Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (Text with EEA relevance)

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(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[(1)],

Acting in accordance with the ordinary legislative procedure[(2)],

Whereas:

(1) Council Directive 89/686/EEC[(3)] was adopted in the context of establishing the internal market, in order to harmonise health and safety requirements for personal protective equipment (PPE) in all Member States and to remove obstacles to trade in PPE between Member States.

(2) Directive 89/686/EEC is based on the 'new approach' principles, as set out in the Council Resolution of 7 May 1985 on a new approach to technical harmonisation and standards[(4)]. Thus, it sets only the essential requirements applying to PPE, whereas technical details are adopted by the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) in accordance with Regulation (EU) No 1025/2012 of the European Parliament and of the Council[(5)]. Conformity with the harmonised standards so set, the reference numbers of which are published in the *Official Journal of the European Union*, provides a presumption of conformity with the requirements of Directive 89/686/EEC. Experience has shown that those basic principles have worked well in that sector and should be maintained and even further promoted.

(3) Experience with the application of Directive 89/686/EEC has shown inadequacies and inconsistencies in the product coverage and conformity assessment procedures. In order to take account of that experience and to provide clarification in relation to the framework within which products covered by this Regulation may be made available on the market, certain aspects of Directive 89/686/EEC should be revised and enhanced.

(4) Since the scope, the essential health and safety requirements and conformity assessment procedures have to be identical in all the Member States there is almost no flexibility in transposing a directive based on the new approach principles into national law. Directive 89/686/EEC should therefore be replaced by a regulation, which is the appropriate legal instrument for imposing clear and detailed rules which do not give room for divergent transposition by Member States.

(5) Regulation (EC) No 765/2008 of the European Parliament and of the Council[6] lays down rules on the accreditation of conformity assessment bodies, provides a framework for the market surveillance of products and for controls on products from third countries, and lays down the general principles of the CE marking.

(6) Decision No 768/2008/EC of the European Parliament and of the Council[7] lays down common principles and reference provisions intended to apply across sectoral legislation. In order to ensure consistency with other sectoral product legislation, it is appropriate to align certain provisions of this Regulation to that Decision, in so far as sectoral specificities do not require a different solution. Therefore, certain definitions, the general obligations of economic operators, the presumption of conformity, EU declaration of conformity, rules on CE marking, requirements for conformity assessment bodies and notification procedures, the conformity assessment procedures and the provisions concerning procedures to deal with PPE presenting a risk should be adapted to that Decision.

(7) Regulation (EU) No 1025/2012 provides for a procedure for objections to harmonised standards where those standards do not entirely satisfy the requirements of this Regulation.

(8) 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.

(9) This Regulation should apply to all forms of supply, including distance selling.

(10) Some products on the market that provide a protective function to the user are excluded from the scope of Directive 89/686/EEC. In order to ensure as high a level of protection for the user of those products as for the user of PPE covered by Directive 89/686/EEC, the scope of this Regulation should include PPE for private use against heat, in line with similar PPE for professional use which is already covered by Directive 89/686/EEC. Artisanal decorative products do not claim to fulfil a protective function, are by definition not personal protective equipment and are therefore not concerned by that inclusion. Clothing intended for private use with reflective or fluorescent elements included for reasons of design or decoration is not personal protective equipment and is therefore not covered by this Regulation. As for 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 but not limited to seasonal clothing, umbrellas and dishwashing gloves, those should also fall outside of the scope of this Regulation. It is also appropriate to clarify the list of excluded PPE set out in Annex I

to Directive 89/686/EEC by adding a reference to products covered by other legislation and therefore excluded from the scope of this Regulation.

(11) Economic operators should be responsible for the compliance of PPE with the requirements of this Regulation, in relation to their respective roles in the supply chain, so as to ensure a high level of protection of public interests, such as health and safety, and the protection of users, and to guarantee fair competition on the Union market.

(12) All economic operators intervening in the supply and distribution chain should take appropriate measures to ensure that they make available on the market only PPE which is in conformity with this Regulation. This Regulation should provide a clear and proportionate distribution of obligations which correspond to the role of each economic operator in the supply and distribution chain.

