
STATUTORY INSTRUMENTS

2018 No. 390

**The Personal Protective Equipment
(Enforcement) Regulations 2018**

PART 1

Preliminary

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Personal Protective Equipment (Enforcement) Regulations 2018 and come into force on 21st April 2018.

(2) In these Regulations—

“the 1974 Act” means the Health and Safety at Work etc. Act 1974**(1)**;

“the 1978 Order” means the Health and Safety at Work (Northern Ireland) Order 1978**(2)**;

“the 1987 Act” means the Consumer Protection Act 1987**(3)**;

“the 2002 Regulations” means the Personal Protective Equipment Regulations 2002**(4)**;

“district council” means a district council within the meaning of the Local Government Act (Northern Ireland) 1972**(5)**;

“EU Regulation 2016/425” means Regulation (EU) No 2016/425**(6)** of the European Parliament and of the Council on personal protective equipment, repealing Council [Directive 89/686/EEC](#)**(7)**, as amended from time to time;

“RAMS” means Regulation (EC) No 765/2008 of the European Parliament and of the Council setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93**(8)**, as amended from time to time;

“risk” means a risk which may result in harm to the health or safety of persons, domestic animals or property, if personal protective equipment (“PPE”) is used in a normal and predictable manner; and

“weights and measures authority” means a local weights and measures authority within the meaning set out in section 69 of the Weights and Measures Act 1985**(9)**.

(3) In these Regulations a reference to—

(1) 1974 c.37.

(2) S.I. 1978/1039 (N.I. 9).

(3) 1987 c.43.

(4) S.I. 2002/1144 as amended by S.I. 2004/693, 2012/1848 and 2015/1630.

(5) 1972 Chapter 9.

(6) OJ No L81, 31.3.2016, p.51.

(7) OJ No L399, 30.12.1989, p.18.

(8) OJ No L 218, 13.8.2008, p.30.

(9) 1985 c.72; section 69 was amended by the Local Government (Wales) Act 1994 (c.19), section 66 and Schedule 16, paragraph 75; the Local Government etc. (Scotland) Act 1994 (c.39), section 180 and Schedule 13, paragraph 144; and the Statute Law (Repeals) Act 1989 (c.43) Schedule 1, Part 1.

- (a) a numbered regulation, paragraph or Schedule is a reference to the regulation, paragraph or Schedule as numbered in these Regulations unless otherwise stated;
 - (b) an Article, paragraph of an Article or Annex is a reference to the Article, paragraph of an Article or Annex as numbered in EU Regulation 2016/425;
 - (c) a “relevant economic operator” in relation to PPE means an economic operator with obligations in respect of PPE under EU Regulation 2016/425; and
 - (d) an “enforcement authority” is to be construed in accordance with regulation 4.
- (4) Expressions and words used in these Regulations which are used in EU Regulation 2016/425 have the same meaning as in EU Regulation 2016/425.

Application, transitional provisions, savings and revocation

- 2.—(1) These Regulations apply to PPE placed on the market on or after 21st April 2018.
- (2) These Regulations do not apply to PPE—
- (a) designed for the uses specified in Article 2(2)(a) to (d); or
 - (b) that falls within Article 2(2)(e).
- (3) Nothing in these Regulations prevents the showing of PPE at trade fairs, exhibitions, demonstrations or the like, which is not in compliance with the provisions of EU Regulation 2016/425, provided that a visible sign clearly indicates that such PPE does not comply with those provisions and that it is not for sale until it is made compliant.
- (4) The 2002 Regulations continue to apply, as if they had not been revoked, to PPE placed on the market before 21st April 2019⁽¹⁰⁾, and in any such case the consequential amendments made by Schedule 5 do not apply.
- (5) If, before 21st April 2019—
- (a) an EC type-examination certificate is issued by an approved body under the 2002 Regulations, pursuant to the EC type-examination procedure set out in Schedule 7 to those Regulations, or
 - (b) an approval decision is made under, and in accordance with, Part B of Schedule 8 (system for ensuring EC quality of production by means of monitoring) to the 2002 Regulations,
- that certificate or decision remains valid until 21st April 2023⁽¹¹⁾, or until its’ expiry date if earlier, for the purpose of satisfying the requirements of an EU declaration of conformity set out in paragraphs 7 or 8 of Annex IX.
- (6) The 2002 Regulations are revoked save to the extent required to give effect to paragraphs (4) and (5).

PART 2

Market Surveillance and Enforcement

Designation of market surveillance authorities

- 3.—(1) The market surveillance authority is—

⁽¹⁰⁾ Article 47(1) of EU Regulation 2016/425 provides for PPE which is in conformity with Council [Directive 89/686/EEC](#) to be placed on the market until 21 April 2019. The 2002 Regulations transposed Council [Directive 89/686/EEC](#).

