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)

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject matter

This 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 and establish rules on the free movement of PPE in the Union.

Article 2

Scope

1 This Regulation applies to PPE.

2 This Regulation does not apply to PPE:

- a specifically designed for use by the armed forces or in the maintenance of law and order;
- b designed to be used for self-defence, with the exception of PPE intended for sporting activities;
- c designed for private use to protect against:
  - (i) atmospheric conditions that are not of an extreme nature,
  - (ii) damp and water during dishwashing;
- d for exclusive use on seagoing vessels or aircraft that are subject to the relevant international treaties applicable in Member States;
- e 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 motorcycles and mopeds.

Article 3

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) ‘personal protective equipment’ (PPE) means:

- (a) 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;

(b) interchangeable components for equipment referred to in point (a) which are essential for its protective function;

(c) connexion systems for equipment referred to in point (a) 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;

(2) 'making available on the market' means any supply of PPE for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(3) 'placing on the market' means the first making available of PPE on the Union market;

(4) 'manufacturer' means any natural or legal person who manufactures PPE or has it designed or manufactured, and markets it under his name or trademark;

(5) 'authorised representative' means any natural or legal person established within the Union who has received a written mandate from a manufacturer to act on his behalf in relation to specified tasks;

(6) 'importer' means any natural or legal person established within the Union who places PPE from a third country on the Union market;

(7) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes PPE available on the market;

(8) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;

(9) 'technical specification' means a document that prescribes technical requirements to be fulfilled by PPE;

(10) 'harmonised standard' means a harmonised standard as defined in point (c) of point 1 of Article 2 of Regulation (EU) No 1025/2012;

(11) 'accreditation' means accreditation as defined in point 10 of Article 2 of Regulation (EC) No 765/2008;

(12) 'national accreditation body' means a national accreditation body as defined in point 11 of Article 2 of Regulation (EC) No 765/2008;

(13) 'conformity assessment' means the process demonstrating whether the essential health and safety requirements of this Regulation relating to PPE have been fulfilled;

(14) 'conformity assessment body' means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

(15) 'recall' means any measure aimed at achieving the return of PPE that has already been made available to the end-user;

(16) 'withdrawal' means any measure aimed at preventing PPE in the supply chain from being made available on the market;

(17) 'Union harmonisation legislation' means any Union legislation harmonising the conditions for the marketing of products;

(18) ‘CE marking’ means a marking by which the manufacturer indicates that PPE is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing.

Article 4

Making available on the market

PPE shall only be made available on the market if, where properly maintained and used for its intended purpose, it complies with this Regulation and does not endanger the health or safety of persons, domestic animals or property.

Article 5

Essential health and safety requirements

PPE shall meet the essential health and safety requirements set out in Annex II which apply to it.

Article 6

Provisions concerning the use of PPE

This Regulation shall not affect Member States' entitlement, in particular when implementing Directive 89/656/EEC, to lay down requirements concerning the use of PPE, provided that those requirements do not affect the design of PPE which is placed on the market in accordance with this Regulation.

Article 7

Free movement

1 Member States shall not impede, for the aspects covered by this Regulation, the making available on the market of PPE which complies with this Regulation.

2 At trade fairs, exhibitions and demonstrations or similar events, Member States shall not prevent the showing of PPE which does not comply with this Regulation, provided that a visible sign clearly indicates that the PPE does not comply with this Regulation and is not available on the market until it has been brought into conformity.

During demonstrations, adequate measures shall be taken to ensure the protection of persons.

CHAPTER II

OBLIGATIONS OF ECONOMIC OPERATORS

Article 8

Obligations of manufacturers

1 When placing PPE on the market, manufacturers shall ensure that it has been designed and manufactured in accordance with the applicable essential health and safety requirements set out in Annex II.

2 Manufacturers shall draw up the technical documentation referred to in Annex III ('technical documentation') and carry out the applicable conformity assessment procedure referred to in Article 19 or have it carried out.

