is new to the Union market when it is placed on the market;** that is to say, it is either new PPE made by a manufacturer established in the Union or PPE, whether new or second-hand, imported from a third country. It applies to all forms of supply, including distance selling.

Obligations of economic operators (manufacturers, importers, distributors): all economic operators intervening in the supply and distribution chain must take appropriate measures to ensure that they make available on the market only PPE which is in conformity with the Regulation. In particular, **manufacturers** must ensure that PPE has been designed and manufactured in accordance with the applicable **essential health and safety requirements** set out in Annex II. They must:

- implement the **conformity assessment procedures** established by the Regulation. These procedures are linked to the degree of risk involved;
- keep the **technical documentation and the EU declaration** of conformity for 10 years after the PPE has been placed on the market;
- 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;
- ensure that the PPE which they place on the market bears a **type, batch or serial number** or other element allowing its identification;
- indicate, on the PPE, **their name, registered trade name or registered trade mark and the postal address** at which they can be contacted or, where that is not possible, on its packaging or in a document accompanying the PPE;

- ensure that **instructions and safety information**, as well as any labelling, is clear, understandable, intelligible and legible;

- 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 the Regulation, in a language which can be easily understood by that authority;

- immediately take the **corrective measures** necessary to bring PPE into conformity, to withdraw it or to recall it, as appropriate.

For their part, **importers** must make sure that they do not place on the market PPE which does not comply with requirements or which present a risk. They must also make sure that the conformity assessment procedures have been carried out and that the CE marking and technical documentation drawn up by manufacturers are available for inspection by the competent national authorities.

CE marking: the CE marking shall be affixed before the PPE is placed on the market and affixed **visibly, legibly and indelibly** to the PPE or affixed to the packaging and to the accompanying documents. 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 take appropriate action in the event of **improper use** of that marking.

Notifying authorities: the Regulation sets requirements for notifying authorities responsible for conformity assessment bodies. These bodies must apply the conformity assessment procedures without creating **unnecessary burdens for economic operators**. Interested parties have the right to appeal against the result of a conformity assessment carried out by a notified body.

Market surveillance: in the context of aligning the legislation on PPE with the new legislative framework for the marketing of products, and in order to ensure legal certainty, the 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.

The new Regulation also contains provisions regarding procedures at national level for dealing with PPE presenting a risk, Union safeguard procedures, and compliant PPE which presents a risk to health and safety.

Transitional provisions: Member States shall not impede the making available on the market of products covered by Directive 89/686/EEC which are in conformity with that Directive and which were placed on the market before 21 April 2019.

ENTRY INTO FORCE: 20.4.2016.

APPLICATION: from 21.4.2018, with the exception of certain provisions which apply from

21.10.2016 or from 21.3.2018.

DELEGATED ACTS: the Commission may adopt delegated acts in respect of amending the categories of risks against which the PPE is intended to protect users. The power to adopt delegated acts shall be conferred on the Commission for a period of **5 years (which may be tacitly extended) from 21 April 2018.** The European Parliament or the Council may raise objections to a delegated act within two months from the date of notification (which may be extended by two months). If the European Parliament or the Commission raise objections, the delegated act will not enter into force.