



STATUTORY INSTRUMENTS.

**S.I. No. 136 of 2018**



EUROPEAN UNION (PERSONAL PROTECTIVE EQUIPMENT)  
REGULATIONS 2018

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EUROPEAN UNION (PERSONAL PROTECTIVE EQUIPMENT)  
REGULATIONS 2018

I, HEATHER HUMPHREYS, Minister for Business, Enterprise and Innovation, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) (as amended by section 2 of the European Communities Act 2007 (No. 18 of 2007)) and for the purpose of giving effect to 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<sup>1</sup> and of giving further effect to Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008<sup>2</sup>, hereby make the following regulations:

PART 1

PRELIMINARY AND GENERAL

*Citation and commencement*

1. (1) These Regulations may be cited as the European Union (Personal Protective Equipment) Regulations 2018.

(2) These Regulations shall come into operation on the 21 April 2018.

*Interpretation*

2. (1) In these Regulations—

“accreditation” has the meaning assigned to it in point 10 of Article 2 of Regulation (EC) No. 765/2008;

“Act of 2005” means the Safety, Health and Welfare at Work Act 2005;

“Act of 2014” means the Competition and Consumer Protection Act 2014;

“Authorised Officer” has the meaning assigned to it in Regulation 31;

“authorised representative” means any natural or legal person established within the market of the Member States who has received a written mandate from a manufacturer to act on his or her behalf in relation to specified tasks;

“CE marking” means a marking by which the manufacturer indicates that the PPE is in conformity with the applicable requirements set out in Union harmonisation legislation providing for its affixing;

<sup>1</sup>OJ No. L 81. 31.3.2016. p.51

<sup>2</sup>OJ No. L 218, 13.8.2008, p. 30.

*Notice of the making of this Statutory Instrument was published in  
“Iris Oifigiúil” of 4th May, 2018.*

“competent national authority” means an authority of a State that is a competent national authority for the purposes of the PPE Regulation;

“conformity assessment” means the process demonstrating whether the essential health and safety requirements of the PPE Regulation and these Regulations relating to PPE have been fulfilled;

“conformity assessment body” means a body that performs conformity assessment activities including calibration, testing, certification and inspection;

“contravention notice” means the notice provided for in Regulation 34;

“Directive” means Council Directive 89/686/EEC of 21 December 1989 on the approximation of the laws of the Member States relating to personal protective equipment<sup>3</sup>, as amended;

“dispose”, in relation to PPE, means getting rid of the PPE in a manner which complies with requirements under the Waste Management Acts 1996 to 2013 and results in preventing the PPE being used, placed on the market or made available on the market;

“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;

“economic operator” means a manufacturer, authorised representative, importer or distributor;

“EU declaration of conformity” means a declaration drawn up in accordance with Article 15 of the PPE Regulation and Regulation 15 of these Regulations;

“forfeiture order” means an order provided for in Regulation 40;

“harmonised standard” has the meaning assigned to it in point (c) of point 1 of Article 2 of Regulation (EU) No. 1025/2012 of 25 October 2012<sup>4</sup>;

“importer” means any natural or legal person established within the market of the Member States who places PPE from a third country on the said market;

“information notice” means the notice provided for in Regulation 41;

“Irish National Accreditation Board” means the national body with responsibility for the accreditation of laboratories, certification bodies and inspection bodies, and notified to the European Commission as being the sole accreditation body for Ireland in line with Regulation (EC) No. 765/2008;

“making available on the market” means any supply of PPE for distribution or use on the market of the Member States in the course of a commercial activity, whether in return for payment or free of charge;

<sup>3</sup>OJ No. L399, 30.12.1989, p. 18

<sup>4</sup>OJ No. L 316, 14.11.2012, p. 12.

“manufacturer” means any natural or legal person who manufactures PPE or has PPE designed or manufactured, and markets it under his or her name or trademark;

“market surveillance” means the activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;

“market surveillance authority” means an authority of a State responsible for carrying out market surveillance on its territory and a reference to market surveillance authority in these Regulations shall, unless the context otherwise discloses, be taken to be a reference to an authority designated under Regulation 3 as a market surveillance authority of the State;

“Member States” means the Member States of the European Union and, in so far as may be necessary to give effect to the obligations of the State pursuant to the Agreement on the European Economic Area signed in Oporto on 2 May 1992, shall be construed as including a reference to those States (not being Member States of the European Union) which are contracting parties to that Agreement;

“notified body” means a conformity assessment body that is a notified body pursuant to the PPE Regulation and in these Regulations a reference to notified body shall, unless the context otherwise discloses, be taken to be a reference to a conformity assessment body that satisfies Regulation 18(2);

“notifying authority” means an authority designated by a Member State pursuant to Article 21 of the PPE Regulation as a notifying authority of that State and a reference to notifying authority in these Regulations shall, unless the context otherwise discloses, be taken to be a reference to an authority so designated as the notifying authority of the State by virtue of Regulation 3 of these Regulations;

“Official Journal” means the Official Journal of the European Union;

“personal protective equipment” 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) connection 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;



“person in charge”, in relation to a place, means—

- (a) the person under whose direction and control the activities at that place are being conducted, or
- (b) the person whom the Authorised Officer has reasonable grounds for believing is the person referred to in subparagraph (a);

“placing on the market” means the first making available of PPE on the market of the Member States;

“PPE” means personal protective equipment to which these Regulations apply by virtue of Regulation 4;

“PPE Regulation” means Regulation (EU) 2016/425 of 9 March 2016;

“prohibition notice” means the notice provided for in Regulation 36;

“recall” means any measure aimed at achieving the return of PPE that has already been made available to the end-user;

“Regulation (EC) No. 765/2008” means Regulation (EC) No 765/2008 of 9 July 2008;

“seizure notice” means the notice provided for in Regulation 39;

“technical specification” means a document that prescribes technical requirements to be fulfilled by PPE;

“Union harmonisation legislation” means any European Union legislation harmonising the conditions for the marketing of products;

“withdrawal”, in relation to PPE, means any measure aimed at preventing PPE in the supply chain from being made available on the market.

(2) A word or expression which is used in these Regulations and which is also used in the PPE Regulation has, unless the context otherwise requires, the same meaning in these Regulations as it has in the PPE Regulation.

(3) References to the repealed Directive shall be construed in existing laws, regulations and administrative provisions of the State as references to the PPE Regulation and shall be read in accordance with the correlation table in Annex X to the PPE Regulation, the text of which is set out in Schedule 10 to these Regulations.

#### *Designation*

3. (1) For the purposes of the PPE Regulation and these Regulations—

- (a) the following are designated as market surveillance authorities:
  - (i) the Health and Safety Authority; and

(ii) the Competition and Consumer Protection Commission, and

(b) the Minister for Business, Enterprise and Innovation is designated as the notifying authority of the State.

(2) An authority designated under paragraph (1) as a market surveillance authority shall be a competent national authority of the State.

(3) The assessment and monitoring referred to in Article 21(1) and (2) of the PPE Regulation shall be carried out by the Irish National Accreditation Board.

(4) The notifying authority shall act in accordance with Articles 21, 22 and 23 of the PPE Regulation and where the notifying authority delegates or otherwise entrusts the notification referred to in Article 21(3) to a body referred to in that Article, the body shall comply with Article 21(3).

#### *Application*

4. (1) Subject to paragraph (2), these Regulations apply to personal protective equipment.

(2) These Regulations do not apply to personal protective equipment:

(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 personal protective equipment 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.

#### *Making available on market*

5. (1) Subject to paragraph (2), a person shall not place on the market or make available on the market any PPE unless, when properly maintained and used for its intended purpose, it complies with the PPE Regulation and these Regulations and does not endanger the health or safety of persons, domestic animals or property.

(2) Paragraph (1) shall not prevent a person from showing PPE which does not comply with the PPE Regulation or these Regulations at a trade fair, exhibition, demonstration or other similar event, provided that—

- (a) a visible sign clearly indicates that the PPE does not comply with the PPE Regulation or these Regulations and further indicates that it is not to be made available on the market until it has been brought into conformity with the PPE Regulation and these Regulations, and
- (b) adequate measures are taken during any demonstration of the PPE to ensure the protection of persons.

## PART 2

### OBLIGATIONS OF ECONOMIC OPERATORS

#### *Obligations of manufacturers*

##### 6. A manufacturer shall—

- (a) ensure that PPE placed on the market by the manufacturer has been designed and manufactured in accordance with the applicable essential health and safety requirements set out in Annex II to the PPE Regulation, the text of which is set out in Schedule 2 to these Regulations,
- (b) draw up the technical documentation referred to in Annex III to the PPE Regulation, the text of which is set out in Schedule 3 to these Regulations, and carry out, or have carried out, the applicable conformity assessment procedure referred to in Regulation 14,
- (c) in a case where compliance of PPE with paragraph (a) has been demonstrated by the conformity assessment procedure carried out under paragraph (b)—
  - (i) draw up an EU declaration of conformity,
  - (ii) ensure that the EU declaration of conformity referred to in subparagraph (c)(i) accompanies the PPE or include in the instructions and information set out in point 1.4 of Annex II to the PPE Regulation the internet address at which the EU declaration of conformity can be accessed,
- (d) in a case where compliance of PPE with paragraph (a) has been demonstrated by the conformity assessment procedure carried out under paragraph (b), affix a CE marking to the PPE in accordance with Regulation 17,
- (e) retain the technical documentation and the EU declaration of conformity for 10 years after the PPE has been placed on the market,
- (f) ensure that procedures are in place for series production to remain in conformity with the PPE Regulation and these Regulations and that changes in PPE design or characteristics and changes in the harmonised standards or in other technical specifications by reference to

which conformity of PPE is declared, are adequately taken into account,

- (g) in a case where it is deemed appropriate by a market surveillance authority with regard to the risks presented by PPE and in order to protect the health and safety of consumer and other end-users—
    - (i) carry out sample testing of PPE made available on the market,
    - (ii) investigate and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls, and
    - (iii) keep distributors informed of any such monitoring,
  - (h) ensure that PPE which the manufacturer has placed 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, ensure that this information is provided on its packaging or in a document accompanying it,
  - (i) indicate on the PPE or, where that is not possible, on its packaging or in a document accompanying the PPE, in a language easily understood by end-users and the market surveillance authorities, the manufacturer's name, registered trade name or registered trade mark and the postal address at which he or she can be contacted, which address shall indicate a single point of contact,
  - (j) ensure that the PPE is accompanied by the instructions and information set out in point 1.4 of Annex II to the PPE Regulation in a language which can be easily understood by consumers and other end-users and that such instructions and information, as well as any labelling, is clear, understandable, intelligible and legible,
  - (k) in a case where the manufacturer has placed on the market PPE and considers or has reason to believe the PPE is not in conformity with the PPE Regulation or these Regulations—
    - (i) immediately take the corrective measures necessary to bring that PPE into conformity, to withdraw it or to recall it, as appropriate, and
    - (ii) where the PPE presents a risk, immediately inform the competent national authorities of the Member States in which the manufacturer made available on the market the PPE of such risk, giving details, in particular, of the non-conformity, and of any corrective measures taken,
- and
- (l) further to a reasoned request from a competent national authority—

- (i) provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the PPE with the PPE Regulation and these Regulations, in a language which can be easily understood by that authority, and
- (ii) co-operate with that authority, at its request, on any action taken to eliminate the risks posed by PPE placed on the market by the manufacturer.

*Authorised representatives*

7. (1) A manufacturer may, by a written mandate, appoint an authorised representative for the purposes of the PPE Regulation and these Regulations.

(2) The obligations referred to in Regulation 6(a) and the obligation to draw up technical documentation referred to in Regulation 6(b) shall not form part of the mandate of an authorised representative appointed under paragraph (1).

(3) An authorised representative appointed under paragraph (1) shall perform the tasks specified in the mandate received from the manufacturer which shall, at least, allow the authorised representative to—

- (a) keep the EU declaration of conformity and the technical documentation at the disposal of the market surveillance authorities of all Member States 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 PPE,
- and
- (c) co-operate with a competent national authority, at its request, on any action taken to eliminate the risks posed by PPE covered by the authorised representative's mandate.

*Obligations of importers*

8. (1) An importer shall not place on the market PPE unless it complies with the PPE Regulation and these Regulations.

(2) An importer shall—

- (a) before placing on the market PPE, ensure that—
  - (i) the appropriate conformity assessment procedure referred to in Regulation 14 has been carried out by the manufacturer,
  - (ii) the manufacturer has drawn up the technical documentation,

- (iii) the PPE bears the CE marking and is accompanied by the documents required under the PPE Regulation and these Regulations, and
  - (iv) the manufacturer has complied with the requirements set out in Regulation 6(*h*) and (*i*),
- (b) in a case where the 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 to the PPE Regulation—
- (i) refrain from placing on the market the PPE until it has been brought into conformity, and
  - (ii) where the PPE presents a risk, inform the manufacturer and the market surveillance authorities of all Member States of such risk,
- (c) indicate on PPE, or where that is not possible, on its packaging or in a document accompanying it, in a language easily understood by end-users and market surveillance authorities referred to in Article 10(3) of the PPE Regulation, the importer's name, registered trade name or registered trade mark and the postal address at which the importer can be contacted,
- (d) ensure that the PPE is accompanied by instructions and information set out in point 1.4 of Annex II to the PPE Regulation in a language which can be easily understood by consumers and other end-users,
- (e) ensure that, while PPE is under the importer's responsibility, storage or transport conditions do not jeopardise its conformity with the applicable essential health and safety requirements set out in Annex II to the PPE Regulation,
- (f) in a case where it is deemed appropriate by a market surveillance authority with regard to the risks presented by PPE and in order to protect the health and safety of consumers and other end-users—
- (i) carry out sample testing of PPE made available on the market,
  - (ii) investigate and, if necessary, keep a register of complaints, of non-conforming PPE and PPE recalls, and
  - (iii) keep distributors informed of any such monitoring,
- (g) in a case where an importer considers or has reason to believe that PPE which the importer has placed on the market is not in conformity with the PPE Regulation or these Regulations—
- (i) immediately take the corrective measures necessary to bring that PPE into conformity, to withdraw it or to recall it, as appropriate, and

- (ii) where the PPE presents a risk, immediately inform the competent national authorities of the Member States in which the importer made available on the market the PPE of such risk, giving details, in particular, of the non-conformity and of any corrective measures taken,
- (h) for 10 years after the PPE has been placed on the market by the importer—
- (i) keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities of all Member States, and
  - (ii) ensure that the technical documentation can be made available to those authorities, upon request,
- and
- (i) further to a reasoned request from a competent national authority—
- (i) 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, and
  - (ii) co-operate with that authority, at its request, on any action taken to eliminate the risks posed by the PPE which the importer has placed on the market.