Where compliance of PPE with the applicable essential health and safety requirements has been demonstrated by the appropriate procedure, manufacturers shall draw up the EU declaration of conformity referred to in Article 15 and affix the CE marking referred to in Article 16.

3 Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the PPE has been placed on the market.

4 Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Regulation. Changes in the design or characteristics of the PPE and changes in the harmonised standards or in other technical specifications by reference to which the conformity of the PPE is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by PPE, manufacturers shall, to protect the health and safety of consumers and other end-users, 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.

5 Manufacturers shall ensure that the PPE which they place on the market bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the PPE does not allow it, that the required information is provided on the packaging or in a document accompanying the PPE.

6 Manufacturers shall 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. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

7 Manufacturers shall ensure that the PPE is accompanied by the instructions and information set out in point 1.4 of Annex II in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. Such instructions and information, as well as any labelling, shall be clear, understandable, intelligible and legible.

8 The manufacturer shall either provide the EU declaration of conformity with the PPE or include in the instructions and information set out in point 1.4 of Annex II the internet address at which the EU declaration of conformity can be accessed.

9 Manufacturers who consider or have reason to believe that PPE which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring that PPE into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the PPE available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

10 Manufacturers shall, 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, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have placed on the market.

Article 9

Authorised representatives

1 A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 8(1) and the obligation to draw up the technical documentation referred to in Article 8(2) shall not form part of the authorised representative's mandate.

2 An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

a keep the EU declaration of conformity and the technical documentation at the disposal of the national market surveillance authorities for 10 years after the PPE has been placed on the market;

b further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of the PPE;

c cooperate with the competent national authorities, at their request, on any action taken to eliminate the risks posed by PPE covered by the authorised representative's mandate.

Article 10

Obligations of importers

1 Importers shall place only compliant PPE on the market.

2 Before placing PPE on the market, importers shall ensure that the appropriate conformity assessment procedure referred to in Article 19 has been carried out by the manufacturer. They shall ensure that the manufacturer has drawn up the technical documentation, that the PPE bears the CE marking and is accompanied by the required documents, and that the manufacturer has complied with the requirements set out in Article 8(5) and (6).

Where an importer considers or has reason to believe that PPE is not in conformity with the applicable essential health and safety requirements set out in Annex II, he shall not place it on the market until it has been brought into conformity. Furthermore, where

the PPE presents a risk, the importer shall inform the manufacturer and the market surveillance authorities to that effect.

3 Importers shall 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. The contact details shall be in a language easily understood by end-users and market surveillance authorities.

4 Importers shall ensure that the PPE is accompanied by the instructions and information set out in point 1.4 of Annex II in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned.

5 Importers shall ensure that, while the PPE is under their responsibility, storage or transport conditions do not jeopardise its conformity with the applicable essential health and safety requirements set out in Annex II.

6 When deemed appropriate with regard to the risks presented by PPE, importers shall, to protect the health and safety of consumers and other end-users, 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.

7 Importers who consider or have reason to believe that PPE which they have placed on the market is not in conformity with this Regulation shall immediately take the corrective measures necessary to bring the PPE into conformity, to withdraw it or to recall it, as appropriate. Furthermore, where the PPE presents a risk, importers shall immediately inform the competent national authorities of the Member States in which they made the PPE available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

8 Importers shall, for 10 years after the PPE has been placed on the market, keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation can be made available to those authorities, upon request.

9 Importers shall, 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 PPE in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have placed on the market.

Article 11

Obligations of distributors

1 When making PPE available on the market, distributors shall act with due care in relation to the requirements of this Regulation.

2 Before making PPE available on the market, distributors shall verify that it bears the CE marking, is accompanied by the required documents and by the instructions and information set out in point 1.4 of Annex II in a language which can be easily understood by consumers and other end-users in the Member State in which PPE is to be made available on the market and that the manufacturer and the importer have complied with the requirements set out in Article 8(5) and (6) and Article 10(3) respectively.