(13) In order to facilitate communication between economic operators, national market surveillance authorities and consumers, Member States should encourage economic operators to include a website address in addition to the postal address.

(14) The manufacturer, having detailed knowledge of the design and production process, is best placed to carry out the conformity assessment procedure. Conformity assessment should therefore remain solely the obligation of the manufacturer.

(15) It is necessary to ensure that PPE from third countries entering the Union market complies with the requirements of this Regulation and, in particular, that appropriate conformity assessment procedures have been carried out by manufacturers. Provision should therefore be made for importers to make sure that PPE they place on the market complies with the requirements of this Regulation and that they do not place on the market PPE which does not comply with such requirements or which present a risk. Provision should also be made for importers to 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.

(16) The distributor makes PPE available on the market after it has been placed on the market by the manufacturer or the importer and should act with due care to ensure that its handling of PPE does not adversely affect the compliance of the PPE.

(17) When placing PPE on the market, every importer should indicate on the PPE his name, registered trade name or registered trade mark and the postal address at which he can be contacted. Exceptions should be provided for in cases where the size or nature of the PPE does not allow it. This includes cases where the importer would have to open the packaging to put his name and address on the PPE.

(18) Efforts should be made by economic operators to ensure that all relevant documentation, such as the user's instructions, whilst ensuring precise and comprehensible information, are easily understandable, take into account technological developments and changes to end-user behaviour, and are as up to date as possible. When PPE is made available on the market in packages containing multiple units, the instructions and information should accompany each smallest commercially available unit.

(19) Any economic operator who either places PPE on the market under his own name or trademark or modifies a product in such a way that compliance with the requirements of this Regulation may be affected should be considered to be the manufacturer and should assume the obligations of the manufacturer.

(20) Distributors and importers, being close to the market place, should be involved in market surveillance tasks carried out by the competent national authorities, and should be prepared to participate actively, providing those authorities with all necessary information relating to the PPE concerned.

(21) Ensuring traceability of PPE throughout the whole supply chain helps to make market surveillance simpler and more efficient. An efficient traceability system facilitates the market surveillance authorities' task of tracing economic operators who made non-compliant PPE available on the market. When keeping the information required under this Regulation for the identification of other economic operators, economic operators should not be required to update such information in respect of other economic operators who have either supplied them with PPE or to whom they have supplied PPE.

(22) In order to simplify and adapt certain essential safety requirements of Directive 89/686/EEC to the current practice, the requirement to label PPE protecting against harmful noise with a comfort index should be removed as experience has shown that it is not possible to measure and establish such an index. As regards mechanical vibrations, it is appropriate to remove the requirement not to exceed the limit values set by Union legislation on the exposure of workers to vibrations since the use of PPE alone is not able to achieve this objective. As regards PPE protecting against radiation, it is no longer necessary to require that the instructions for use supplied by the manufacturer indicate transmission curves, since the indication of the protection factor is more useful and is sufficient for the user.

(23) It is necessary to clearly specify the relationship with, and the scope of this Regulation as regards, the entitlement of Member States to lay down requirements for the use of PPE at the workplace, in particular pursuant to Council Directive 89/656/EEC[(8)], in order to avoid any confusion and ambiguity and hence ensure the free movement of compliant PPE. Article 4 of that Directive obliges employers to provide PPE which complies with the relevant Union provisions on design and manufacture with respect to safety and health. Pursuant to that Article, manufacturers of PPE who provide that PPE to their employees must ensure that such PPE fulfils the requirements laid down in this Regulation.

(24) Market surveillance authorities should have easy access to the EU declaration of conformity. In order to fulfil that requirement, manufacturers should ensure that PPE is accompanied either by a copy of the EU declaration of conformity or by the internet address at which the EU declaration of conformity can be accessed.

(25) To ensure effective access to information for market surveillance purposes, the information required to identify all applicable Union acts for PPE should be available in a single EU declaration of conformity. In order to reduce the administrative burden on

economic operators, it should be possible for that single EU declaration of conformity to be a dossier made up of relevant individual declarations of conformity.