*Obligations of distributors*

9. A distributor shall—

- (a) when making available on the market PPE, act with due care in relation to the requirements of the PPE Regulation and these Regulations,
- (b) before making available on the market PPE, verify that—
  - (i) the PPE bears the CE marking,
  - (ii) the PPE is accompanied by the required documents and by the instructions and information set out in point 1.4 of Annex II to the PPE Regulation in a language which can be easily understood by consumers and other end-users in the Member State in which the PPE is to be made available on the market,
  - (iii) the manufacturer and the importer have complied with the requirements set out in Regulations 6(h), 6(i) and 8(2)(c) respectively,

- (c) in a case where the 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 to the PPE Regulation—
  - (i) refrain from making available on the market the PPE until it has been brought into conformity, and
  - (ii) where the PPE presents a risk, inform the manufacturer or the importer and the market surveillance authorities of all Member States of such risk,
- (d) ensure that, while PPE is under the distributor's responsibility, storage or transport conditions do not jeopardise its conformity with the applicable essential health and safety requirements set out in Annex II to the PPE Regulation,
- (e) in a case where the distributor considers or has reason to believe that PPE which the distributor has made available on the market is not in conformity with the PPE Regulation or these Regulations—
  - (i) ensure that the corrective measures necessary to bring the PPE into conformity, to withdraw it or to recall it, as appropriate, are taken, and
  - (ii) where that PPE presents a risk, immediately inform the competent national authorities of the Member States in which the distributor has made available on the market the PPE of such risk, giving details, in particular, of the non-conformity and of any corrective measures taken,

and
- (f) further to a reasoned request from a competent national authority—
  - (i) provide it with all the information and documentation, in paper or electronic form, necessary to demonstrate the conformity of the PPE, and
  - (ii) co-operate with that authority, at its request, on any action taken to eliminate the risks posed by the PPE which the distributor has made available on the market.

*Cases in which obligations of manufacturers apply to importers and distributors*

10. An importer or distributor shall be considered a manufacturer for the purposes of the PPE Regulation and these Regulations, and shall be subject to the obligations of the manufacturer under Regulation 6 where the importer or distributor—

- (a) places on the market PPE under his or her name or trademark, or



- (b) modifies PPE already placed on the market in such a way that compliance with the PPE Regulation or these Regulations may be affected.

*Identification of economic operators*

11. (1) An economic operator (in this Regulation “first named economic operator”) shall, on request, identify the following to a market surveillance authority:

- (a) any economic operator who has supplied the first named economic operator with PPE;
- (b) any economic operator to whom the first named economic operator has supplied PPE.

(2) The first named economic operator shall be able to present the information referred to in paragraph (1) for 10 years after the first named economic operator has been supplied with or has supplied the PPE referred to in that paragraph.

### PART 3

#### CONFORMITY OF PPE

*Presumption of conformity on basis of harmonised standards*

12. Without prejudice to the powers of the State under Articles 38 and 40 of the PPE Regulation, PPE which is in conformity with harmonised standards or parts thereof, the references of which have been published in the Official Journal, shall be presumed to be in conformity with the essential health and safety requirements set out in Annex II to the PPE Regulation, or parts thereof.

*Risk categories of PPE*

13. PPE shall be classified according to the risk categories set out and entitled Category I, Category II and Category III in Annex I to the PPE Regulation, the text of which is set out in Schedule 1 to these Regulations.

*Conformity assessment procedures*

14. (1) The procedures to be followed for conformity assessment of Category I PPE, Category II PPE and Category III PPE are:

- (a) Category I: internal production control (module A) set out in Annex IV to the PPE Regulation, the text of which is set out in Schedule 4 to these Regulations;
- (b) Category II: EU type-examination (module B) set out in Annex V to the PPE Regulation, the text of which is set out in Schedule 5 to these Regulations, followed by conformity to type based on internal production control (module C) set out in Annex VI to the PPE Regulation, the text of which is set out in Schedule 6 to these Regulations;

- (c) Category III: Subject to paragraph (2), EU type-examination (module B) set out in Annex V to the PPE Regulation 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 to the PPE Regulation, the text of which is set out in Schedule 7 to these Regulations;
  - (ii) conformity to type based on quality assurance of the production process (module D) set out in Annex VIII to the PPE Regulation, the text of which is set out in Schedule 8 to these Regulations.

(2) Where PPE is produced as a single unit to fit an individual user and classified according to Category III, the procedure referred to in paragraph (1)(b) may be followed.

*EU declaration of conformity*

15. (1) An EU declaration of conformity for PPE shall—

- (a) state that the fulfilment of the applicable essential health and safety requirements set out in Annex II to the PPE Regulation has been demonstrated,
  - (b) have the model structure set out in Annex IX to the PPE Regulation, the text of which is set out in Schedule 9 to these Regulations,
  - (c) contain the elements specified in the relevant modules set out in Annexes IV, VI, VII and VIII to the PPE Regulation,
  - (d) be continuously updated,
- and
- (e) be translated into the language or languages required by the Member State in which the PPE is placed on the market or made available on the market.

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

(3) 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 the PPE Regulation and these Regulations.

*General principles of CE marking*

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

*Rules and conditions for affixing CE marking and other markings*

17. (1) Subject to paragraph (2), before PPE is placed on the market, the CE marking shall be affixed visibly, legibly and indelibly to the PPE.

(2) Where it is not possible or not warranted on account of the nature of the PPE to affix the CE marking in accordance with paragraph (1), before the PPE is placed on the market, the CE marking shall be affixed to—

- (a) the PPE packaging, and
- (b) the documents accompanying the PPE.

(3) For PPE falling within Category III of Annex I to the PPE Regulation, 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 to the PPE Regulation which identification number shall be affixed—

- (a) by the notified body itself, or
- (b) in accordance with the instructions of the notified body, by the manufacturer or his or her 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) A person shall not affix a CE marking unless—

- (a) the PPE to which it relates conforms with the PPE Regulation and these Regulations, and
- (b) the CE marking is affixed in accordance with the PPE Regulation and these Regulations.

## PART 4

## NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

*Notified bodies*

18. (1) The notifying authority shall notify the European Commission and all other Member States of the conformity assessment bodies authorised under the PPE Regulation and these Regulations to carry out third party conformity assessment tasks.

(2) A conformity assessment body shall be a notified body when the following conditions are satisfied:

- (a) the body has been notified to the European Commission and all other Member States as being a conformity assessment body authorised in terms of paragraph (1); and

- (b) no objections have been raised by the European Commission or other Member States within the time periods set down under Article 28(5) of the PPE Regulation to the notification referred to in paragraph (1).

*Applications for notification by conformity assessment bodies*

19. (1) A conformity assessment body seeking to become a notified body shall—

- (a) submit to the notifying authority an application, which application shall be in accordance with Article 27 of the PPE Regulation and shall be accompanied by the appropriate fee as may be prescribed by the notifying authority, and
- (b) meet the requirements set down in paragraphs 2 to 11 of Article 24 of the PPE Regulation.

(2) Without prejudice to paragraph (1), 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, it shall be presumed to comply with the requirements set down in Article 24 of the PPE Regulation insofar as the applicable harmonised standards cover those requirements.

*Notification of conformity assessment bodies*

20. (1) A notification made by the notifying authority under Regulation 18(1) shall be made in accordance with the notification procedure set down in Article 28(2), (3) and (4) of the PPE Regulation.

(2) The notifying authority shall not notify the European Commission and all Member States that a conformity assessment body is authorised in terms of Regulation 18(1) unless the body has satisfied Regulation 19(1).

*Changes to notification*

21. (1) The notifying authority shall notify the European Commission and the other Member States of any subsequent relevant changes to the notification made under Regulation 18(1).

(2) Where the notifying authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Article 24 of the PPE Regulation, or that it is failing to fulfil its obligations under Article 32 or 34 of the PPE Regulation or under these Regulations, the authority shall restrict, suspend or revoke the notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfil those obligations, and shall immediately inform the European Commission and all other Member States accordingly.

(3) In the event of restriction, suspension or revocation of notification, or where the notified body has ceased its activity, the notifying authority shall take appropriate steps to ensure that the files of that notified body are either processed by another body considered to be a notified body for the purposes of the

PPE Regulation or kept available for the notifying authority of the State and market surveillance authorities of all the Member States at their request.

(4) The notifying authority shall inform the notified body concerned of its decision to take the measure referred to in paragraph (2) and allow that body an opportunity to make representations to it within 7 days of being so informed.

(5) The notifying authority shall establish a panel (in this Regulation “appeal panel”) for the purpose of considering appeals under this Regulation and the following shall apply:

(a) Subject to subparagraph (b), an appeal panel shall consist of at least 3 but not more than 5 persons appointed by the notifying authority, one of whom shall be designated by the notifying authority to be chairperson of the panel;

(b) where an appeal is taken against a decision of the notifying authority under this Regulation, an appeal panel shall not consist of any person who made the decision or was involved in the decision;

(c) an appeal panel shall establish its own procedure.

(6) The notifying authority may establish more than one appeal panel to consider one or more appeals.

(7) Where the notifying authority decides to restrict, suspend or revoke a notification pertaining to a notified body, the notified body may, within 14 days beginning on the day of being informed of the decision, appeal the decision to an appeal panel and in determining the appeal, the appeal panel may, if it considers it appropriate to do so, confirm the decision, vary it or allow the appeal and shall notify the appellant of its decision.

(8) Where an appeal is brought under paragraph (7), the appellant may apply for implementation of the decision the subject of the appeal to be suspended pending the outcome of the appeal and the appeal panel may grant this application if it sees fit.

(9) Where a decision is made under paragraph (7), any person aggrieved may, within 14 days beginning on the day on which the decision is made, appeal against the decision to a judge of the District Court in the District Court district in which the notified body ordinarily resides and in determining the appeal the judge may, if he or she considers it appropriate to do so, confirm the decision of the appeal panel, vary it or allow the appeal.

(10) Where an appeal is brought under paragraph (9), the appellant may apply to the District Court for implementation of the decision the subject of the appeal to be suspended pending the outcome of the appeal and the District Court may grant this application if it sees fit.

(11) A decision under paragraph (9) shall be final, save that, on successful application to the High Court, an appeal from the decision shall lie to the High Court on a specified question of law.

(12) An application referred to in paragraph (11) does not affect the decision of the District Court.

(13) All expenses reasonably incurred by the notifying authority in relation to an appeal, whether before an appeal panel, the District Court or the High Court, shall be borne by the appellant where the appeal panel or the court confirms or varies the decision of the notifying authority.

(14) The notifying authority may recover any expenses referred to in paragraph (13) as a simple contract debt in a court of competent jurisdiction.

*Subsidiaries of, and subcontracting by, notified bodies*

22. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary, it shall ensure that such subcontractor or subsidiary complies with Article 26 of the PPE Regulation.

*Operational obligations of notified bodies*

23. (1) Subject to paragraph (2), a notified body shall—

- (a) carry out conformity assessments in accordance with the conformity assessment procedures provided for in Annexes V, VII and VIII to the PPE Regulation,
- (b) ensure that conformity assessments are carried out in a proportionate manner, avoiding unnecessary burdens for economic operators,
- (c) perform its activities taking due account of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of applicable PPE technology and the mass or serial nature of the production process,
- (d) in a case where it finds that the essential health and safety requirements set out in Annex II to the PPE Regulation or corresponding harmonised standards or other technical specifications have not been met by a manufacturer, require the manufacturer to take appropriate corrective measures and refrain from issuing a certificate or approval decision,
- (e) in a case where, in the course of the monitoring of conformity following the issue of a certificate or an approval decision, the notified body finds that PPE no longer complies, require the manufacturer to take appropriate corrective measures and suspend or revoke the certificate or the approval decision if necessary,
- (f) in a case where corrective measures under paragraph (e) are not taken by the manufacturer or do not have the required effect, restrict, suspend or revoke any certificate or approval decision, as appropriate,

- (g) inform the manufacturer referred to in subparagraph (f) of the decision to take the measure referred to in subparagraph (f),
- and
- (h) participate in the sectoral group of notified bodies established in accordance with Article 36 of the PPE Regulation.

(2) In carrying out its functions under subparagraphs (b) and (c) of paragraph (1), a notified body shall nevertheless respect the degree of rigour and the level of protection required for the compliance of the PPE with the PPE Regulation and these Regulations.

*Appeals against decisions of notified bodies*

24. (1) The notifying authority shall establish a panel (in this Regulation “appeal panel”) for the purpose of considering appeals against restrictions, suspensions or revocations rendered by notified bodies under Regulation 23 and the following shall apply:

- (a) subject to subparagraph (b), an appeal panel shall consist of at least 3 but not more than 5 persons appointed by the notifying authority, one of whom shall be designated by the notifying authority to be chairperson of the panel;
- (b) where an appeal is taken against a decision of a notified body to take a measure referred to in subparagraph (f) of Regulation 23(1), an appeal panel shall not consist of any person who decided or was involved in the decision;
- (c) an appeal panel shall establish its own procedure.

(2) The notifying authority may establish more than one appeal panel to consider one or more appeals.

(3) Where a notified body decides to take a measure referred to in subparagraph (f) of Regulation 23(1), the manufacturer affected by the decision may, within 14 days beginning on the day of being informed of the decision, appeal the decision to an appeal panel and in determining the appeal, the appeal panel may, if it considers it appropriate to do so, confirm the decision, vary it or allow the appeal and shall notify the appellant of its decision.

(4) Where an appeal is brought under paragraph (3), the appellant may apply for implementation of the decision the subject of the appeal to be suspended pending the outcome of the appeal and the appeal panel may grant this application if it sees fit.

(5) Where a decision is made under paragraph (3), any person aggrieved may, within 14 days beginning on the day on which the decision is made, appeal against the decision to a judge of the District Court in the District Court district in which the manufacturer ordinarily resides and in determining the appeal the

judge may, if he or she considers it appropriate to do so, confirm the decision of the appeal panel, vary it or allow the appeal.

(6) Where an appeal is brought under paragraph (5), the appellant may apply to the District Court for implementation of the decision the subject of an appeal to be suspended pending the outcome of the appeal and the District Court may grant this application if it sees fit.

(7) A decision under paragraph (5) shall be final, save that, on successful application to the High Court, an appeal from the decision shall lie to the High Court on a specified question of law.

(8) An application referred to in paragraph (7) does not affect the decision of the District Court.

*Information obligation on notified bodies*

25. A notified body shall—

- (a) inform the notifying authority of the matters referred to in Article 34(1) of the PPE Regulation, and
- (b) provide the other bodies notified under the PPE 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.

## PART 5

### MARKET SURVEILLANCE AND SAFEGUARD PROCEDURE

*Market surveillance authority*

26. A market surveillance authority shall organise and carry out market surveillance on PPE and carry out its duties relating to market surveillance in accordance with Articles 15(3) and 16 to 29 of Regulation (EC) No. 765/2008.

*Procedure for dealing with PPE presenting a risk at national level*

27. (1) Where a market surveillance authority has sufficient reason to believe that PPE presents a risk to the health or safety of persons, it shall carry out an evaluation in relation to the PPE covering all relevant requirements laid down in the PPE Regulation and these Regulations.

(2) The economic operator relating to the PPE referred to in paragraph (1) (in this Part “relevant economic operator”) shall co-operate as necessary with the market surveillance authority in carrying out an evaluation under paragraph (1).

(3) Where, in the course of an evaluation referred to in paragraph (1), the market surveillance authority finds that the PPE does not comply with the requirements laid down in the PPE Regulation or these Regulations, it shall—



- (a) 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 the authority prescribes, and
- (b) where applicable, inform the notified body that carried out the conformity assessment procedure on the PPE of the non-conformity of the PPE with the PPE Regulation or these Regulations or both and measures taken under subparagraph (a).