Where a distributor considers or has reason to believe that PPE is not in conformity with the applicable essential health and safety requirements set out in Annex II, he shall not make the PPE available on the market until it has been brought into conformity. Furthermore, where the PPE presents a risk, the distributor shall inform the manufacturer or the importer to that effect as well as the market surveillance authorities.

3 Distributors shall ensure that, while PPE is under their responsibility, its storage or transport conditions do not jeopardise its conformity with the applicable essential health and safety requirements set out in Annex II.

4 Distributors who consider or have reason to believe that PPE which they have made available on the market is not in conformity with this Regulation shall make sure that the corrective measures necessary to bring it into conformity, to withdraw it or to recall it, as appropriate, are taken. Furthermore, where the PPE presents a risk, distributors shall immediately inform the competent national authorities of the Member States in which they have made the PPE available on the market to that effect, giving details, in particular, of the non-conformity and of any corrective measures taken.

5 Distributors shall, 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. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by PPE which they have made available on the market.

Article 12

Cases in which obligations of manufacturers apply to importers and distributors

An importer or distributor shall be considered a manufacturer for the purposes of this Regulation and he shall be subject to the obligations of the manufacturer set out in Article 8 where he places PPE on the market under his name or trademark or modifies PPE already placed on the market in such a way that compliance with this Regulation may be affected.

Article 13

Identification of economic operators

Economic operators shall, on request, identify the following to the market surveillance authorities:

(a) any economic operator who has supplied them with PPE;

(b) any economic operator to whom they have supplied PPE.

Economic operators shall be able to present the information referred to in the first paragraph for 10 years after they have been supplied with the PPE and for 10 years after they have supplied the PPE.

CHAPTER III

CONFORMITY OF THE PPE

Article 14

Presumption of conformity of PPE

PPE which is in conformity with harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union* shall be presumed to be in conformity with the essential health and safety requirements set out in Annex II covered by those standards or parts thereof.

Article 15

EU declaration of conformity

1 The EU declaration of conformity shall state that the fulfilment of the applicable essential health and safety requirements set out in Annex II has been demonstrated.

2 The EU declaration of conformity shall have the model structure set out in Annex IX, shall contain the elements specified in the relevant modules set out in Annexes IV, VI, VII and VIII and shall be continuously updated. It shall be translated into the language or languages required by the Member State in which the PPE is placed or made available on the market.

3 Where PPE is subject to more than one Union act requiring an EU declaration of conformity, a single EU declaration of conformity shall be drawn up in respect of all such Union acts. That declaration shall contain the identification of the Union acts concerned, including their publication references.

4 By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for the compliance of the PPE with the requirements laid down in this Regulation.

Article 16

General principles of the CE marking

The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

Article 17

Rules and conditions for affixing the CE marking

1 The CE marking shall be affixed visibly, legibly and indelibly to the PPE. Where that is not possible or not warranted on account of the nature of the PPE, it shall be affixed to the packaging and to the documents accompanying the PPE.

2 The CE marking shall be affixed before the PPE is placed on the market.

3 For category III PPE, the CE marking shall be followed by the identification number of the notified body involved in the procedure set out in Annex VII or VIII.

The identification number of the notified body shall be affixed by the body itself or, under its instructions, by the manufacturer or his authorised representative.

4 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.

5 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.

CHAPTER IV

CONFORMITY ASSESSMENT

Article 18

Risk categories of PPE

The PPE shall be classified according to the risk categories set out in Annex I.

Article 19

Conformity assessment procedures

The conformity assessment procedures to be followed for each of the risk categories set out in Annex I are as follows:

(a) Category I: internal production control (module A) set out in Annex IV;

(b) Category II: EU type-examination (module B) set out in Annex V, followed by conformity to type based on internal production control (module C) set out in Annex VI;

(c) Category III: EU type-examination (module B) set out in Annex V, and either of the following:

  (i) conformity to type based on internal production control plus supervised product checks at random intervals (module C2) set out in Annex VII;

  (ii) conformity to type based on quality assurance of the production process (module D) set out in Annex VIII.