⁽¹¹⁾ Article 47(2) of the EU Regulation 2016/425 provides for EC type-examination certificates and approval decisions issued under Council [Directive 89/686/EEC](#) to remain valid until 21 April 2023 unless they expire before that date.

- (a) in the case of PPE for private use or consumption (other than that referred to in paragraph (2)(b))—
 - (i) in Great Britain, within its area, a weights and measures authority; and
 - (ii) in Northern Ireland, within its area, a district council;
- (b) in the case of PPE for use or operation in the circumstances set out in paragraph (2)—
 - (i) subject to paragraph (3), in Great Britain, the Health and Safety Executive; and
 - (ii) in Northern Ireland, the Health and Safety Executive for Northern Ireland.
- (2) The circumstances referred to in paragraphs (1)(b) are where the PPE is designed—
 - (a) for use or operation, whether exclusively or not, by persons at work; or
 - (b) for use, otherwise than at work, in non-domestic premises made available to persons at a place where they may use the PPE provided for their own use there.
- (3) In so far as these Regulations apply to PPE intended exclusively or primarily for use on relevant nuclear sites, the market surveillance authority is the Office for Nuclear Regulation.
- (4) In paragraph (3) “relevant nuclear site” means a site which is—
 - (a) a GB nuclear site (within the meaning given in section 68 of the Energy Act 2013⁽¹²⁾);
 - (b) an authorised defence site (within the meaning given in regulation 2(1) of the Health and Safety (Enforcing Authority) Regulations 1998⁽¹³⁾); or
 - (c) a new nuclear build site (within the meaning given in regulation 2A of those Regulations⁽¹⁴⁾).

Enforcement Authorities

4.—(1) Subject to paragraph (2), EU Regulation 2016/425, these Regulations and RAMS (in its application to PPE) must be enforced by the market surveillance authority.

(2) Notwithstanding paragraph (1), the Secretary of State may enforce EU Regulation 2016/425, these Regulations and RAMS (in its application to PPE).

(3) In Scotland only the Lord Advocate may commence proceedings for an offence under these Regulations.

Enforcement Powers

5.—(1) Schedule 1 makes provision for enforcement powers under the 1987 Act where the enforcement authority is—

- (a) a weights and measures authority;
- (b) a district council; or
- (c) the Secretary of State.

(2) Schedule 2 makes provision for enforcement powers under the 1974 Act where the enforcement authority is the Health and Safety Executive or the Office for Nuclear Regulation.

(3) Schedule 3 makes provision for enforcement powers under the 1978 Order where the enforcement authority is the Health and Safety Executive for Northern Ireland.

(4) In addition to the powers available to an enforcement authority by virtue of paragraph (1), (2) or (3), as appropriate, the enforcement authority may use the powers in Schedule 4 (compliance, withdrawal and recall notices).

⁽¹²⁾ 2013 c.32.

⁽¹³⁾ S.I. 1998/494 amended by S.I. 2014/469. There are other amendments not relevant to these Regulations.

⁽¹⁴⁾ Regulation 2A was inserted by S.I. 2014/469 and amended by S.I. 2015/51 (regulation 38, Schedule 5).

Notification to the Secretary of State of enforcement action etc

6. A market surveillance authority must immediately notify the Secretary of State of any action taken by it, evaluation made or other opinion formed by it, or other matter within its knowledge which is required by Article 38 to be communicated to the Commission or the other member States.

Offences

7.—(1) It is an offence for an economic operator to contravene the requirements and obligations set out in—

- (a) Article 8 (obligations of manufacturers);
- (b) Article 10 (obligations of importers);
- (c) Article 11 (obligations of distributors);
- (d) Article 13 (identification of economic operators);
- (e) Article 16 (general principles of CE marking); and
- (f) Article 17 (rules and conditions for affixing the CE marking).

(2) It is an offence for an economic operator to fail to—

- (a) cooperate with;
- (b) provide information to; and
- (c) comply with any of the requirements of,

the market surveillance authority acting under Article 38.

(3) It is an offence for an economic operator to fail to take the action required under—

- (a) Article 40 (compliant PPE which presents a risk); or
- (b) Article 41 (formal non-compliance).

(4) It is an offence for a person—

- (a) to intentionally obstruct an enforcement authority acting in the execution or enforcement of EU Regulation 2016/425;
- (b) without reasonable cause, to fail to give such an enforcement authority any assistance or information which that person may reasonably require for those purposes;
- (c) to knowingly or recklessly furnish to such an enforcement authority any information knowing it to be false or misleading in a material particular; or
- (d) to fail to produce a document or record for such an enforcement authority when required to do so.