(4) Article 21 of Regulation (EC) No. 765/2008 shall apply to any measure referred to in paragraph 3(a) of this Regulation.

(5) Where the market surveillance authority considers that non-compliance referred to in paragraph (3) is not restricted to the State, it shall inform the European Commission and all other Member States of the results of the evaluation and of the actions which it has required the relevant economic operator to take.

(6) The relevant economic operator shall ensure that all appropriate corrective action is taken in respect of all the PPE that it has placed on the market or made available on the market.

(7) Where the relevant economic operator does not take adequate corrective action within the period referred to in paragraph (3)(a), the market surveillance authority shall, without delay, take all appropriate provisional measures to prohibit or restrict the PPE from being made available on the market of the State, to withdraw the PPE from that market or to recall it.

(8) The market surveillance authority shall inform the European Commission and all other Member States, without delay, of any measures taken under paragraph (7) and shall—

- (a) 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 measures taken by the State and the arguments put forward by the relevant economic operator, and
- (b) in particular, indicate whether the non-compliance is due to either—
  - (i) the failure of the PPE to meet requirements relating to health or safety of persons, or
  - (ii) shortcomings in the harmonised standards referred to in Article 14 of the PPE Regulation conferring a presumption of conformity.

(9) Where another Member State has initiated the procedure under Article 38 of the PPE Regulation, a competent national authority of the State shall, without delay, inform the European Commission and all other Member States—

- (a) of any measures adopted and of any additional information at its disposal relating to the non-compliance of the PPE the subject matter of the procedure, and
- (b) in the event it disagrees with the adopted measure of the first-mentioned Member State, of its objections.

(10) Where, within three months of receipt of the information referred to in paragraph (8) by the European Commission and all other Member States, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a competent national authority of the State under paragraph (7), the measure shall be deemed to be justified.

*Safeguard procedure*

28. (1) Where the European Commission adopts an implementing act in accordance with Article 39 of the PPE Regulation determining that a measure taken by a competent national authority of the State under Article 38 of the PPE Regulation or Regulation 27 of these Regulations is justified, the market surveillance authority shall ensure that the non-compliant PPE is withdrawn from the market of the State and inform the European Commission that the PPE has been so withdrawn.

(2) Where the European Commission adopts an implementing act in accordance with Article 39 of the PPE Regulation determining that a measure taken by a competent national authority of the State under Article 38 of the PPE Regulation or Regulation 27 of these Regulations is unjustified, that competent national authority shall withdraw that measure.

*Compliant PPE which presents a risk*

29. (1) Where, having carried out an evaluation under Regulation 27, a competent national authority of the State finds that, although the PPE is in compliance with the PPE Regulation and these Regulations, it presents a risk to the health or safety of persons, the competent national authority shall—

- (a) require the relevant economic operator to take all appropriate measures to ensure that the PPE, 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 the authority may prescribe, and
- (b) immediately inform the European Commission and all other Member States that, although the PPE is in compliance with the PPE Regulation and these Regulations, it presents a risk to the health or safety of persons and include all available details, in particular—
  - (i) the data necessary for the identification of the PPE,

- (ii) the origin and the supply chain of the PPE,
- (iii) the nature of the risk involved, and
- (iv) the nature and the duration of the national measures taken.

(2) The relevant economic operator shall ensure that the corrective action required under paragraph (1) is taken in respect of all the PPE that the relevant economic operator has made available on the market.

## PART 6

### POWERS OF MARKET SURVEILLANCE AUTHORITY

#### *General*

30. A market surveillance authority may appoint in writing such and so many persons as it thinks fit to be Authorised Officers for the purposes of enforcement of the provisions of the PPE Regulation and these Regulations.

#### *Authorised Officer*

31. (1) An Authorised Officer shall be a person—

- (a) appointed as an Authorised Officer pursuant to section 35 of the Act of 2014, or
- (b) appointed under section 33 or 62 of the Act of 2005.

(2) An Authorised Officer shall, when exercising any power conferred on him or her by the PPE Regulation or these Regulations, if requested to do so by any person affected, produce the warrant of appointment, or a copy of it, furnished to him or her under section 35 of the Act of 2014 or the certificate of authorisation, or a copy of it, furnished to him or her under section 62(2) of the Act of 2005, together with a form of personal identification.

#### *Powers of Authorised Officer*

32. (1) Without prejudice to any power or powers under any other provision of these Regulations, an Authorised Officer shall, for the purposes of enforcement of the provisions of the PPE Regulation and these Regulations, have the power to do one or more of the following:

- (a) subject to paragraphs (3) and (5), at any time enter without warrant—
  - (i) any place of business of an economic operator, or
  - (ii) any other place where entry of the place is necessary to ensure that the objectives of the PPE Regulation and these Regulations are achieved;
- (b) make inquiries in respect of, search, examine or inspect, as appropriate—

- (i) any place, or any part of any place, referred to in subparagraph (a),
  - (ii) any activity, process, procedure, matter or thing at, or carried on at, a place referred to at subparagraph (a),
  - (iii) any PPE or any record relating to such PPE to ascertain whether the PPE Regulation or these Regulations have been or are being complied with and, for that purpose, take with him or her and use any equipment or materials he or she considers necessary;
- (c) require that a place referred to in subparagraph (a) and its contents remain undisturbed for as long as is reasonably necessary for the purposes of any inquiry, search, examination, investigation or inspection under the PPE Regulation or these Regulations;
- (d) require any person in charge of, employed at or other relevant person at, a place referred to in subparagraph (a) to—
- (i) produce to the Authorised Officer any PPE or partly completed PPE in possession or under the control of the person,
  - (ii) produce to the Authorised Officer any books, documents or records, and where such books, documents or records are kept in a non-legible form, reproduce them in a legible form, and
  - (iii) give to the Authorised Officer such information as the Authorised Officer may reasonably require in relation to any entries in the books, documents and records referred to in subparagraph (d)(ii);
- (e) inspect and take copies of or extracts from any books, documents or records or any electronic information system at a place referred to in subparagraph (a), including in the case of information in a non-legible form, copies of or extracts from such information in a permanent legible form, or require that such copies or extracts be provided;
- (f) require a person in charge of, employed at or other relevant person at, a place referred to in subparagraph (a) by whom or on whose behalf a computer is or has been used to produce or store records or require any other person having control of, or otherwise concerned with, the operation of the computer, to afford the Authorised Officer access to the records on that computer and all reasonable assistance as the Authorised Officer may require in respect of accessing such records;
- (g) remove from a place referred to in subparagraph (a) and detain any books, documents or records (including any information stored in a non-legible form) and any copies taken of such books, documents or records for such period as the Authorised Officer reasonably considers necessary for further examination or until the conclusion of any legal proceedings to which they relate;

- (h) require that any books, documents or records at a place referred to in subparagraph (a) be maintained for such period as may be reasonable;
- (i) require the person in charge of, employed at or other relevant person at, a place referred to in subparagraph (a) to give the Authorised Officer such information as the Authorised Officer may reasonably require for the purposes of any inquiry, search, examination, investigation or inspection under the PPE Regulation or these Regulations;
- (j) require the person in charge of, employed at or other relevant person at, a place referred to in subparagraph (a) to give the Authorised Officer such assistance and facilities within the person's power or control as are reasonably necessary to enable the Authorised Officer to exercise any of his or her powers under these Regulations;
- (k) require any person (whether such person is at a place referred to in subparagraph (a) or otherwise) to produce to the Authorised Officer any records that the Authorised Officer may reasonably require that are under power or control of that person;
- (l) examine any person (whether such person is at a place referred to in subparagraph (a) or otherwise) whom the Authorised Officer reasonably believes to be able to give to the Authorised Officer information relevant to any inquiry, search, examination, investigation or inspection under the PPE Regulation or these Regulations and require the person to answer such questions as the Authorised Officer may ask relevant to the inquiry, search, examination, investigation or inspection and to sign a declaration of the truth of the answers;
- (m) require that any procedure be followed for the purposes of any inquiry, search, examination, investigation or inspection under the PPE Regulation or these Regulations;
- (n) take any measurements or photographs or make any tape, electrical or other recordings that the Authorised Officer considers necessary for the purposes of any inquiry, search, examination, investigation or inspection under the PPE Regulation or these Regulations;
- (o) take samples of air, soil, water or waste at or near a place referred to in subparagraph (a);
- (p) where appropriate, install, use and maintain at a place referred to in subparagraph (a) monitoring instruments, systems and seals for the purposes of the PPE Regulation or these Regulations;
- (q) cause any PPE found at any place in respect of which there has been or there appears to the Authorised Officer to have been a contravention of the PPE Regulation or these Regulations to be subjected, at the place it is found or any other location, to any testing, examination or analysis (but not so as to damage or destroy it unless this is necessary for the purposes of the PPE Regulation or these

Regulations) and where an Authorised Officer proposes to exercise the power conferred by this subparagraph and if so requested by the person in charge, cause anything that is to be done by virtue of this subparagraph to be done in the presence of the person in charge save that the person in charge is responsible for his or her own costs in attending at the exercise of any power under this subparagraph and cannot unreasonably delay the Authorised Officer in the exercise of those powers;

- (r) For the purposes of exercising a power under paragraph (q)—
  - (i) require the person in charge to supply to the Authorised Officer without charge any PPE or samples thereof, and
  - (ii) where necessary, remove, or have removed, to another location, any PPE or samples thereof;
- (s) remove and retain for such period as is necessary any PPE found at a place for one or more of the following purposes:
  - (i) to examine or arrange for the examination, testing or analysis of the PPE in accordance with paragraph (q);
  - (ii) to ensure that the PPE is not tampered with before the examination, testing or analysis of it under subparagraph (s)(i) is completed;
  - (iii) to ensure that the PPE is available for use as evidence in any proceedings.

(2) Where PPE is found at a place referred to in paragraph (1)(q), and an inquiry is made by an Authorised Officer in the course of a search, examination, investigation or inspection as to the identity of the person who supplied the PPE, the person in charge shall give the Authorised Officer the name and address of the supplier from whom the PPE was purchased or otherwise obtained.

(3) An Authorised Officer shall not enter a private dwelling other than—

- (a) with the consent of the occupier, or
- (b) in accordance with a warrant of the District Court issued under paragraph (6) authorising such entry.

(4) The market surveillance authority may authorise such and so many other persons as it considers appropriate to accompany an Authorised Officer in the performance of his or her functions.

(5) Where an Authorised Officer is prevented from entering a place referred to in paragraph (1)(a), or in any other case where the Authorised Officer reasonably believes that entry to such a place will be prevented, the Authorised Officer

may apply to a judge of the District Court in whose District Court district the place is situated for a warrant authorising entry of such place.

(6) Where an application is made under paragraph (5), if a judge of the District Court is satisfied by information on oath of an Authorised Officer that there are reasonable grounds for believing that—

- (a) there is at any place any PPE or any books, documents, records or information (including information stored in a non-legible form) relating to a place or to PPE that the Authorised Officer requires to inspect for the purposes of the PPE Regulation or these Regulations, or
- (b) there is, or is likely to be, at a place referred to in subparagraph (a) evidence of a contravention of the PPE Regulation or these Regulations,

the judge may issue a warrant authorising an Authorised Officer, accompanied by such other Authorised Officers or such other competent persons as may be appropriate or members of the Garda Síochána as may be necessary, at any time or times, within one month from the date of issue of the warrant, on production of the warrant if requested, to enter the place specified in the warrant, if necessary by the use of reasonable force, and perform the functions conferred on an Authorised Officer by these Regulations.

(7) Where an Authorised Officer has reasonable grounds for apprehending any serious obstruction in the performance of any of his or her functions or otherwise considers it necessary, he or she may be accompanied by a member or members of the Garda Síochána and by any other person or persons authorised by a market surveillance authority, when performing any functions conferred on him or her by or under the PPE Regulation or these Regulations.

(8) Where an Authorised Officer, upon reasonable grounds, believes that a person has committed an offence under the PPE Regulation or these Regulations he or she may require the person to provide him or her with the person's name and the address at which that person ordinarily resides.

(9) A statement or admission made by a person pursuant to a requirement under paragraph (1)(i) or (l) shall not be admissible in proceedings brought against that person for any offence other than an offence under Regulation 44(4) relating to a breach of, or failure to comply with, any obligation in the said paragraph (1)(i) or (l).

(10) In this Regulation, reference to PPE shall be deemed to include PPE components and constituent materials.

*Direction to end non-compliance*

33. Where an Authorised Officer finds that an economic operator has not complied with the PPE Regulation or these Regulations in one or more of the following ways, he or she may serve a direction on that person to put an end to the non-compliance within a specified period of time:

- (a) the CE marking has been affixed in violation of Article 30 of Regulation (EC) No. 765/2008 or of Article 17 of the PPE Regulation or of Regulation 17 of these Regulations;
- (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 of the PPE Regulation or Regulation 17 of these Regulations or, where required by that Article or Regulation to be affixed, has not been affixed;
- (d) the EU declaration of conformity has not been drawn up;
- (e) the EU declaration of conformity has not been drawn up correctly;
- (f) the technical documentation is either not available or not complete;
- (g) the information referred to in Article 8(6) or 10(3) of the PPE Regulation or Regulation 6(i) or 8(2)(c) of these Regulations is absent, false or incomplete;
- (h) any other administrative requirement provided for in Article 8 or 10 of the PPE Regulation or Regulation 6 or 8 of these Regulations is not fulfilled;
- (i) there is non-compliance with any other requirement under the PPE Regulation or these Regulations.

*Contravention notice*

34. (1) An Authorised Officer who is of the opinion that an economic operator—

- (a) is contravening or has contravened any of the provisions of the PPE Regulation or these Regulations, or
- (b) has failed to comply with a direction under Regulation 33,

may serve a contravention notice on the economic operator.

(2) A contravention notice shall—

- (a) state that the Authorised Officer is of the opinion referred to in paragraph (1),
- (b) specify the grounds for the opinion,
- (c) specify every provision (including the particular paragraph and subparagraph of such provision as appropriate) upon which the opinion is based,



- (d) direct that the person, where required, do one or more of the following:
  - (i) remedy the contravention or the matters occasioning the contravention notice;
  - (ii) refrain from placing on the market the PPE to which the notice relates;
  - (iii) refrain from making available on the market that PPE;
  - (iv) withdraw that PPE from the market;
  - (v) recall that PPE;
  - (vi) dispose of that PPE;
  - (vii) destroy that PPE;

by a date specified in the contravention notice that shall not be earlier than the expiration of the period within which an appeal may be made under Regulation 35,

- (e) inform the person on whom the contravention notice is served that he or she may appeal the notice to the District Court in accordance with Regulation 35,
- (f) state that if the person on whom the contravention notice is served fails to comply with the notice within the time period specified in the notice, that person commits an offence,

and

- (g) be signed and dated by the Authorised Officer.

(3) A contravention notice may include—

- (a) directions as to the measures to be taken to remedy any contravention or matter to which the contravention notice relates, or to otherwise comply with the notice,
- (b) directions to bring the contravention notice to the attention of any person who may be affected by it or to the attention of the public generally,

and

- (c) any other requirement that the Authorised Officer considers appropriate.