  By way of derogation, for PPE produced as a single unit to fit an individual user and classified according to Category III, the procedure referred to in point (b) may be followed.

CHAPTER V

NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Article 20

Notification

Member States shall notify the Commission and the other Member States of bodies authorised to carry out third-party conformity assessment tasks under this Regulation.

Article 21

Notifying authorities

1 Member States shall designate a notifying authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, including compliance with Article 26.

2 Member States may decide that the assessment and monitoring referred to in paragraph 1 shall be carried out by a national accreditation body within the meaning of and in accordance with Regulation (EC) No 765/2008.

3 Where the notifying authority delegates or otherwise entrusts the assessment, notification or monitoring referred to in paragraph 1 of this Article to a body which is not a governmental entity, that body shall be a legal entity and shall comply *mutatis mutandis* with the requirements laid down in Article 22. In addition, that body shall have arrangements to cover liabilities arising out of its activities.

4 The notifying authority shall take full responsibility for the tasks performed by the body referred to in paragraph 3.

Article 22

Requirements relating to notifying authorities

1 A notifying authority shall be established in such a way that no conflict of interest with conformity assessment bodies occurs.

2 A notifying authority shall be organised and operated so as to safeguard the objectivity and impartiality of its activities.

3 A notifying authority shall be organised in such a way that each decision relating to notification of a conformity assessment body is taken by competent persons different from those who carried out the assessment.

4 A notifying authority shall not offer or provide any activities that conformity assessment bodies perform or consultancy services on a commercial or competitive basis.

5 A notifying authority shall safeguard the confidentiality of the information it obtains.

6 A notifying authority shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.

Article 23

Information obligation on notifying authorities

Member States shall inform the Commission of their procedures for the assessment and notification of conformity assessment bodies and the monitoring of notified bodies, and of any changes thereto.

The Commission shall make that information publicly available.

Article 24

Requirements relating to notified bodies

1 For the purposes of notification, a conformity assessment body shall meet the requirements laid down in paragraphs 2 to 11.

2 A conformity assessment body shall be established under the national law of a Member State and have legal personality.

3 A conformity assessment body shall be a third-party body independent of the organisation or the PPE it assesses.

A body belonging to a business association or professional federation representing undertakings involved in the design, manufacturing, provision, assembly, use or maintenance of PPE which it assesses, may, on the condition that its independence and the absence of any conflict of interest are demonstrated, be considered such a body.

4 A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be the designer, manufacturer, supplier, purchaser, owner, user or maintainer of the PPE which they assess, nor the representative of any of those parties. This does not preclude the use of assessed PPE that are necessary for the operations of the conformity assessment body or the use of such PPE for personal purposes.

A conformity assessment body, its top-level management and the personnel responsible for carrying out the conformity assessment tasks shall not be directly involved in the design, manufacture, marketing, use or maintenance of PPE, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified. This shall in particular apply to consultancy services.

Conformity assessment bodies shall ensure that the activities of their subsidiaries or subcontractors do not affect the confidentiality, objectivity or impartiality of their conformity assessment activities.

5 Conformity assessment bodies and their personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or groups of persons with an interest in the results of those activities.

6 A conformity assessment body shall be capable of carrying out all the conformity assessment tasks assigned to it by Annexes V, VII and VIII and in relation to which it has been notified, whether those tasks are carried out by the conformity assessment body itself or on its behalf and under its responsibility.

At all times and for each conformity assessment procedure and each kind of PPE for which it has been notified, a conformity assessment body shall have at its disposal the necessary:

a personnel with technical knowledge and sufficient and appropriate experience to perform the conformity assessment tasks;

b descriptions of procedures in accordance with which conformity assessment is carried out, ensuring the transparency and the ability of reproduction of those procedures. It shall have appropriate policies and procedures in place that distinguish between tasks it carries out as a notified body and other activities;

c procedures for the performance of activities which take due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the PPE technology in question and the mass or serial nature of the production process.