(26) In order to increase the efficiency of market surveillance, it is necessary to extend the obligation to draw up complete technical documentation to all PPE.

(27) In order to ensure that PPE is examined on the basis of the state of the art, the limit of validity of the EU type-examination certificate should be set at a maximum of five years. A process for reviewing the certificate should be provided for. A minimum content of the certificate should be required in order to facilitate the work of the market surveillance authorities.

(28) A simplified procedure should be applied in the case of renewal of the EU type-examination certificate where the manufacturer has not modified the approved type and the harmonised standards or other technical specifications applied by the manufacturer have not been changed and continue to meet the essential health and safety requirements in the light of the state of the art. In such cases, additional tests or examinations should not be necessary and the administrative burden and related costs should be kept to a minimum.

(29) The CE marking, indicating the conformity of a product, is the visible consequence of a whole process comprising conformity assessment in a broad sense. The general principles governing the CE marking are set out in Regulation (EC) No 765/2008. Rules governing the affixing of the CE marking on PPE should be laid down in this Regulation.

(30) In order to ensure compliance with the essential health and safety requirements laid down in this Regulation, it is necessary to lay down appropriate conformity assessment procedures to be followed by the manufacturer. Directive 89/686/EEC classifies PPE into three categories that are subject to different conformity assessment procedures. In order to ensure a consistently high level of safety of all PPE, the range of products subject to one of the conformity assessment procedures relating to the production phase should be enlarged. The conformity assessment procedures for each category of PPE should be set, as far as possible, on the basis of the conformity assessment modules laid down in Decision No 768/2008/EC.

(31) The conformity assessment procedures should be adapted to the specific conditions of the manufacture of PPE produced in series where each item is adapted to fit an individual user, and of PPE produced as a single unit to fit an individual user.

(32) It is necessary to ensure a uniformly high level of performance of bodies performing conformity assessment of PPE throughout the Union, and all such bodies should perform their functions at the same level and under conditions of fair competition. Therefore obligatory requirements should be set for conformity assessment bodies wishing to be notified in order to provide conformity assessment services.

(33) If a conformity assessment body demonstrates conformity with the criteria laid down in harmonised standards, it should be presumed to comply with the corresponding requirements set out in this Regulation.

(34) In order to ensure a consistent level of quality in the performance of conformity assessment of PPE, it is also necessary to set requirements for notifying authorities and other bodies involved in the assessment, notification and monitoring of notified bodies.

(35) The system set out in this Regulation should be complemented by the accreditation system provided for in Regulation (EC) No 765/2008. Since accreditation is an essential means of verifying the competence of conformity assessment bodies, it should also be used for the purposes of notification.

(36) Transparent accreditation as provided for in Regulation (EC) No 765/2008, 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.

(37) Conformity assessment bodies frequently subcontract parts of their activities linked to the assessment of conformity or have recourse to a subsidiary. In order to safeguard the level of protection required for the PPE to be placed on the market, it is essential that conformity assessment subcontractors and subsidiaries fulfil the same requirements as notified bodies in relation to the performance of conformity assessment tasks. Therefore, it is important that the assessment of the competence and the performance of bodies to be notified, and the monitoring of bodies already notified, cover also activities carried out by subcontractors and subsidiaries.

(38) Since notified bodies may offer their services throughout the Union, it is appropriate to give the other Member States and the Commission the opportunity to raise objections concerning a notified body. It is therefore important to provide for a period during which any doubts or concerns as to the competence of conformity assessment bodies can be clarified before they start operating as notified bodies.

(39) In the interests of competitiveness, it is crucial that notified bodies apply the conformity assessment procedures without creating unnecessary burdens for economic operators. For the same reason, and to ensure equal treatment of economic operators, consistency in the technical application of the conformity assessment procedures needs to be ensured. That can best be achieved through appropriate coordination and cooperation between notified bodies.

(40) Interested parties should have the right to appeal against the result of a conformity assessment carried out by a notified body. For that reason, it is important to ensure that an appeal procedure against decisions taken by notified bodies is available.