(4) Subject to Regulation 35(5), the contravention notice shall take effect on the later of—

- (a) the expiration of the period for making an appeal to the District Court, or
  - (b) the day specified in the contravention notice.
- (5) A person on whom a contravention notice has been served under paragraph (1) shall comply with the notice.
- (6) A person on whom a contravention notice has been served who is of the opinion that the notice has been complied with, shall confirm such compliance in writing to the Authorised Officer.
- (7) Where a person on whom a contravention notice has been served confirms in accordance with paragraph (6), the Authorised Officer, on being satisfied that the person has complied with the notice, shall within one month of receipt of such confirmation, give notice to the person of compliance with the contravention notice.
- (8) An Authorised Officer may—
- (a) withdraw or amend a contravention notice at any time, or
  - (b) where no appeal is made or pending under Regulation 35, extend the period specified under paragraph (2)(d) of this Regulation.

*Appeal against contravention notice*

35. (1) A person on whom a contravention notice is served may, within 14 days beginning on the day on which the notice is served on him or her, appeal against the notice to a judge of the District Court in the District Court district in which the notice was served and in determining the appeal the judge may, if he or she considers it appropriate to do so, confirm, vary or cancel the notice.

(2) A person who appeals under paragraph (1) shall at the same time notify the market surveillance authority of the appeal and the grounds for the appeal and the authority shall be entitled to appear, be heard and adduce evidence at the hearing of the appeal.

(3) Where a decision is made under paragraph (1), any person aggrieved may, within 14 days beginning on the day on which the decision was made, appeal it to the Circuit Court in the circuit in which the contravention notice was served and in determining the appeal, the court may, if it considers it appropriate to do so, confirm the decision of the District Court, vary it or allow the appeal.

(4) A decision under paragraph (3) shall be final, save that, by leave of the High Court, an appeal from the decision shall lie to the High Court on a specified question of law.

(5) Where an appeal is taken and the contravention notice is not withdrawn by the Authorised Officer, the notice shall take effect on the later of—

- (a) the day next following the day on which the contravention notice is confirmed or varied on final appeal,
- (b) the day next following the day on which the appeal is discontinued, or
- (c) the day specified in the contravention notice.

(6) Subject to paragraph (7), in the case of PPE which the Authorised Officer does not consider to present a serious risk requiring rapid intervention under Article 20 of Regulation (EC) No. 765/2008, the intended recipient of a contravention notice that includes a direction referred to in Regulation 34(2)(d)(ii), (iii), (iv) or (v) shall have the opportunity to make representations to a market surveillance authority within 10 working days of first being advised of the Authorised Officer's intention to serve a contravention notice on that person.

(7) Where an opportunity to make representations referred to in paragraph (6) is not possible because of the urgency of the measure directed in the contravention notice as referred to in the said paragraph (6), as justified by health or safety requirements or other grounds relating to public interests, the market surveillance authority shall give the recipient of the notice the opportunity to be heard as soon as possible after the service of the notice on that person and the service of the notice shall be reviewed promptly thereafter.

*Prohibition notice — PPE presenting a serious risk*

36. (1) Where an Authorised Officer is of the opinion that PPE presents, or is likely to present, a serious risk to the health or safety of persons, including a serious risk the effects of which are not immediate, the Authorised Officer may serve a prohibition notice on the economic operator relating to the PPE, regardless of whether or not there is or is likely to be a contravention of the PPE Regulation or these Regulations.

(2) For the avoidance of doubt, where PPE does not have any marking (on its packaging or otherwise) or document required under the PPE Regulation or these Regulations, an Authorised Officer may form an opinion referred to in paragraph (1).

(3) A prohibition notice shall—

- (a) state that the Authorised Officer is of the opinion referred to in paragraph (1),
- (b) specify the grounds for the opinion,
- (c) where in the opinion of the Authorised Officer there is or is likely to be a contravention of any provision of the PPE Regulation or these Regulations, specify every such provision (including the particular paragraph and subparagraph of such provision as appropriate),
- (d) prohibit any activity of the economic operator that results in the PPE referred in paragraph (1) being placed on the market or made available on the market,

- (e) inform the person on whom the prohibition notice is served that he or she may appeal the notice to the District Court in accordance with Regulation 37,
  - (f) state that if the person on whom the prohibition notice is served fails to comply with the notice, that person commits an offence, and
  - (g) be signed and dated by the Authorised Officer.
- (4) A prohibition notice may include—
- (a) directions as to the measures to be taken by the economic operator to stop the activity referred to in paragraph 3(d), to remedy any contravention of the PPE Regulation or these Regulations or any matter to which the prohibition notice relates, or to otherwise comply with the notice, including directions to do one or more of the following regarding the PPE referred to in paragraph (1):
    - (i) refrain from placing on the market the PPE;
    - (ii) refrain from making available on the market the PPE;
    - (iii) withdraw the PPE from the market;
    - (iv) recall the PPE;
    - (v) dispose of the PPE;
    - (vi) destroy the PPE;
  - (b) directions to bring the prohibition notice to the attention of any person who may be affected by it, or to the attention of the public generally,  
  
and
  - (c) any other requirement that the Authorised Officer considers appropriate.
- (5) Subject to Regulation 37(9), a prohibition notice shall take effect immediately at the time the notice is received by the person on whom it is served.
- (6) A person on whom a prohibition notice has been served under paragraph (1) shall comply with the notice.
- (7) A person on whom a prohibition notice has been served who is of the opinion that the notice has been complied with, shall confirm such compliance in writing to the Authorised Officer.
- (8) Where a person on whom a prohibition notice has been served confirms in accordance with paragraph (7), the Authorised Officer, on being satisfied that the person has complied with the notice, shall within one month of receipt of

such confirmation give notice to the person of compliance with the prohibition notice.

- (9) An Authorised Officer may at any time withdraw a prohibition notice if—
- (a) the Authorised Officer is satisfied that the PPE to which the prohibition notice relates no longer gives rise to a serious risk to health or safety of persons, or
  - (b) the Authorised Officer is satisfied that the prohibition notice was issued in error or is incorrect in some material respect.

*Appeal against prohibition notice*

37. (1) A person on whom a prohibition notice is served may, within 7 days beginning on the day on which the notice is served on him or her, appeal against the notice to a judge of the District Court in the District Court district in which the notice was served and in determining the appeal the judge may, if he or she considers it appropriate to do so, confirm, vary or cancel the notice.

(2) A person who appeals under paragraph (1) shall at the same time notify the market surveillance authority of the appeal and the grounds for the appeal and the authority shall be entitled to appear, be heard and adduce evidence at the hearing of the appeal.

(3) Where a decision is made under paragraph (1), any person aggrieved by that decision may, within 7 days beginning on the day on which the decision was made, appeal it to the Circuit Court in the circuit in which the prohibition notice was served and in determining the appeal, the court may, if it considers it appropriate to do so, confirm the decision of the District Court, vary it or allow the appeal.

(4) A decision under paragraph (3) shall be final, save that, by leave of the High Court, an appeal from the decision shall lie to the High Court on a specified question of law.

(5) Subject to paragraph (6), the bringing of an appeal against a prohibition notice shall not have the effect of suspending the operation of the notice.

(6) Where a person brings an appeal under this Regulation, the appellant may apply to the court determining the appeal (being the District Court, Circuit Court or High Court) to have the operation of the prohibition notice suspended until the determination or discontinuation of the appeal before that court and, on such application, the court may, if it thinks proper to do so, grant the application.

(7) Where, on the hearing of an appeal under this Regulation, a prohibition notice is not cancelled, notwithstanding paragraph (6), the judge by whom the appeal is heard may, on the application of the appellant, suspend the operation of the notice for such period as in the circumstances of the case the judge considers appropriate.

(8) A person who applies for the suspension of the operation of a prohibition notice shall at the same time notify the market surveillance authority of the application and the grounds for the application.

(9) Where an appeal is brought under this Regulation and the court (being the District Court, Circuit Court or High Court) has granted a suspension on the operation of the prohibition notice, the prohibition notice shall take effect on the later of—

- (a) the day next following the day on which the notice is confirmed or varied on final appeal,
- (b) the day next following the day on which the appeal is discontinued, or
- (c) the day next following the expiration of the period of final suspension.

*Order of High Court to direct compliance of prohibition notice*

38. (1) Where a person fails to comply with a prohibition notice an Authorised Officer may apply ex parte to the High Court for an order directing immediate compliance with the notice.

(2) The High Court may, upon an application under this Regulation, if satisfied that the person on whom the prohibition notice is served has failed to comply with the notice, grant an order referred to in paragraph (1).

*Seizure notice — seizure and disposal of PPE presenting a serious risk*

39. (1) Where an Authorised Officer is of the opinion that PPE presents a serious risk, the Authorised Officer or any person directed by the Authorised Officer, may seize and destroy or dispose of the PPE in such manner and such time and place as the Authorised Officer may direct.

(2) The Authorised Officer may require the economic operator relating to the PPE referred to in paragraph (1), where known, to reimburse the cost or any portion of the cost of any measure taken under that paragraph.

(3) An Authorised Officer who has seized, or intends to seize, PPE under paragraph (1) shall serve a seizure notice on the economic operator relating to the PPE, which seizure notice shall—

- (a) state that the PPE has been or is intended to be seized and that it is intended to destroy or dispose of the PPE,
- (b) specify the grounds for the seizure and intended destruction or disposal of the PPE,
- (c) where in the opinion of the Authorised Officer there is or is likely to be a contravention of any provision of the PPE Regulation or these Regulations, specify every such provision (including the particular paragraph and subparagraph of such provision as appropriate),

(d) inform the person on whom the seizure notice is served that he or she may appeal the notice to the District Court in accordance with this Regulation,

and

(e) be signed and dated by the Authorised Officer.

(4) A person on whom a seizure notice is served may, within 21 days beginning on the day on which the seizure notice is served on him or her, appeal against the notice to the appropriate court (as defined in paragraph (17)) and in determining the appeal, the court may, if it considers it appropriate to do so, confirm, vary or cancel the notice or make any other order as it considers appropriate.

(5) An appeal under paragraph (4) shall state the grounds on which the appeal is made and shall be made by written notice, which notice shall be lodged with the office of the appropriate court.

(6) A person who appeals under paragraph (4) shall at the same time furnish a copy of the notice referred to in paragraph (5) to the appropriate market surveillance authority and the authority shall be entitled to appear, be heard and adduce evidence at the hearing of the appeal.

(7) If, during the hearing of an appeal under paragraph (4) to the District Court, that court forms the opinion that the value of the PPE the subject of the appeal exceeds that court's jurisdiction in tort, it may, if it so thinks fit, transfer the appeal to the Circuit Court or the High Court, whichever it considers appropriate having regard to its opinion of the value of the PPE.

(8) If, during the hearing of an appeal under paragraph (4) to the Circuit Court, that court forms the opinion that the value of the PPE, the subject of the appeal, exceeds that court's jurisdiction in tort, it may, if it so thinks fit, transfer the appeal to the High Court.

(9) Paragraphs (7) and (8) are without prejudice to the jurisdiction of a court (being either the District Court or the Circuit Court) to determine an appeal under paragraph (4) in relation to which it was, at the time of the hearing of the appeal, the appropriate court.

(10) Where a decision is made under paragraph (4), any person aggrieved may, within 21 days beginning on the day on which the decision was made, appeal the decision to the following court:

(a) where the decision under paragraph (4) was made by the District Court, the Circuit Court;

(b) where the decision under paragraph (4) was made by the Circuit Court, the High Court;

(c) where the decision under paragraph (4) was made by the High Court, the Court of Appeal.

(11) On hearing an appeal under paragraph (10), the court may, if it considers it appropriate to do so, confirm the decision of the appropriate court, vary it or allow the appeal.

(12) A decision under paragraph (11) of the Circuit Court shall be final, save that, by leave of the High Court, an appeal from the decision shall lie to the High Court on a specified question of law.

(13) A decision under paragraph (11) of the High Court shall be final, save that, by leave of the Court of Appeal, an appeal from the decision shall lie to the Court of Appeal on a specified question of law.

(14) An appeal under paragraph (4) to the District Court shall be determined by a judge of the District Court for the District Court district in which the PPE the subject of the appeal was placed on the market or the appellant ordinarily resides.

(15) An appeal under this Regulation (whether under paragraph (4) or (10)) to the Circuit Court shall be determined by a judge of the Circuit Court for the circuit in which the PPE the subject of the appeal was placed on the market or the appellant ordinarily resides.

(16) Where an appeal is made under paragraph (4), the PPE the subject of the appeal shall not be destroyed or disposed of until at least the day following the determination or discontinuation of the final appeal.

(17) In this Regulation “appropriate court” means—

(a) in any case where the estimated value of the PPE the subject of the appeal does not exceed €15,000, or such other amount as may stand specified for the time being by law as that Court’s jurisdiction in tort, the District Court,

(b) in any case where the estimated value of the PPE referred to in subparagraph (a) exceeds the jurisdiction of the District Court in tort but does not exceed €75,000, or such other amount as may stand specified for the time being by law as that Court’s jurisdiction in tort, the Circuit Court,

and

(c) in any case not coming within subparagraph (a) and (b), the High Court.

(18) In this Regulation “dispose” includes any manner of disposal which in the opinion of the Authorised Officer will least endanger the public and includes surrender of the PPE to a member of the Garda Síochána or to any other competent agency or organisation for its destruction, or the certified return of



the PPE to the economic operator relating to the PPE, in order to remove it from the market, at the expense of the economic operator, manager, or person having lawful possession of the PPE at the time of seizure, where known.

*Forfeiture order*

40. (1) A market surveillance authority may apply for an order for the forfeiture to the market surveillance authority of any PPE on the grounds that the PPE does not comply with the PPE Regulation or these Regulations or, when properly maintained and used for its intended purpose or otherwise used under conditions which can be reasonably foreseen, is liable to be a risk to the health or safety of persons.

(2) An application under paragraph (1) shall be made to the appropriate court.

(3) Upon hearing an application under paragraph (1), the appropriate court may, if it considers it appropriate to do so, grant a forfeiture order.

(4) The appropriate court may order that the person against whom a forfeiture order is sought pay the costs of seizure and destruction or disposal of the PPE the subject of the order.

(5) A forfeiture order granted under paragraph (3) may contain such provision as appears to the court to be appropriate for delaying the coming into force of the order pending the making and determination of any appeal.

(6) If, during the hearing of an application under paragraph (1) to the District Court, that court forms the opinion that the value of the PPE the subject of the appeal exceeds that court's jurisdiction in tort, it may, if it so thinks fit, transfer the appeal to the Circuit Court or the High Court, whichever it considers appropriate having regard to its opinion of the value of the PPE.

(7) If, during the hearing of an application under paragraph (1) to the Circuit Court, that court forms the opinion that the value of the PPE, the subject of the appeal, exceeds that court's jurisdiction in tort, it may, if it so thinks fit, transfer the appeal to the High Court.

(8) Paragraphs (6) and (7) are without prejudice to the jurisdiction of a court (being either the District Court or the Circuit Court) to determine an application under paragraph (1) in relation to which it was, at the time of the hearing of the application, the appropriate court.

(9) Where a decision is made under paragraph (3), any person aggrieved may, within 21 days beginning on the day the decision was made, appeal the decision to the following court:

- (a) where the decision under paragraph (3) was made by the District Court, the Circuit Court;
- (b) where the decision under paragraph (3) was made by the Circuit Court, the High Court;

(c) where the decision under paragraph (3) was made by the High Court, the Court of Appeal.