A conformity assessment body shall have the means necessary to perform the technical and administrative tasks connected with the conformity assessment activities in an appropriate manner and shall have access to all necessary equipment or facilities.

7 The personnel responsible for carrying out conformity assessment tasks shall have the following:

a sound technical and vocational training covering all the conformity assessment activities in relation to which the conformity assessment body has been notified;

b satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

c appropriate knowledge and understanding of the essential health and safety requirements set out in Annex II, of the applicable harmonised standards, and of the relevant provisions of Union harmonisation legislation and of national legislation;

d the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

8 The impartiality of the conformity assessment bodies, their top level management and of the personnel responsible for carrying out the conformity assessment tasks shall be guaranteed.

The remuneration of the top level management and personnel responsible for carrying out the conformity assessment tasks of a conformity assessment body shall not depend on the number of assessments carried out or on the results of those assessments.

9 Conformity assessment bodies shall take out liability insurance unless liability is assumed by the Member State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.

10 The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks under Annexes V, VII and VIII or any provision of national law giving effect to it, except in relation to the competent authorities of the Member State in which its activities are carried out. Proprietary rights shall be protected.

11 Conformity assessment bodies shall participate in, or ensure that their personnel responsible for carrying out the conformity assessment tasks are informed of, the relevant standardisation activities and the activities of the notified body coordination group established

under Article 36 and shall apply as general guidance the administrative decisions and documents produced as a result of the work of that group.

Article 25

Presumption of conformity of notified bodies

Where a conformity assessment body demonstrates its conformity with the criteria laid down in the relevant harmonised standards or parts thereof the references of which have been published in the *Official Journal of the European Union*, it shall be presumed to comply with the requirements set out in Article 24 in so far as the applicable harmonised standards cover those requirements.

Article 26

Subsidiaries of and subcontracting by notified bodies

1 Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that the subcontractor or the subsidiary meets the requirements set out in Article 24 and shall inform the notifying authority accordingly.

2 Notified bodies shall take full responsibility for the tasks performed by subcontractors or subsidiaries wherever these are established.

3 Activities may be subcontracted or carried out by a subsidiary only with the agreement of the client.

4 Notified bodies shall keep at the disposal of the notifying authority the relevant documents concerning the assessment of the qualifications of the subcontractor or the subsidiary and the work carried out by them under Annexes V, VII and VIII.

Article 27

Application for notification

1 A conformity assessment body shall submit an application for notification to the notifying authority of the Member State in which it is established.

2 The application for notification shall be accompanied by a description of the conformity assessment activities, the conformity assessment module or modules and the kinds of PPE for which that body claims to be competent, as well as by an accreditation certificate, where one exists, issued by a national accreditation body attesting that the conformity assessment body fulfils the requirements laid down in Article 24.

3 Where the conformity assessment body concerned cannot provide an accreditation certificate, it shall provide the notifying authority with all the documentary evidence necessary for the verification, recognition and regular monitoring of its compliance with the requirements laid down in Article 24.

Article 28

Notification procedure

1 Notifying authorities may notify only conformity assessment bodies which have satisfied the requirements laid down in Article 24.

2 They shall notify the Commission and the other Member States using the electronic notification tool developed and managed by the Commission.

3 The notification shall include full details of the conformity assessment activities, the conformity assessment module or modules and the kinds of PPE concerned and the relevant attestation of competence.

4 Where a notification is not based on an accreditation certificate referred to in Article 27(2), the notifying authority shall provide the Commission and the other Member States with documentary evidence which attests to the conformity assessment body's competence and the arrangements in place to ensure that that body will be monitored regularly and will continue to satisfy the requirements laid down in Article 24.