(41) Member States should take all appropriate measures to ensure that PPE covered by this Regulation may be placed on the market only if, when properly stored and used for its intended purpose, or under conditions of use which can be reasonably foreseen, it does

not endanger the health or safety of persons. PPE covered by this Regulation should be considered as non-compliant with the essential health and safety requirements laid down in this Regulation only under conditions of use which can be reasonably foreseen, that is when such use could result from lawful and readily predictable human behaviour.

(42) In order to ensure legal certainty, it is necessary 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. This Regulation should not prevent Member States from choosing the competent authorities to carry out those tasks.

(43) Directive 89/686/EEC already provides for a safeguard procedure which is necessary to allow for the possibility of contesting the conformity of a product. In order to increase transparency and to reduce processing time, it is necessary to improve the existing safeguard procedure, with a view to making it more efficient and drawing on the expertise available in Member States.

(44) The existing system should be supplemented by a procedure under which interested parties are informed of measures intended to be taken with regard to PPE presenting a risk to the health or safety of persons. It should also allow market surveillance authorities, in cooperation with the relevant economic operators, to act at an earlier stage in respect of such PPE.

(45) Where the Member States and the Commission agree as to the justification of a measure taken by a Member State, no further involvement of the Commission should be required, except where non-compliance can be attributed to shortcomings of a harmonised standard.

(46) In order to take into account technical progress and knowledge or new scientific evidence, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending the categories of risks against which the PPE is intended to protect users. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(47) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[(9)].

(48) The advisory procedure should be used for the adoption of implementing acts requesting the notifying Member State to take the necessary corrective measures in respect of notified bodies that do not meet or no longer meet the requirements for their notification.

(49) The examination procedure should be used for the adoption of implementing acts with respect to compliant PPE which presents a risk to the health or safety of persons or to other aspects of public interest protection.

(50) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to compliant PPE which presents a risk to the health or safety of persons, imperative grounds of urgency so require.

(51) In line with established practice, the committee set up by this Regulation can play a useful role in examining matters concerning the application of this Regulation raised either by its chair or by a representative of a Member State in accordance with its rules of procedure.

(52) When matters relating to this Regulation, other than its implementation or infringements, are being examined, i.e. in a Commission expert group, the European Parliament should in line with existing practice receive full information and documentation and, where appropriate, an invitation to attend such meetings.

(53) The Commission should, by means of implementing acts and, given their special nature, acting without the application of Regulation (EU) No 182/2011, determine whether measures taken by Member States in respect of non-compliant PPE are justified or not.

(54) In order to allow manufacturers and other economic operators sufficient time to adapt to the requirements of this Regulation, it is necessary to provide for a sufficient transitional period after the entry into force of this Regulation during which PPE which complies with Directive 89/686/EEC may still be placed on the market.

(55) Member States should lay down rules on penalties applicable to infringements of this Regulation and ensure that those rules are enforced. The penalties provided for should be effective, proportionate and dissuasive.

(56) Since the objective of this Regulation, namely to ensure that PPE on the market fulfils the requirements providing for a high level of protection of health and safety of users, whilst guaranteeing the functioning of the internal market, cannot be sufficiently achieved by the Member States, but can rather, by reason of its scale and effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(57) Directive 89/686/EEC has been amended several times. Since further substantial amendments are to be made and in order to ensure a uniform implementation throughout the Union, Directive 89/686/EEC should be repealed,

HAVE ADOPTED THIS REGULATION:

(**1**) OJ C 451, 16.12.2014, p. 76.

(**2**) Position of the European Parliament of 20 January 2016 (not yet published in the Official Journal) and decision of the Council of 12 February 2016.

(**3**) Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment (OJ L 399, 30.12.1989, p. 18).

(**4**) OJ C 136, 4.6.1985, p. 1.

(**5**) Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC(52), 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council (OJ L 316, 14.11.2012, p. 12).

(**6**) Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (OJ L 218, 13.8.2008, p. 30).

(**7**) Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC (OJ L 218, 13.8.2008, p. 82).

(**8**) Council Directive 89/656/EEC of 30 November 1989 on the minimum health and safety requirements for the use by workers of personal protective equipment at the workplace (third individual directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 393, 30.12.1989, p. 18).

(**9**) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).