(10) On hearing an appeal under paragraph (9), the court may, if it considers it appropriate to do so, confirm the decision of the appropriate court, vary it or allow the appeal.

(11) A decision under paragraph (10) of the Circuit Court shall be final, save that, by leave of the High Court, an appeal from the decision shall lie to the High Court on a specified question of law.

(12) A decision under paragraph (10) of the High Court shall be final, save that, by leave of the Court of Appeal, an appeal from the decision shall lie to the Court of Appeal on a specified question of law.

(13) An application under paragraph (1) to the District Court shall be determined by a judge of the District Court for the District Court district in which the PPE the subject of the order sought was placed on the market or the person against whom the order is sought ordinarily resides.

(14) An application under paragraph (1) to the Circuit Court and any appeal under paragraph (9) to the Circuit Court shall be determined in the circuit in which the PPE the subject of the application under paragraph (1) was placed on the market or the person against whom the order was sought in an application under paragraph (1) ordinarily resides.

(15) Where a forfeiture order is granted and there is no stay on the coming into force of the order, the PPE the subject of the forfeiture order may be seized on behalf of the market surveillance authority by an Authorised Officer and destroyed, disposed of or released as the Authorised Officer considers appropriate.

(16) In this Regulation—

(a) “appropriate court” has the meaning assigned to it under Regulation 39(17); and

(b) “dispose” has the meaning assigned to it under Regulation 39(18).

*Information notice*

41. (1) A market surveillance authority, or an Authorised Officer, may serve an information notice on a person which may require the person to give to the authority or the Authorised Officer, within such period and in such form as may be specified in the notice, any information specified in the notice that the authority or the Authorised Officer may reasonably require for the proper performance of his or her functions under the PPE Regulation or these Regulations.

(2) An information notice shall—

- (a) inform the person on whom the information notice is served that he or she may appeal the notice to the District Court in accordance with this Regulation,
- (b) state that if the person on whom the information notice is served fails to comply with the notice, that person commits an offence, and
- (c) be signed and dated by the Authorised Officer.

(3) The period specified in the information notice referred to in paragraph (1) may be extended at the discretion of the market surveillance authority or Authorised Officer on the written application of the person on whom the notice is served or at the volition of the authority or Authorised Officer issuing the notice.

(4) A person on whom an information notice is served may, within 7 days beginning on the day on which the notice is served on him or her, appeal against the notice to a judge of the District Court in the District Court district in which the notice was served and in determining the appeal the judge may, if he or she considers it appropriate to do so, confirm, vary or cancel the notice.

(5) A person who appeals under paragraph (4) shall at the same time notify the market surveillance authority of the appeal and the grounds for the appeal and the authority shall be entitled to appear, be heard and adduce evidence at the hearing of the appeal.

(6) Where a decision is made under paragraph (4), any person aggrieved by that decision may, within 7 days beginning on the day on which the decision was made, appeal it to the Circuit Court in the circuit in which the information notice was served and in determining the appeal, the court may, if it considers it appropriate to do so, confirm the decision of the District Court, vary it or allow the appeal.

(7) A decision under paragraph (6) shall be final, save that, by leave of the High Court, an appeal from the decision shall lie to the High Court on a specified question of law.

(8) Where, upon the hearing of an appeal under this Regulation (whether under paragraph (4), (6) or (7)), an information notice is not cancelled by the court, the judge by whom the appeal is heard may, on the application of the appellant, suspend the operation of the information notice for such period as in the circumstances of the case the judge considers appropriate.

(9) Subject to paragraph (10), a person on whom an information notice is served shall comply with the notice before the later of—

- (a) the expiration of the period to comply specified in the information notice, or
- (b) where the period referred to in subparagraph (a) is extended under paragraph (3), the expiration of that extended period.

(10) Where an appeal is brought under this Regulation, the person on whom the information notice is served shall comply with the notice before—

(a) the day next following the day on which the information notice is confirmed or varied on final appeal,

(b) the day next following the day on which the appeal is discontinued,

(c) the expiration of the period to comply specified in the information notice,

or

(d) where the operation of the information notice has been suspended, the expiration of the period of final suspension,

whichever occurs latest.

#### *Publication of information*

42. (1) A market surveillance authority may, in the interest of the protection of health or safety and in consultation, where appropriate, with another market surveillance authority of the State or another State, take such measures as it considers appropriate to bring to the attention of the public matters giving rise to any direction served under Regulation 33, contravention notice served under Regulation 34, prohibition notice served under Regulation 36, seizure notice served under Regulation 39 or forfeiture order granted under Regulation 40.

(2) The market surveillance authority may, in the interest of the protection of health or safety, take such measures as it considers appropriate to bring to the attention of the public any other matter of concern arising from the requirements of the PPE Regulation or these Regulations.

#### *Sharing information on application of PPE Regulation*

43. (1) The notifying authority shall comply with Article 31(2) of the PPE Regulation.

(2) A market surveillance authority may provide information to any European Union information network, the European Commission or a market surveillance authority of another Member State for the purpose of sharing information related to the application of the PPE Regulation and shall also raise any concern it may have of the type referred to in Article 42(2) of the PPE Regulation in accordance with that Article.

## PART 7

## OFFENCES AND PENALTIES

*Offences*

44. (1) A person who contravenes a provision or requirement of—

- (a) Articles 8, 9, 10, 11, 13, 15, 17 of the PPE Regulation, or
- (b) Regulations 5(1), 5(2) 6, 7, 8, 9, 11, 17(5), 27(2), 27(6), 29(2) of these Regulations,

commits an offence.

(2) A person who fails to comply with any requirement of a notice served on him or her under Regulation 34, 36 or 41 or any term of a forfeiture order granted under Regulation 40 that is required to be complied by him or her commits an offence.

(3) A person who, in relation to CE marking, other marking or any document required for the purposes of the PPE Regulation or these Regulations does one or more of the following commits an offence:

- (a) forges or counterfeits any such document;
- (b) gives or signs a document knowing it to be false in any material particular or makes a marking knowing it to be false in any material particular;
- (c) knowingly uses a marking or document that is forged or counterfeited, or that is false in any material particular;
- (d) knowingly uses as applying to any person or PPE a marking or document which does not so apply;
- (e) knowingly connives at any such forging, counterfeiting, giving, signing, or using referred to in subparagraphs (a) to (d);
- (f) knowingly makes a false entry in any such document that is so required to be kept, served or sent;
- (g) knowingly uses any false entry referred to in subparagraph (f);
- (h) knowingly and without lawful authority has in his or her possession one or more of the following:
  - (i) a forged marking;
  - (ii) a forged document;
  - (iii) an altered marking;

(iv) an altered document.

(4) Any person who obstructs or interferes with an Authorised Officer or a member of the Garda Síochána in the course of exercising a power conferred on him or her by these Regulations or by a warrant under Regulation 32(6) or who impedes or prevents the exercise by the Authorised Officer or member, as the case may be, of such power, or fails or refuses to comply with a request or requirement of, or to answer a question asked by, an Authorised Officer or such a member pursuant to a power conferred by these Regulations, or in purported compliance with such request or requirement or answer to such question asked, gives information to the Authorised Officer or member that he or she knows to be false or misleading in any material respect, commits an offence.

(5) A person who falsely represents himself or herself to be an Authorised Officer commits an offence.

(6) A person who, at any time during the period of 3 months immediately following the affixing of a notice in accordance with Regulation 48(1)(e) removes, alters, damages or defaces the notice without lawful authority commits an offence.

(7) A person who states to a market surveillance authority that another person has committed an offence under this Regulation or has failed to comply with a provision of these Regulations, knowing the statement to be false, commits an offence.

(8) A person who, in purported compliance with a requirement in an information notice, furnishes information to a market surveillance authority that he or she knows to be false or misleading in a material respect, commits an offence.

(9) A person who prevents or attempts to prevent any person from answering any question to which an Authorised Officer may require an answer under Regulation 32, commits an offence.

(10) A person who fails to comply with a bona fide request, instruction or direction from an Authorised Officer in the exercise of his or her functions under these Regulations, commits an offence.

(11) Where an offence under a provision of these Regulations is committed by reason of a failure to do something at or within a time fixed by or under that provision, the offence shall be deemed to continue until that thing is done.

#### *Penalties*

45. (1) A person guilty of an offence under Regulation 44 shall be liable—

(a) on summary conviction, to a class A fine or imprisonment for a term not exceeding 6 months or both, or

(b) on conviction on indictment, to a fine not exceeding €500,000 or imprisonment for a term not exceeding 2 years or both.

(2) Where a person is convicted of an offence under these Regulations in proceedings brought by a market surveillance authority, or instituted following an investigation by or on behalf of the authority, the court shall, unless it is satisfied that there are special and substantial reasons for not so doing, order the person to pay to the authority the costs and expenses, measured by the court, incurred by the authority in relation to the investigation, detection and prosecution of the offence, including the costs and expenses incurred in the taking of samples, the carrying out of tests, examinations and analyses and in respect of the remuneration and other expenses of employees, consultants and advisers engaged by the authority.

*Offences by bodies corporate*

46. Where an offence under these Regulations has been committed by a body corporate and is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, a person being a director, manager, secretary or other officer of the body corporate, or a person who was purporting to act in any such capacity, that person as well as the body corporate commits an offence and shall be liable to be proceeded against and punished as if he or she had committed the first-mentioned offence.

*Prosecution of offences*

47. (1) Subject to paragraph (2), summary proceedings in relation to an offence under these Regulations may be brought and prosecuted by a market surveillance authority.

(2) Notwithstanding section 10(4) of the Petty Sessions (Ireland) Act 1851 and section 5(4) of the European Communities (Amendment) Act 1993, summary proceedings for an offence under Regulation 44 may be instituted at any time within 3 years from the date on which the offence was committed or alleged to have been committed.

## PART 8

### MISCELLANEOUS

*Service of notices, directions etc*

48. (1) Subject to paragraphs (2) and (3), a direction, notice or other measure under Regulation 33, 34, 36, 39 or 41 shall be in writing, addressed to the person being served by name and may be served on the person by doing any of the following:

- (a) delivering it to the person;
- (b) leaving it at the address at which the person carries on business or ordinarily resides or, in the case in which an address for service has been furnished, at that address;
- (c) sending it by post in a prepaid registered letter to the address at which the person carries on business or ordinarily resides or, in a case in which an address for service has been furnished, to that address;

- (d) where there is a facility for receiving the text of the notice by electronic means at the address at which the person carries on business or ordinarily resides, transmitting the text of the notice by such means to such address, provided that the notice is also delivered in any of the other ways referred to in this paragraph; or
- (e) if the address at which the person ordinarily resides cannot be ascertained by reasonable enquiry and the notice being served relates to a premises, by delivering it to the premises or by affixing it in a conspicuous position on or near the premises.

(2) Where a direction, notice or other measure under Regulation 33, 34, 36, 39, or 41 is to be served on a person who is the owner or occupier of land or property and the name of the person cannot be ascertained by reasonable inquiry, it may be addressed to the person by using the words “the owner” or, as the case may require, “the occupier”.

(3) For the purposes of these Regulations, a company within the meaning of the Companies Acts 2014 shall be deemed to be ordinarily resident at its registered office, and every other body corporate and every unincorporated body shall be deemed to be ordinarily resident at its principal office or place of business.

#### *Immunity*

49. None of the following persons, that is to say, a market surveillance authority, an Authorised Officer or a member of staff of a market surveillance authority shall be liable in damages in respect of any act done or omitted to be done by it or him or her in the performance, or purported performance, of that person’s functions under these Regulations, unless the act or omission concerned was done in bad faith.

#### *Indemnification*

50. A market surveillance authority shall, subject to the provisions of any enactment or rule of law, indemnify an Authorised Officer appointed by it, or a member of staff of a market surveillance authority, in respect of any act done or omitted to be done by him or her in the performance, or purported performance, of his or her functions under these Regulations as such Authorised Officer or member of staff, unless the act or omission concerned was done in bad faith.

#### *Restriction on disclosure of information*

51. (1) A person in receipt of information as a result of the application of these Regulations shall treat the information as confidential.

(2) Without prejudice to the generality of the foregoing, business, professional and trade secrets shall be treated as confidential unless the disclosure of such information is for one or more of the following reasons:

- (a) for the purpose of the discharge of functions under these Regulations;
- (b) required to be provided by law;



- (c) made with the consent of the person to whom the information applies;
- (d) for the purposes of—
  - (i) any legal proceedings (including by means of a report to a coroner holding an inquest under the Coroners Acts 1962 and 2005 on the body of a person whose death may have been caused through personal injury), or
  - (ii) any investigation or special report under section 70 of the Act of 2005;
- (e) necessary in order to protect the health or safety of persons;
- (f) required by a provision or provisions of the PPE Regulation or these Regulations;
- (g) ordered by a court of law.

*Transitional provisions*

52. (1) Without prejudice to paragraph (2), any product covered by the Directive that conforms with that Directive and is placed on the market at any time before the 21 April 2019 may continue to be made available on the market.

(2) Any EC type-examination certificate or approval decision issued under the Directive shall remain valid until 21 April 2023 unless it expires before that date.

*Revocation*

53. The European Communities (Personal Protective Equipment) Regulations 1993 (S.I. No. 272 of 1993), European Communities (Personal Protective Equipment) (Amendment) Regulations 1994 (S.I. No. 13 of 1994), the European Communities (Personal Protective Equipment) (CE Marking) Regulations 1994 (S.I. No. 457 of 1994) and the European Communities (Personal Protective Equipment) (Amendment) Regulations 1997 (S.I. No. 81 of 1997) cited together as the European Communities (Personal Protective Equipment) Regulations 1993 to 1997, are revoked.

## **SCHEDULE 1**

### **Text of Annex I to the PPE Regulation**

#### **RISK CATEGORIES OF PPE**

This Annex lays down the categories of risk against which PPE is intended to protect users.

##### **Category I**

Category I includes exclusively the following minimal risks:

- (a) superficial mechanical injury;
- (b) contact with cleaning materials of weak action or prolonged contact with water;
- (c) contact with hot surfaces not exceeding 50 °C;
- (d) damage to the eyes due to exposure to sunlight (other than during observation of the sun);
- (e) atmospheric conditions that are not of an extreme nature.

##### **Category II**

Category II includes risks other than those listed in Categories I and III;

##### **Category III**

Category III includes exclusively the risks that may cause very serious consequences such as death or irreversible damage to health relating to the following:

- (a) substances and mixtures which are hazardous to health;
- (b) atmospheres with oxygen deficiency;
- (c) harmful biological agents;
- (d) ionising radiation;
- (e) high-temperature environments the effects of which are comparable to those of an air temperature of at least 100 °C;
- (f) low-temperature environments the effects of which are comparable to those of an air temperature of –50 °C or less;
- (g) falling from a height;

- (h) electric shock and live working;
- (i) drowning;
- (j) cuts by hand-held chainsaws;
- (k) high-pressure jets;
- (l) bullet wounds or knife stabs;
- (m) harmful noise.