5 The body concerned may perform the activities of a notified body only where no objections are raised by the Commission or the other Member States within two weeks of a notification where an accreditation certificate is used or within two months of a notification where accreditation is not used.

Only such a body shall be considered a notified body for the purposes of this Regulation.

6 The notifying authority shall notify the Commission and the other Member States of any subsequent relevant changes to the notification.

Article 29

Identification numbers and lists of notified bodies

1 The Commission shall assign an identification number to a notified body.

It shall assign a single such number even where the body is notified under several Union acts.

2 The Commission shall make publicly available the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified.

The Commission shall ensure that the list is kept up to date.

Article 30

Changes to notifications

1 Where a notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 24, or that it is failing to fulfil its obligations, the notifying authority shall restrict, suspend or withdraw the notification, as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil

those obligations. It shall immediately inform the Commission and the other Member States accordingly.

2 In the event of restriction, suspension or withdrawal of notification, or where the notified body has ceased its activity, the notifying Member State shall take appropriate steps to ensure that the files of that body are either processed by another notified body or kept available for the responsible notifying and market surveillance authorities at their request.

Article 31

Challenge of the competence of notified bodies

1 The Commission shall investigate all cases where it doubts, or doubt is brought to its attention regarding, the competence of a notified body or the continued fulfilment by a notified body of the requirements and responsibilities to which it is subject.

2 The notifying Member State shall provide the Commission, on request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.

3 The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4 Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall adopt an implementing act requesting the notifying Member State to take the necessary corrective measures, including the withdrawal of the notification if necessary.

That implementing act shall be adopted in accordance with the advisory procedure referred to in Article 44(2).

Article 32

Operational obligations of notified bodies

1 Notified bodies shall carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annexes V, VII and VIII.

2 Conformity assessments shall be carried out in a proportionate manner, avoiding unnecessary burdens for economic operators. Conformity assessment bodies shall perform their activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the PPE technology in question and the mass or serial nature of the production process.

In so doing they shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the PPE with the requirements of this Regulation.

3 Where a notified body finds that the essential health and safety requirements set out in Annex II or the corresponding harmonised standards or other technical specifications have not been met by a manufacturer, it shall require the manufacturer to take appropriate corrective measures and shall not issue a certificate or approval decision.

4 Where, in the course of the monitoring of conformity following the issue of a certificate or approval decision, a notified body finds that a PPE no longer complies, it shall

require the manufacturer to take appropriate corrective measures and shall suspend or withdraw the certificate or the approval decision if necessary.

5 Where corrective measures are not taken or do not have the required effect, the notified body shall restrict, suspend or withdraw any certificates or approval decisions, as appropriate.

Article 33

Appeal against decisions of notified bodies

Notified bodies shall ensure that a transparent and accessible appeal procedure against their decisions is available.

Article 34

Information obligation on notified bodies

1 Notified bodies shall inform the notifying authority of the following:

a any refusal, restriction, suspension or withdrawal of a certificate or approval decision;

b any circumstances affecting the scope of or conditions for notification;

c any request for information which they have received from market surveillance authorities regarding conformity assessment activities;

d on request, conformity assessment activities performed within the scope of their notification and any other activity performed, including cross-border activities and subcontracting.

2 Notified bodies shall provide the other bodies notified under this Regulation carrying out similar conformity assessment activities covering the same kinds of PPE with relevant information on issues relating to negative and, on request, positive conformity assessment results.

Article 35

Exchange of experience

The Commission shall provide for the organisation of exchange of experience between the Member States' national authorities responsible for notification policy.

Article 36

Coordination of notified bodies

The Commission shall ensure that appropriate coordination and cooperation between bodies notified under this Regulation are put in place and properly operated in the form of a sectoral group of notified bodies.

Notified bodies shall participate in the work of that group, directly or by means of designated representatives.