**SCHEDULE 2****Text of Annex II to the PPE Regulation****ESSENTIAL HEALTH AND SAFETY REQUIREMENTS****PRELIMINARY REMARKS**

1. The essential health and safety requirements laid down in this Regulation are compulsory.
2. Obligations related to essential health and safety requirements apply only where the corresponding risk exists for the PPE in question.
3. The essential health and safety requirements are to be interpreted and applied in such a way as to take into account the state of the art and current practice at the time of design and manufacture, as well as technical and economic considerations which are consistent with a high degree of health and safety protection.
4. The manufacturer shall carry out a risk assessment in order to identify the risks which apply to his PPE. He shall then design and manufacture it taking into account that assessment.
5. When designing and manufacturing the PPE, and when drafting the instructions, the manufacturer shall envisage not only the intended use of the PPE, but also the reasonably foreseeable uses. Where applicable, the health and safety of persons other than the user shall be ensured.

1. **GENERAL REQUIREMENTS APPLICABLE TO ALL PPE**

PPE must provide adequate protection against the risks against which it is intended to protect.

- 1.1. Design principles

- 1.1.1. Ergonomics

PPE must be designed and manufactured so that, in the foreseeable conditions of use for which it is intended, the user can perform the risk-related activity normally whilst enjoying appropriate protection of the highest level possible.

- 1.1.2. Levels and classes of protection

- 1.1.2.1. Optimum level of protection

The optimum level of protection to be taken into account in the design is that beyond which the constraints imposed by the wearing of the PPE

would prevent its effective use during the period of exposure to the risk or the normal performance of the activity.

#### 1.1.2.2. Classes of protection appropriate to different levels of risk

Where differing foreseeable conditions of use are such that several levels of the same risk can be distinguished, appropriate classes of protection must be taken into account in the design of the PPE.

### 1.2. Innocuousness of PPE

#### 1.2.1. Absence of inherent risks and other nuisance factors

PPE must be designed and manufactured so as not to create risks or other nuisance factors under foreseeable conditions of use.

##### 1.2.1.1. Suitable constituent materials

The materials of which the PPE is made, including any of their possible decomposition products, must not adversely affect the health or safety of users.

##### 1.2.1.2. Satisfactory surface condition of all PPE parts in contact with the user

Any part of the PPE that is in contact or is liable to come into contact with the user when the PPE is worn must be free of rough surfaces, sharp edges, sharp points and the like which could cause excessive irritation or injuries.

##### 1.2.1.3. Maximum permissible user impediment

Any impediment caused by PPE to the actions to be carried out, the postures to be adopted and sensory perceptions shall be minimised. Furthermore, use of the PPE must not engender actions which might endanger the user.

### 1.3. Comfort and effectiveness

#### 1.3.1. Adaptation of PPE to user morphology

PPE must be designed and manufactured in such a way as to facilitate its correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, the actions to be carried out and the postures to be adopted. For this purpose, it must be possible to adapt the PPE to fit the morphology of the user by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate range of sizes.

#### 1.3.2. Lightness and strength

PPE must be as light as possible without prejudicing its strength and effectiveness.

PPE must satisfy the specific additional requirements in order to provide adequate protection against the risks for which it is intended and PPE must be capable of withstanding environmental factors in the foreseeable conditions of use.

1.3.3. Compatibility of different types of PPE intended for simultaneous use

If the same manufacturer places on the market several PPE models of different types in order to ensure the simultaneous protection of adjacent parts of the body, they must be compatible.

1.3.4. Protective clothing containing removable protectors

Protective clothing containing removable protectors constitutes PPE and shall be assessed as a combination during conformity assessment procedures.

1.4. Manufacturer's instructions and information

In addition to the name and address of the manufacturer, the instructions that must be supplied with the PPE must contain all relevant information on:

- (a) instructions for storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on the PPE or the user when applied in accordance with the relevant instructions;
- (b) performance as recorded during relevant technical tests to check the levels or classes of protection provided by the PPE;
- (c) where applicable, accessories that may be used with the PPE and the characteristics of appropriate spare parts;
- (d) where applicable, the classes of protection appropriate to different levels of risk and the corresponding limits of use;
- (e) where applicable, the month and year or period of obsolescence of the PPE or of certain of its components;
- (f) where applicable, the type of packaging suitable for transport;
- (g) the significance of any markings (see point 2.12);
- (h) the risk against which the PPE is designed to protect;
- (i) the reference to this Regulation and, where applicable, the references to other European Union harmonisation legislation;
- (j) the name, address and identification number of the notified body or bodies involved in the conformity assessment of the PPE;

(k) references to the relevant harmonised standard(s) used, including the date of the standard(s), or references to the other technical specifications used;

(l) the internet address where the EU declaration of conformity can be accessed.

The information referred to in points (i), (j), (k) and (l) need not be contained in the instructions supplied by the manufacturer if the EU declaration of conformity accompanies the PPE.

## 2. ADDITIONAL REQUIREMENTS COMMON TO SEVERAL TYPES OF PPE

### 2.1. PPE incorporating adjustment systems

If PPE incorporates adjustment systems, the latter must be designed and manufactured so that, after adjustment, they do not become undone unintentionally in the foreseeable conditions of use.

### 2.2. PPE enclosing the parts of the body to be protected

PPE must be designed and manufactured in a way that perspiration resulting from use is minimised. Otherwise it must be equipped with means of absorbing perspiration.

### 2.3. PPE for the face, eyes and respiratory system

Any restriction of the user's face, eyes, field of vision or respiratory system by the PPE shall be minimised.

The screens for those types of PPE must have a degree of optical neutrality that is compatible with the degree of precision and the duration of the activities of the user.

If necessary, such PPE must be treated or provided with means to prevent misting-up.

Models of PPE intended for users requiring sight correction must be compatible with the wearing of spectacles or contact lenses.

### 2.4. PPE subject to ageing

If it is known that the design performance of new PPE may be significantly affected by ageing, the month and year of manufacture and/or, if possible, the month and year of obsolescence must be indelibly and unambiguously marked on each item of PPE placed on the market and on its packaging.

If the manufacturer is unable to give an undertaking with regard to the useful life of the PPE, his instructions must provide all the information necessary to enable the purchaser or user to establish a reasonable

obsolescence month and year, taking into account the quality level of the model and the effective conditions of storage, use, cleaning, servicing and maintenance.

Where appreciable and rapid deterioration in PPE performance is likely to be caused by ageing resulting from the periodic use of a cleaning process recommended by the manufacturer, the latter must, if possible, affix a marking to each item of PPE placed on the market indicating the maximum number of cleaning operations that may be carried out before the equipment needs to be inspected or discarded. Where such a marking is not affixed, the manufacturer must give that information in his instructions.

2.5. PPE which may be caught up during use

Where the foreseeable conditions of use include, in particular, the risk of the PPE being caught up by a moving object thereby creating a danger for the user, the PPE must be designed and manufactured in such a way that a constituent part will break or tear, thereby eliminating the danger.

2.6. PPE for use in potentially explosive atmospheres

PPE intended for use in potentially explosive atmospheres must be designed and manufactured in such a way that it cannot be the source of an electric, electrostatic or impact-induced arc or spark likely to cause an explosive mixture to ignite.

2.7. PPE intended for rapid intervention or to be put on or removed rapidly

Those types of PPE must be designed and manufactured in such a way as to minimise the time required for putting on and removing the equipment.

Where PPE comprises fixing systems enabling the PPE to be maintained in the correct position on the user or removed, it must be possible to operate such systems quickly and easily.

2.8. PPE for intervention in very dangerous situations

The instructions supplied by the manufacturer with PPE for intervention in very dangerous situations must include, in particular, data intended for competent, trained persons who are qualified to interpret them and ensure their application by the user.

The instructions must also describe the procedure to be adopted in order to verify that PPE is correctly adjusted and functional when worn by the user.

Where PPE incorporates an alarm which is activated in the absence of the level of protection normally provided, the alarm must be designed



and placed so that it can be perceived by the user in the foreseeable conditions of use.

- 2.9. PPE incorporating components which can be adjusted or removed by the user

Where PPE incorporates components which can be attached, adjusted or removed by the user for replacement purposes, such components must be designed and manufactured so that they can be easily attached, adjusted and removed without tools.

- 2.10. PPE for connection to complementary equipment external to the PPE

Where PPE incorporates a connexion system permitting its connection to other complementary equipment, the means of attachment must be designed and manufactured in such a way as to enable it to be mounted only on appropriate equipment.

- 2.11. PPE incorporating a fluid circulation system

Where PPE incorporates a fluid circulation system, the latter must be chosen or designed and placed in such a way as to permit adequate fluid renewal in the vicinity of the entire part of the body to be protected, irrespective of the actions, postures or movements of the user under the foreseeable conditions of use.

- 2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety

Where PPE bears one or more identification markings or indicators directly or indirectly relating to health and safety, those identification markings or indicators must, if possible, take the form of harmonised pictograms or ideograms. They must be perfectly visible and legible and remain so throughout the foreseeable useful life of the PPE. In addition, those markings must be complete, precise and comprehensible so as to prevent any misinterpretation. In particular, where such markings include words or sentences, the latter must be written in a language easily understood by consumers and other end-users, as determined by the Member State where the PPE is made available on the market.

Where PPE is too small to allow all or part of the necessary marking to be affixed, the relevant information must be mentioned on the packaging and in the manufacturer's instructions.

- 2.13. PPE capable of signalling the user's presence visually

PPE intended for foreseeable conditions of use in which the user's presence must be visibly and individually signalled must have one (or more) judiciously positioned means or devices for emitting direct or reflected visible radiation of appropriate luminous intensity and photometric and colorimetric properties.

## 2.14. Multi-risk PPE

PPE intended to protect the user against several potentially simultaneous risks must be designed and manufactured in such a way as to satisfy, in particular, the essential health and safety requirements specific to each of those risks.

## 3. ADDITIONAL REQUIREMENTS SPECIFIC TO PARTICULAR RISKS

## 3.1. Protection against mechanical impact

## 3.1.1. Impact caused by falling or ejected objects and collisions of parts of the body with an obstacle

PPE intended to protect against this type of risk must be sufficiently shock-absorbent to prevent injury resulting, in particular, from the crushing or penetration of the protected part, at least up to an impact-energy level above which the excessive dimensions or mass of the means of shock-absorption would preclude effective use of the PPE for the foreseeable period of wear.

## 3.1.2. Falls

## 3.1.2.1. Prevention of falls due to slipping

The outsoles of protective footwear intended to prevent slipping must be designed and manufactured or equipped with additional means so as to ensure adequate grip, having regard to the nature or state of the surface.

## 3.1.2.2. Prevention of falls from a height

PPE intended to prevent falls from a height or their effects must incorporate a body harness and a connexion system which can be connected to a reliable external anchorage point. It must be designed and manufactured so that, under the foreseeable conditions of use, the vertical drop of the user is minimised to prevent collision with obstacles while the braking force does not attain the threshold value at which physical injury or the opening or breakage of any PPE component which might cause the user to fall can be expected to occur.

Such PPE must also ensure that, after braking, the user is maintained in a correct position in which he may await help if necessary.

The manufacturer's instructions must specify, in particular, all relevant information relating to:

- (a) the characteristics required for the reliable external anchorage point and the necessary minimum clearance below the user;

- (b) the proper way of putting on the body harness and of attaching the connexion system to the reliable external anchorage point.

### 3.1.3. Mechanical vibration

PPE designed to prevent the effects of mechanical vibrations must be capable of ensuring adequate attenuation of harmful vibration components for the part of the body at risk.

### 3.2. Protection against static compression of a part of the body

PPE designed to protect a part of the body against static compressive stress must be sufficiently capable of attenuating its effects so as to prevent serious injury or chronic complaints.

### 3.3. Protection against mechanical injuries

PPE constituent materials and other components designed to protect all or a part of the body against superficial injuries, such as abrasion, perforation, cuts or bites, must be chosen or designed and incorporated so as to ensure that those types of PPE provide sufficient resistance to abrasion, perforation and gashing (see also point 3.1) under the foreseeable conditions of use.

### 3.4. Protection in liquids

#### 3.4.1. Prevention of drowning

PPE designed to prevent drowning must be capable of returning to the surface as quickly as possible, without danger to health, a user who may be exhausted or unconscious after falling into a liquid medium, and of keeping the user afloat in a position which permits breathing while awaiting help.

PPE may be wholly or partially inherently buoyant or may be inflated by gas which can be manually or automatically released, or inflated orally.

Under the foreseeable conditions of use:

- (a) PPE must, without prejudice to its satisfactory operation, be capable of withstanding the effects of impact with the liquid medium and the environmental factors inherent in that medium;
- (b) inflatable PPE must be capable of inflating rapidly and fully.

Where particular foreseeable conditions of use so require, certain types of PPE must also satisfy one or more of the following additional requirements:

- (a) they must have all the inflation devices referred to in the second subparagraph, and/or a light or sound- signalling device;

- (b) they must have a device for hitching and attaching the body so that the user may be lifted out of the liquid medium;
- (c) they must be suitable for prolonged use throughout the period of activity exposing the user, possibly dressed, to the risk of falling into the liquid medium or requiring the user's immersion in it.

#### 3.4.2. Buoyancy aids

Clothing intended to ensure an effective degree of buoyancy, depending on its foreseeable use, shall be safe when worn and afford positive support in the liquid medium. In foreseeable conditions of use, this PPE must not restrict the user's freedom of movement but must enable the user, in particular, to swim or take action to escape from danger or to rescue other persons.

#### 3.5. Protection against the harmful effects of noise

PPE intended to prevent the harmful effects of noise must be capable of attenuating the latter so that the exposure of the user does not exceed the limit values laid down by Directive 2003/10/EC of the European Parliament and of the Council<sup>5</sup>

Each item of PPE must bear labelling indicating the noise attenuation level provided by the PPE. Should that not be possible, the labelling must be fixed to the packaging.

#### 3.6. Protection against heat and/or fire

PPE designed to protect all or a part of the body against the effects of heat and/or fire must possess thermal insulation capacity and mechanical strength appropriate to the foreseeable conditions of use.

##### 3.6.1. PPE constituent materials and other components

Constituent materials and other components intended for protection against radiant and convective heat must possess an appropriate coefficient of transmission of incident heat flux and be sufficiently incombustible to preclude any risk of spontaneous ignition under the foreseeable conditions of use.

Where the external surface of those materials and components must be reflective, the reflective power must be appropriate to the intensity of the heat flux due to radiation in the infrared range.

Materials and other components of equipment intended for brief use in high-temperature environments and of PPE which may be splashed by hot products such as molten material must also possess sufficient thermal capacity to retain most of the stored heat until after the user has left the danger area and removed the PPE.

<sup>5</sup>OJ L 42, 15.2.2003, p. 38.

PPE materials and other components which may be splashed by hot products must also possess sufficient mechanical-impact absorbency (see point 3.1).

PPE materials and other components which may accidentally come into contact with flame and those used in the manufacture of industrial or fire-fighting equipment must also possess a degree of non-flammability and thermal or arc heat protection corresponding to the risk class associated with the foreseeable conditions of use. They must not melt when exposed to flames nor contribute to flame propagation.