CHAPTER VI

UNION MARKET SURVEILLANCE, CONTROL OF PPE ENTERING THE UNION MARKET AND UNION SAFEGUARD PROCEDURE

Article 37

Union market surveillance and control of PPE entering the Union market

Article 15(3) and Articles 16 to 29 of Regulation (EC) No 765/2008 shall apply to PPE covered by Article 2(1) of this Regulation.

Article 38

Procedure at national level for dealing with PPE presenting a risk

1 Where the market surveillance authorities of one Member State have sufficient reason to believe that PPE covered by this Regulation presents a risk to the health or safety of persons, they shall carry out an evaluation in relation to the PPE concerned covering all relevant requirements laid down in this Regulation. The relevant economic operators shall cooperate as necessary with the market surveillance authorities for that purpose.

Where, in the course of the evaluation referred to in the first subparagraph, the market surveillance authorities find that the PPE does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take all appropriate corrective action to bring the PPE into compliance with those requirements, to withdraw the PPE from the market, or to recall it within a reasonable period, commensurate with the nature of the risk, as they may prescribe.

The market surveillance authorities shall inform the relevant notified body accordingly.

Article 21 of Regulation (EC) No 765/2008 shall apply to the measures referred to in the second subparagraph of this paragraph.

2 Where the market surveillance authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operator to take.

3 The economic operator shall ensure that all appropriate corrective action is taken in respect of all the PPE concerned that it has made available on the market throughout the Union.

4 Where the relevant economic operator does not take adequate corrective action within the period referred to in the second subparagraph of paragraph 1, the market surveillance authorities shall take all appropriate provisional measures to prohibit or restrict the PPE being made available on their national market, to withdraw the PPE from that market or to recall it.

The market surveillance authorities shall inform the Commission and the other Member States, without delay, of those measures.

5 The information referred to in the second subparagraph of paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant PPE, the origin of the PPE, the nature of the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant

economic operator. In particular, the market surveillance authorities shall indicate whether the non-compliance is due to either of the following:

a failure of the PPE to meet requirements relating to the health or safety of persons; or

b shortcomings in the harmonised standards referred to in Article 14 conferring a presumption of conformity.

6 Member States other than the Member State initiating the procedure under this Article shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the PPE concerned, and, in the event of disagreement with the adopted national measure, of their objections.

7 Where, within three months of receipt of the information referred to in the second subparagraph of paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

8 Member States shall ensure that appropriate restrictive measures, such as withdrawal of the PPE from the market, are taken in respect of the PPE concerned without delay.

Article 39

Union safeguard procedure

1 Where, on completion of the procedure set out in Article 38(3) and (4), objections are raised against a measure taken by a Member State, or where the Commission considers a national measure to be contrary to Union legislation, the Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall adopt an implementing act determining whether the national measure is justified or not.

The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

2 If the national measure is considered justified, all Member States shall take the necessary measures to ensure that the non-compliant PPE is withdrawn from their market, and shall inform the Commission accordingly. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.

3 Where the national measure is considered justified and the non-compliance of the PPE is attributed to shortcomings in the harmonised standards referred to in point (b) of Article 38(5) of this Regulation, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

Article 40

Compliant PPE which presents a risk

1 Where, having carried out an evaluation under Article 38(1), a Member State finds that although PPE is in compliance with this Regulation, it presents a risk to the health or safety of persons, it shall require the relevant economic operator to take all appropriate measures to ensure that the PPE concerned, when placed on the market, no longer presents that risk, to

withdraw the PPE from the market or to recall it within a reasonable period, commensurate with the nature of the risk, as it may prescribe.

2 The economic operator shall ensure that corrective action is taken in respect of all the PPE concerned that he has made available on the market throughout the Union.

3 The Member State shall immediately inform the Commission and the other Member States. That information shall include all available details, in particular the data necessary for the identification of the PPE concerned, the origin and the supply chain of the PPE, the nature of the risk involved and the nature and duration of the national measures taken.