### 3.6.2. Complete PPE ready for use

Under the foreseeable conditions of use:

- (a) the quantity of heat transmitted by PPE to the user must be sufficiently low to prevent the heat accumulated during wear in the part of the body at risk from attaining, under any circumstances, the pain or health impairment threshold;
- (b) PPE must, if necessary, prevent liquid or steam penetration and must not cause burns resulting from contact between its protective integument and the user.

If PPE incorporates refrigeration devices for the absorption of incident heat by means of liquid evaporation or solid sublimation, the design of such devices must be such that any volatile substances released are discharged beyond the outer protective integument and not towards the user.

If PPE incorporates a breathing device, that device must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.

The manufacturer's instructions accompanying PPE intended for brief use in high-temperature environments must, in particular, provide all relevant data for the determination of the maximum permissible user exposure to the heat transmitted by the equipment when used in accordance with its intended purpose.

### 3.7. Protection against cold

PPE designed to protect all or a part of the body against the effects of cold must possess thermal insulating capacity and mechanical strength appropriate to the foreseeable conditions of use for which it is intended.

#### 3.7.1. PPE constituent materials and other components

Constituent materials and other components suitable for protection against cold must possess a coefficient of transmission of incident thermal flux as low as required under the foreseeable conditions of use.

Flexible materials and other components of PPE intended for use in a low-temperature environment must retain the degree of flexibility required for the necessary gestures and postures.

PPE materials and other components which may be splashed by cold products must also possess sufficient mechanical-impact absorbency (see point 3.1).

### 3.7.2. Complete PPE ready for use

Under the foreseeable conditions of use, the following requirements apply:

- (a) the flux transmitted by PPE to the user must be sufficiently low to prevent the cold accumulated during wear at any point on the part of the body being protected, including the tips of fingers and toes in the case of hands or feet, from attaining, under any circumstances, the pain or health impairment threshold;
- (b) PPE must as far as possible prevent the penetration of such liquids as rain water and must not cause injuries resulting from contact between its cold protective integument and the user.

If PPE incorporates a breathing device, that device must adequately fulfil the protective function assigned to it under the foreseeable conditions of use.

The manufacturer's instructions accompanying PPE intended for brief use in low-temperature environments must provide all relevant data concerning the maximum permissible user exposure to the cold transmitted by the equipment.

## 3.8. Protection against electric shock

### 3.8.1. Insulating equipment

PPE designed to protect all or part of the body against the effects of electric current must be sufficiently insulated against the voltages to which the user is likely to be exposed under the most unfavourable foreseeable conditions.

To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure that the leakage current measured through the protective integument under test conditions at voltages correlated with those likely to be encountered in situ is minimised and, in any event, below a maximum conventional permissible value which correlates with the tolerance threshold.

Together with their packaging, PPE types intended exclusively for use during work or activities in electrical installations which are or may be

under tension must bear markings indicating, in particular, their protection class or corresponding operating voltage, their serial number and their date of manufacture. A space must also be provided outside the protective integument of such PPE for the subsequent inscription of the date of entry into service and those of the periodic tests or inspections to be conducted.

The manufacturer's instructions must indicate, in particular, the exclusive use for which those PPE types are intended and the nature and frequency of the dielectric tests to which they are to be subjected during their useful life.

### 3.8.2. Conductive equipment

Conductive PPE intended for live working at high voltages shall be designed and manufactured in such a way as to ensure that there is no difference of potential between the user and the installations on which he is intervening.

## 3.9. Radiation protection

### 3.9.1. Non-ionising radiation

PPE designed to prevent acute or chronic eye damage from sources of non-ionising radiation must be capable of absorbing or reflecting the majority of the energy radiated in the harmful wavelengths without unduly affecting the transmission of the innocuous part of the visible spectrum, the perception of contrasts and the ability to distinguish colours where required by the foreseeable conditions of use.

To that end, eye protective equipment must be designed and manufactured so as to possess, for each harmful wavelength, a spectral transmission factor such that the radiant-energy illumination density capable of reaching the user's eye through the filter is minimised and under no circumstances exceeds the maximum permissible exposure value. PPE designed to protect the skin against non-ionising radiation must be capable of absorbing or reflecting the majority of the energy radiated in the harmful wavelengths.

Furthermore, the glasses must not deteriorate or lose their properties as a result of the effects of radiation emitted under the foreseeable conditions of use and all marketed specimens must bear the protection-factor number corresponding to the spectral distribution curve of their transmission factor.

Glasses suitable for radiation sources of the same type must be classified in the ascending order of their protection factors and the manufacturer's instructions must indicate, in particular, how to select the appropriate PPE taking into account the relevant conditions of use such as the distance from the source and the spectral distribution of the energy radiated at that distance.

The relevant protection factor number must be marked on all specimens of filtering eye protective equipment by the manufacturer.

### 3.9.2. Ionising radiation

#### 3.9.2.1. Protection against external radioactive contamination

PPE constituent materials and other components designed to protect all or a part of the body against radioactive dust, gases, liquids or mixtures thereof must be chosen or designed and incorporated so as to ensure that this equipment effectively prevents the penetration of the contaminants under the foreseeable conditions of use.

Depending on the nature or condition of these contaminants, the necessary leak-tightness can be provided by the impermeability of the protective integument and/or by any other appropriate means, such as ventilation and pressurisation systems designed to prevent the back-scattering of these contaminants.

Any decontamination measures to which PPE is subject must not prejudice its possible reuse during the foreseeable useful life of those types of equipment.

#### 3.9.2.2. Protection against external irradiation

PPE intended to provide complete user protection against external irradiation or, failing this, adequate attenuation thereof, must be designed to counter only weak electron (e.g. beta) or weak photon (e.g. X, gamma) radiation.

The constituent materials and other components of these types of PPE must be chosen or designed and incorporated so as to provide the degree of user protection required by the foreseeable conditions of use without leading to an increase in exposure time as a result of the impedance of user gestures, posture or movement (see point 1.3.2).

PPE must bear a mark indicating the type and equivalent thickness of the constituent material(s) suitable for the foreseeable conditions of use.

### 3.10. Protection against substances and mixtures which are hazardous to health and against harmful biological agents

#### 3.10.1. Respiratory protection

PPE intended for the protection of the respiratory system must make it possible to supply the user with breathable air when exposed to a polluted atmosphere and/or an atmosphere having an inadequate oxygen concentration.



The breathable air supplied to the user by PPE must be obtained by appropriate means, for example after filtration of the polluted air through PPE or by supply from an external unpolluted source.

The constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure appropriate user respiration and respiratory hygiene for the period of wear concerned under the foreseeable conditions of use.

The leak-tightness of the facepiece and the pressure drop on inspiration and, in the case of the filtering devices, purification capacity must keep contaminant penetration from a polluted atmosphere low enough not to be prejudicial to the health or hygiene of the user.

The PPE must bear details of the specific characteristics of the equipment which, in conjunction with the instructions, enable a trained and qualified user to employ the PPE correctly.

In the case of filtering equipment, the manufacturer's instructions must also indicate the time limit for the storage of new filters kept in their original packaging.

### 3.10.2. Protection against cutaneous and ocular contact

PPE intended to prevent the surface contact of all or part of the body with substances and mixtures which are hazardous to health or with harmful biological agents must be capable of preventing the penetration or permeation of such substances and mixtures and agents through the protective integument under the foreseeable conditions of use for which the PPE is intended.

To this end, the constituent materials and other components of those types of PPE must be chosen or designed and incorporated so as to ensure, as far as possible, complete leak-tightness, which will allow where necessary prolonged daily use or, failing this, limited leak-tightness necessitating a restriction of the period of wear.

Where, by virtue of their nature and the foreseeable conditions of their use, certain substances and mixtures which are hazardous to health or harmful biological agents possess high penetrative power which limits the duration of the protection provided by the PPE in question, the latter must be subjected to standard tests with a view to their classification on the basis of their performance. PPE which is considered to be in conformity with the test specifications must bear a marking indicating, in particular, the names or, in the absence of the names, the codes of the substances used in the tests and the corresponding standard period of protection. The manufacturer's instructions must also contain, in particular, an explanation of the codes (if necessary), a detailed description of the standard tests and all appropriate information for the determination of the maximum permissible period of wear under the different foreseeable conditions of use.

### 3.11. Diving equipment

The breathing equipment must make it possible to supply the user with a breathable gaseous mixture, under foreseeable conditions of use and taking account in particular of the maximum depth of immersion.

Where the foreseeable conditions of use so require, the diving equipment must comprise the following:

- (a) a suit which protects the user against cold (see point 3.7) and/or pressure resulting from the depth of immersion (see point 3.2);
- (b) an alarm designed to give the user prompt warning of an approaching failure in the supply of breathable gaseous mixture (see point 2.8);
- (c) a lifesaving device enabling the user to return to the surface (see point 3.4.1).

**SCHEDULE 3****Text of Annex III to the PPE Regulation****TECHNICAL DOCUMENTATION FOR PPE**

The technical documentation shall specify the means used by the manufacturer to ensure the conformity of the PPE with the applicable essential health and safety requirements referred to in Article 5 and set out in Annex II. The technical documentation shall include at least the following elements:

- (a) a complete description of the PPE and of its intended use;
- (b) an assessment of the risks against which the PPE is intended to protect;
- (c) a list of the essential health and safety requirements that are applicable to the PPE;
- (d) design and manufacturing drawings and schemes of the PPE and of its components, sub-assemblies and circuits;
- (e) the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (d) and of the operation of the PPE;
- (f) the references of the harmonised standards referred to in Article 14 that have been applied for the design and manufacture of the PPE. In the event of partial application of harmonised standards, the documentation shall specify the parts which have been applied;
- (g) where harmonised standards have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements;
- (h) the results of the design calculations, inspections and examinations carried out to verify the conformity of the PPE with the applicable essential health and safety requirements;
- (i) reports on the tests carried out to verify the conformity of the PPE with the applicable essential health and safety requirements and, where appropriate, to establish the relevant protection class;
- (j) a description of the means used by the manufacturer during the production of the PPE to ensure the conformity of the PPE produced with the design specifications;
- (k) a copy of the manufacturer's instructions and information set out in point 1.4 of Annex II;

- (l) for PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model;
- (m) for PPE produced in series where each item is adapted to fit an individual user, a description of the measures to be taken by the manufacturer during the fitting and production process to ensure that each item of PPE complies with the approved type and with the applicable essential health and safety requirements.

**SCHEDULE 4****Text of Annex IV to the PPE Regulation****INTERNAL PRODUCTION CONTROL**

(Module A)

1. Internal production control is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3 and 4, and ensures and declares on his sole responsibility that the PPE concerned satisfies the applicable requirements of this Regulation.
2. Technical documentation

The manufacturer shall establish the technical documentation described in Annex III.
3. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured PPE with the technical documentation referred to in point 2 and with the applicable requirements of this Regulation.
4. CE marking and EU declaration of conformity
  - 4.1. The manufacturer shall affix the CE marking to each individual PPE that satisfies the applicable requirements of this Regulation.
  - 4.2. The manufacturer shall draw up a written EU declaration of conformity for a PPE model and keep it, together with the technical documentation, at the disposal of the national authorities for 10 years after the PPE has been placed on the market. The EU declaration of conformity shall identify the PPE for which it has been drawn up. A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.
5. Authorised representative

The manufacturer's obligations set out in point 4 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

**SCHEDULE 5****Text of Annex V to the PPE Regulation****EU TYPE-EXAMINATION**

(Module B)

1. EU type-examination is the part of a conformity assessment procedure in which a notified body examines the technical design of PPE and verifies and attests that the technical design of the PPE meets the requirements of this Regulation that apply to it.
2. EU type-examination shall be carried out by assessment of the adequacy of the technical design of the PPE through examination of the technical documentation, plus examination of a specimen, representative of the production envisaged, of the complete PPE (production type).
3. Application for EU type-examination

The manufacturer shall lodge an application for EU type-examination with a single notified body of his choice.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
  - (b) a written declaration that the same application has not been lodged with any other notified body;
  - (c) the technical documentation described in Annex III;
  - (d) the specimen(s) of the PPE representative of the production envisaged. The notified body may request further specimens if needed for carrying out the test programme. For PPE produced in series where each item is adapted to fit an individual user, specimens shall be provided that are representative of the range of different users, and for PPE produced as a single unit to accommodate the special needs of an individual user, a basic model shall be provided.
4. EU type-examination
- The notified body shall:
- (a) examine the technical documentation to assess the adequacy of the technical design of the PPE. In conducting such an examination, point (j) of Annex III need not be taken into account;

- (b) for PPE produced in series where each item is adapted to fit an individual user, examine the description of the measures to assess their adequacy;
- (c) for PPE produced as a single unit to fit an individual user, examine the instructions for manufacturing such PPE on the basis of the approved basic model to assess their adequacy;
- (d) verify that the specimen(s) have been manufactured in conformity with the technical documentation, and identify the elements which have been designed in accordance with the applicable provisions of the relevant harmonised standards as well as the elements which have been designed in accordance with other technical specifications;
- (e) carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant harmonised standards, these have been applied correctly;
- (f) carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant harmonised standards have not been applied, the solutions adopted by the manufacturer, including those in other technical specifications applied, meet the corresponding essential health and safety requirements and have been applied correctly.

## 5. Evaluation report

The notified body shall draw up an evaluation report that records the activities undertaken in accordance with point 4 and their outcomes. Without prejudice to its obligations vis-à-vis the notifying authorities, the notified body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

## 6. EU type-examination certificate

- 6.1. Where the type meets the applicable essential health and safety requirements, the notified body shall issue an EU type-examination certificate to the manufacturer. The period of validity of a newly issued certificate and, where appropriate, of a renewed certificate shall not exceed five years.
- 6.2. The EU type-examination certificate shall contain at least the following information:
  - (a) the name and identification number of the notified body;
  - (b) the name and address of the manufacturer and, if the application is lodged by the authorised representative, the latter's name and address;
  - (c) identification of the PPE covered by the certificate (type number);

- (d) a statement that the PPE type complies with the applicable essential health and safety requirements;
  - (e) where harmonised standards have been fully or partially applied, the references of those standards or parts thereof;
  - (f) where other technical specifications have been applied, their references;
  - (g) where applicable, the performance level(s) or protection class of the PPE;
  - (h) for PPE produced as a single unit to fit an individual user, the range of permissible variations of relevant parameters based on the approved basic model;
  - (i) the date of issue, the date of expiry and, where appropriate, the date(s) of renewal;
  - (j) any conditions attached to the issue of the certificate;
  - (k) for category III PPE, a statement that the certificate shall only be used in conjunction with one of the conformity assessment procedures referred to in point (c) of Article 19.
- 6.3. The EU type-examination certificate may have one or more annexes attached.
- 6.4. Where the type does not satisfy the applicable essential health and safety requirements, the notified body shall refuse to issue an EU type-examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.
7. Review of the EU type-examination certificate
- 7.1. The notified body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable essential health and safety requirements, and shall determine whether such changes require further investigation. If so, the notified body shall inform the manufacturer accordingly.
- 7.2. The manufacturer shall inform the notified body that holds the technical documentation relating to the EU type-examination certificate of all modifications to the approved type and of all modifications of the technical documentation that may affect the conformity of the PPE with the applicable essential health and safety requirements or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original EU type-examination certificate.