4 The Commission shall without delay enter into consultation with the Member States and the relevant economic operator or operators and shall evaluate the national measures taken. On the basis of the results of that evaluation, the Commission shall decide by means of implementing acts whether the national measure is justified or not and, where necessary, propose appropriate measures.

The implementing acts referred to in the first subparagraph of this paragraph shall be adopted in accordance with the examination procedure referred to in Article 44(3).

On duly justified imperative grounds of urgency relating to the protection of health and safety of persons, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 44(4).

5 The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator or operators.

Article 41

Formal non-compliance

1 Without prejudice to Article 38, where a Member State makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned:

a the CE marking has been affixed in violation of Article 30 of Regulation (EC) No 765/2008 or of Article 17 of this Regulation;

b the CE marking has not been affixed;

c the identification number of the notified body involved in the production control phase has been affixed in violation of Article 17 or has not been affixed;

d the EU declaration of conformity has not been drawn up or has not been drawn up correctly;

e the technical documentation is either not available or not complete;

f the information referred to in Article 8(6) or Article 10(3) is absent, false or incomplete;

g any other administrative requirement provided for in Article 8 or Article 10 is not fulfilled.

2 Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the PPE being made available on the market or ensure that it is recalled or withdrawn from the market.

CHAPTER VII

DELEGATED AND IMPLEMENTING ACTS

Article 42

Delegated power

1 In order to take into account technical progress and knowledge or new scientific evidence with respect to the category of a specific risk, the Commission shall be empowered to adopt delegated acts in accordance with Article 43 in order to amend Annex I by reclassifying the risk from one category to another.

2 A Member State which has concerns about the classification of a risk into a specific risk category referred to in Annex I shall immediately inform the Commission of its concerns and provide reasons in support.

3 Prior to adopting a delegated act, the Commission shall carry out a thorough assessment of the risks that require reclassification and the impact of such reclassification.

Article 43

Exercise of the delegation

1 The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2 The power to adopt delegated acts referred to in Article 42 shall be conferred on the Commission for a period of five years from 21 April 2018. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

It is of particular importance that the Commission follow its usual practice and carry out consultations with experts, including Member States' experts, before adopting those delegated acts.

3 The delegation of powers referred to in Article 42 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4 As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5 A delegated act adopted pursuant to Article 42 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 44

Committee procedure

1 The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2 Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.

3 Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

4 Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

5 The committee shall be consulted by the Commission on any matter for which consultation of sectoral experts is required by Regulation (EU) No 1025/2012 or by any other Union legislation.

The committee may furthermore examine any other matter 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.

CHAPTER VIII

TRANSITIONAL AND FINAL PROVISIONS

Article 45

Penalties

1 Member States shall lay down the rules on penalties applicable to infringements by economic operators of the provisions of this Regulation. Such rules may include criminal penalties for serious infringements.

The penalties provided for shall be effective, proportionate and dissuasive.

Member States shall notify those rules to the Commission by 21 March 2018, and shall notify it without delay of any subsequent amendment affecting them.

2 Member States shall take all measures necessary to ensure that their rules on penalties applicable to infringements by economic operators of the provisions of this Regulation are enforced.

Article 46

Repeal

Directive 89/686/EEC is repealed with effect from 21 April 2018.

References to the repealed Directive shall be construed as references to this Regulation and shall be read in accordance with the correlation table in Annex X.

Article 47

Transitional provisions

1 Without prejudice to paragraph 2, 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.

2 EC type-examination certificates and approval decisions issued under Directive 89/686/EEC shall remain valid until 21 April 2023 unless they expire before that date.

Article 48

Entry into force and application

1 This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

2 This Regulation shall apply from 21 April 2018, with the exception of:

a Articles 20 to 36 and Article 44, which shall apply from 21 October 2016;

b Article 45(1), which shall apply from 21 March 2018.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 9 March 2016.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

J.A. HENNIS-PLASSCHAERT