- 7.3. The manufacturer shall ensure that the PPE continues to fulfil the applicable essential health and safety requirements in light of the state of the art.
- 7.4. The manufacturer shall ask the notified body to review the EU type-examination certificate either:
- (a) in the case of a modification to the approved type referred to in point 7.2;
  - (b) in the case of a change in the state of the art referred to in point 7.3;
  - (c) at the latest, before the date of expiry of the certificate.

In order to allow the notified body to fulfil its tasks, the manufacturer shall submit his application at the earliest 12 months and at the latest 6 months prior to the expiry date of the EU type-examination certificate.

- 7.5. The notified body shall examine the PPE type and, where necessary in the light of the changes made, carry out the relevant tests to ensure that the approved type continues to fulfil the applicable essential health and safety requirements. If the notified body is satisfied that the approved type continues to fulfil the applicable health and safety requirements, it shall renew the EU type-examination certificate. The notified body shall ensure that the review procedure is finalised before the expiry date of the EU type-examination certificate.
- 7.6. Where the conditions referred to in points (a) and (b) of point 7.4 are not met, a simplified review procedure shall apply. The manufacturer shall supply the notified body with the following:
- (a) his name and address and data identifying the EU type-examination certificate concerned;
  - (b) confirmation that there has been no modification to the approved type as referred to in point 7.2, including materials, sub-components or sub-assemblies, nor to the relevant harmonised standards or other technical specifications applied;
  - (c) confirmation that there has been no change in the state of the art as referred to in point 7.3;
  - (d) where not already supplied, copies of current product drawings and photographs, product marking and information supplied by the manufacturer; and
  - (e) for category III products, where not already available to the notified body, information on the results of the supervised product checks at random intervals carried out in accordance with Annex VII, or on the results of audits of his quality system carried out in accordance with Annex VIII.

Where the notified body has confirmed that no modification to the approved type referred to in point 7.2 and no change in the state of the art referred to in point 7.3 has occurred, the simplified review procedure shall be applied and the examinations and tests referred to in point 7.5 shall not be carried out. In such cases, the notified body shall renew the EU type-examination certificate.

The costs associated with that renewal shall be proportionate to the administrative burden of the simplified procedure.

If the notified body finds that a change in the state of the art referred to in point 7.3 has occurred, the procedure set out in point 7.5 shall apply.

- 7.7. If, following the review, the notified body concludes that the EU type-examination certificate is no longer valid, the body shall withdraw it and the manufacturer shall cease the placing on the market of the PPE concerned.
8. Each notified body shall inform its notifying authority concerning the EU type-examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

Each notified body shall inform the other notified bodies concerning the EU type-examination certificates and/or any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and, upon request, concerning such certificates and/or additions thereto which it has issued.

The Commission, the Member States and the other notified bodies may, on request, obtain a copy of the EU type-examination certificates and/or additions thereto. On a reasoned request, the Commission and the Member States may obtain a copy of the technical documentation and the results of the examinations carried out by the notified body.

The notified body shall keep a copy of the EU type-examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer, for a period of five years after the expiry of the validity of that certificate.

9. The manufacturer shall keep a copy of the EU type-examination certificate, its annexes and additions, together with the technical documentation at the disposal of the national authorities, for 10 years after the PPE has been placed on the market.
10. The manufacturer's authorised representative may lodge the application referred to in point 3 and fulfil the obligations set out in points 7.2, 7.4 and 9, provided that they are specified in the mandate.

**SCHEDULE 6****Text of Annex VI to the PPE Regulation****CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL**

(Module C)

1. Conformity to type based on internal production control is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2 and 3, and ensures and declares under his sole responsibility that the PPE concerned is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured PPE with the type described in the EU type-examination certificate and with the applicable requirements of this Regulation.

3. CE marking and EU declaration of conformity

- 3.1. The manufacturer shall affix the CE marking to each individual PPE that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.

- 3.2. The manufacturer shall draw up a written EU declaration of conformity for a PPE model and keep it at the disposal of the national authorities for 10 years after the PPE has been placed on the market. The EU declaration of conformity shall identify the PPE for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

4. Authorised representative

The manufacturer's obligations set out in point 3 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

**SCHEDULE 7****Text of Annex VII to the PPE Regulation****CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECKS AT RANDOM INTERVALS**

(Module C2)

1. Conformity to type based on internal production control plus supervised product checks at random intervals is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 3, 5.2 and 6, and ensures and declares on his sole responsibility that the PPE, which has been subject to the provisions of point 4, is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.

2. Manufacturing

The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type-examination certificate and with the applicable requirements of this Regulation.

3. Application for supervised product checks at random intervals

Before placing PPE on the market, the manufacturer shall lodge an application for supervised product checks at random intervals with a single notified body of his choice.

The application shall include the following:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address;
- (b) a written declaration that the same application has not been lodged with any other notified body;
- (c) the identification of the PPE concerned.

Where the chosen body is not the body that has carried out the EU type-examination, the application shall also include the following:

- (a) the technical documentation described in Annex III;
- (b) a copy of the EU type-examination certificate.

4. Product checks

- 4.1. The notified body shall carry out product checks in order to verify the homogeneity of production and the conformity of the PPE with the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.
- 4.2. The product checks shall be carried out at least once a year, at random intervals determined by the notified body. The first product checks shall be carried out no more than one year after the date of issue of the EU type-examination certificate.
- 4.3. An adequate statistical sample of the manufactured PPE shall be selected by the notified body at a place agreed between the body and the manufacturer. All items of PPE of the sample shall be examined, and appropriate tests set out in the relevant harmonised standard(s) and/or equivalent tests set out in other relevant technical specifications shall be carried out in order to verify the conformity of the PPE with the type described in the EU type-examination certificate and with the applicable essential health and safety requirements.
- 4.4. Where the notified body referred to in point 3 is not the body that issued the relevant EU type-examination certificate, it shall contact that body in the event of difficulties in connection with the assessment of the conformity of the sample.
- 4.5. The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process ensures the homogeneity of production and performs within acceptable limits, with a view to ensuring conformity of the PPE.
- 4.6. If the examination and testing reveal that the production is not homogeneous, or that the PPE does not comply with the type described in the EU type-examination certificate or with the applicable essential health and safety requirements, the notified body shall take measures appropriate to the fault(s) recorded and inform the notifying authority thereof.
5. Test report
  - 5.1. The notified body shall provide the manufacturer with a test report.
  - 5.2. The manufacturer shall keep the test report at the disposal of the national authorities for 10 years after the PPE has been placed on the market.
  - 5.3. The manufacturer shall, under the responsibility of the notified body, affix the notified body's identification number during the manufacturing process.
6. CE marking and EU declaration of conformity
  - 6.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3, the latter's identification number to each individual item of PPE that is in conformity with the

type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.

- 6.2. The manufacturer shall draw up a written EU declaration of conformity for each PPE model and keep it at the disposal of the national authorities for 10 years after the PPE has been placed on the market. The EU declaration of conformity shall identify the PPE model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

7. Authorised representative

The manufacturer's obligations may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate. An authorised representative may not fulfil the manufacturer's obligations set out in point 2.

**SCHEDULE 8****Text of Annex VIII to the PPE Regulation****CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS**

(Module D)

1. Conformity to type based on quality assurance of the production process is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in points 2, 5 and 6, and ensures and declares on his sole responsibility that the PPE concerned is in conformity with the type described in the EU type- examination certificate and satisfies the applicable requirements of this Regulation.

2. Manufacturing

The manufacturer shall operate an approved quality system for production, final product inspection and testing of the PPE concerned as specified in point 3, and shall be subject to surveillance as specified in point 4.

3. Quality system

3.1. The manufacturer shall lodge an application for assessment of his quality system with a single notified body of his choice.

The application shall include:

- (a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;
- (b) the address of the manufacturer's premises where the audits can be carried out;
- (c) a written declaration that the same application has not been lodged with any other notified body;
- (d) the identification of the PPE concerned;
- (e) the documentation concerning the quality system.

Where the chosen body is not the body that has carried out the EU type-examination, the application shall also include the following:

- (a) the technical documentation of the PPE described in Annex III;
- (b) a copy of the EU type-examination certificate.

- 3.2. The quality system shall ensure that the PPE is in conformity with the type described in the EU type-examination certificate and complies with the applicable requirements of this Regulation.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. The quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

The quality system documentation shall, in particular, contain an adequate description of:

- (a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;
  - (b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;
  - (c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;
  - (d) the quality records, such as inspection reports and test data, calibration data and qualification reports on the personnel concerned; and
  - (e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.
- 3.3. The notified body shall assess the quality system to determine whether it satisfies the requirements referred to in point 3.2.

It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant harmonised standard.

In addition to experience in quality management systems, the auditing team shall have at least one member with experience of evaluation in the field of PPE and technology concerned, and knowledge of the applicable essential health and safety requirements. The audit shall include an assessment visit to the manufacturer's premises. The auditing team shall review the technical documentation of the PPE referred to in point 3.1 to verify the manufacturer's ability to identify the applicable essential health and safety requirements and to carry out the necessary examinations with a view to ensuring conformity of the PPE with those requirements. The result of that assessment shall be notified to the manufacturer. The notification shall contain the conclusions of the audit and the reasoned assessment decision.



- 3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.
  - 3.5. The manufacturer shall keep the notified body that has approved the quality system informed of any intended change to the quality system. The notified body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary. It shall notify the manufacturer of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.
  - 3.6. The notified body shall authorise the manufacturer to affix the notified body's identification number to each individual item of PPE that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.
4. Surveillance under the responsibility of the notified body
    - 4.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.
    - 4.2. The manufacturer shall, for assessment purposes, allow the notified body access to the manufacture, inspection, testing and storage sites and shall provide it with all necessary information, in particular:
      - (a) the quality system documentation;
      - (b) the quality records, such as inspection reports and test data, calibration data and qualification reports on the personnel concerned.
    - 4.3. The notified body shall carry out periodic audits, at least once a year, to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.
    - 4.4. In addition, the notified body may pay unexpected visits to the manufacturer. During such visits the notified body may, if necessary, carry out examinations or tests of the PPE, or have them carried out, in order to verify that the quality system is functioning correctly. The notified body shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.
5. CE marking and EU declaration of conformity
    - 5.1. The manufacturer shall affix the CE marking and, under the responsibility of the notified body referred to in point 3.1, the latter's identification number to each individual item of PPE that is in conformity with the type described in the EU type-examination certificate and satisfies the applicable requirements of this Regulation.

- 5.2. The manufacturer shall draw up a written EU declaration of conformity for each PPE model and keep it at the disposal of the national authorities for 10 years after the PPE has been placed on the market. The EU declaration of conformity shall identify the PPE model for which it has been drawn up.

A copy of the EU declaration of conformity shall be made available to the relevant authorities upon request.

6. The manufacturer shall, for 10 years after the PPE has been placed on the market, keep at the disposal of the national authorities:
  - (a) the documentation referred to in point 3.1;
  - (b) the information related to the change referred to in point 3.5, as approved;
  - (c) the decisions and reports of the notified body referred to in points 3.5, 4.3 and 4.4.
7. The notified body shall inform its notifying authority of quality system approvals issued or withdrawn, and shall, periodically or upon request, make available to its notifying authority the list of such quality system approvals refused, suspended or otherwise restricted.

The notified body shall inform the other notified bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of such quality system approvals which it has issued.

8. Authorised representative

The manufacturer's obligations set out in points 3.1, 3.5, 5 and 6 may be fulfilled by his authorised representative, on his behalf and under his responsibility, provided that they are specified in the mandate.

**SCHEDULE 9****Text of Annex IX to the PPE Regulation****EU DECLARATION OF CONFORMITY No....<sup>6</sup>**

1. PPE (product, type, batch or serial number):
2. Name and address of the manufacturer and, where applicable, his authorised representative:
3. This declaration of conformity is issued under the sole responsibility of the manufacturer:
4. Object of the declaration (identification of PPE allowing traceability; where necessary for the identification of the PPE, a colour image of sufficient clarity may be included):
5. The object of the declaration described in point 4 is in conformity with the relevant Union harmonisation legislation: ...
6. References to the relevant harmonised standards used, including the date of the standard, or references to the other technical specifications, including the date of the specification, in relation to which conformity is declared:
7. Where applicable, the notified body ... (name, number) ... performed the EU type-examination (Module B) and issued the EU type-examination certificate ... (reference to that certificate).
8. Where applicable, the PPE is subject to the conformity assessment procedure ... (either conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) or conformity to type based on quality assurance of the production process (Module D)) ... under surveillance of the notified body ... (name, number).
9. Additional information:

Signed for and on behalf of: ...

(place and date of issue):

(name, function) (signature):

<sup>6</sup>It is optional for the manufacturer to assign a number to the declaration of conformity

**SCHEDULE 10****Text of Annex X to the PPE Regulation****CORRELATION TABLE**

<b>Directive 89/686/EEC</b>	<b>This Regulation</b>
Article 1(1)	Articles 1 and 2(1)
Article 1(2) and (3)	Article 3 point (1)
Article 1(4)	Article 2(2)
Article 2(1)	Article 4
Article 2(2)	Article 6
Article 2(3)	Article 7(2)
Article 3	Article 5
Article 4(1)	Article 7(1)
Article 4(2)	—
Article 5(1), (4), (5)	—
Article 5(2)	Article 14
Article 6	Article 44
Article 7	Articles 37-41
Article 8(1)	Article 8(2) first subparagraph
Article 8(2)-(4)	Articles 18 and 19 and Annex I
Article 9	Articles 20, 24(1), 25, and 30(1)
Article 10	Annex V
Article 11(A)	Annex VII
Article 11(B)	Annex VIII
Article 12(1)	Article 15
Articles 12(2) and 13	Articles 16 and 17
Article 14	—
Article 15	—
Article 16(1) first subparagraph and (2)	—
Article 16(1) second subparagraph	Article 48(2)
Annex I	Article 2(2)

<b>Directive 89/686/EEC</b>	<b>This Regulation</b>
Annex II	Annex II
Annex III	Annex III
Annex IV	Article 16
Annex V	Article 24(2)-(11)
Annex VI	Annex IX



Given under my Official Seal  
19 April 2018.

HEATHER HUMPHREYS,  
Minister for Business, Enterprise and Innovation.

## EXPLANATORY NOTE

*(This note is not part of the Instrument and does not purport to be a legal interpretation.)*

The Regulations transpose into national legislation the provisions of 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. These Regulations also set out the obligations on economic operators in relation to these products and the required conformity assessment procedures for PPE. These Regulations also give further effect to 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 and include duties to have proper market surveillance procedures consistent with EU Regulation 765/2008.

The Regulations provide that the making available on the market of PPE in conformity with Directive 89/686/EEC continues to be lawful up to 21 April 2019.

The Regulations revoke and replace the European Communities (Personal Protective Equipment) Regulations, 1993 (S.I. No. 272 of 1993), the European Communities (Personal Protective Equipment) (Amendment) Regulations, 1994. (S.I. No. 13 of 1994), the European Communities (Personal Protective Equipment) (CE Marking) Regulations, 1994 (S.I. No. 457 of 1994) and the European Communities (Personal Protective Equipment) (Amendment) Regulations, 1997 (S.I. No. 81 of 1997) cited together as the European Communities (Personal Protective Equipment) Regulations 1993 to 1997, from 21 April 2018.

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