(5) Proceedings must not be commenced against an economic operator under paragraph (1), (2) or (3) if the economic operator has been given a time period within which to comply or take action, and that time period has not expired.

Penalties

8. A person guilty of an offence under these Regulations is liable on summary conviction—

- (a) in England and Wales, to a fine or imprisonment for a term not exceeding three months, or to both;
- (b) in Scotland and Northern Ireland, to a fine not exceeding level 5 on the standard scale or imprisonment for a term not exceeding three months, or to both;

Defence of due diligence

9.—(1) In proceedings for an offence under these Regulations, it is a defence for a person (“P”) to show that P took all reasonable steps and exercised all due diligence to avoid committing the offence.

(2) P may not rely on a defence under paragraph (1) which involves a third party allegation unless P has—

- (a) served notice in accordance with paragraph (3); or
- (b) obtained leave of the court.

(3) The notice must—

- (a) give any information in the possession of P which identifies or assists in identifying the person who—
 - (i) is alleged to have committed the act or default; or
 - (ii) supplied the information on which P relies; and
- (b) be served on the person bringing the proceedings not less than seven clear days before—
 - (i) the hearing of the proceedings in England, Wales and Northern Ireland;
 - (ii) the trial date in Scotland.

(4) P may not rely on a defence under paragraph (1) which involves an allegation that the commission of the offence was due to reliance on information supplied by another person unless it was reasonable in all the circumstances to have relied on the information, having regard in particular to—

- (a) the steps that P took, and those which might reasonably have been taken, for the purpose of verifying the information; and
- (b) whether P had any reason to disbelieve the information.

(5) In this regulation, “third party allegation” means an allegation that the commission of the offence was due to—

- (a) the act or default of another person; or
- (b) reliance on information supplied by another person.

Liability of persons other than the principal offender

10.—(1) Where the commission by a person (“P”) of an offence under these Regulations is due to anything which another person (“S”) did or failed to do in the course of business, S is guilty of that offence and may be proceeded against and punished, whether or not proceedings are taken against P.

(2) Where a body corporate commits an offence under these Regulations, a relevant person is also guilty of the offence where the offence was committed by the body corporate—

- (a) with the consent or connivance of a relevant person; or
- (b) as a result of the negligence of a relevant person.

(3) In paragraph (2) a “relevant person” means—

- (a) a director, manager, secretary or other similar officer of the body corporate;
- (b) in relation to a body corporate managed by its members, a member of that body performing managerial functions;
- (c) a partner in relation to a Scottish partnership; or
- (d) a person purporting to act as a person described in subparagraphs (a), (b) or (c).

Time limit for prosecution of offences

11.—(1) In England and Wales an information relating to an offence under these Regulations that is triable by a magistrates' court may be so tried if it is laid within 12 months after the date on which evidence sufficient in the opinion of the prosecutor to justify the proceedings comes to the knowledge of the prosecutor.

(2) In Scotland—

- (a) summary proceedings for an offence may only be commenced within 12 months after the date on which evidence sufficient in the Lord Advocate's opinion to justify the proceedings came to the Lord Advocate's knowledge, and
- (b) section 136(3) of the Criminal Procedure (Scotland) Act 1995⁽¹⁵⁾ (time limit for certain offences) applies for the purpose of this paragraph as it applies for the purpose of that section.

(3) In Northern Ireland summary proceedings for an offence may be instituted within 12 months after the date on which evidence sufficient in the opinion of the prosecutor to justify proceedings comes to the knowledge of the prosecutor.

(4) No proceedings are to be brought more than three years after the commission of the offence.

(5) For the purposes of this regulation a certificate of the prosecutor (or in Scotland, the Lord Advocate) as to the date on which such evidence as is referred to above came to their notice is conclusive evidence of that fact.

(6) This regulation has effect subject to paragraph (1)(n) of Schedule 2 (enforcement powers of the Health and Safety Executive and the Office for Nuclear Regulation under the 1974 Act) and to paragraph (1)(n) of Schedule 3 (enforcement powers of the Health and Safety Executive for Northern Ireland under the 1978 Order).

Written notice under Article 38 and service of documents

12.—(1) In a case falling within Article 38 (procedure at national level for dealing with PPE presenting a risk), a market surveillance authority must provide notice when requiring the economic operator to, within a reasonable period—

- (a) take appropriate corrective action;
- (b) withdraw the PPE from the market; or
- (c) recall the PPE.

(2) The notice given under paragraph (1) must—

- (a) give reasons for the action required;
- (b) provide a time limit for compliance; and
- (c) be served in accordance with paragraphs (3) to (6).

(3) Any document required or authorised by EU Regulation 2016/425 or these Regulations to be served on a person may be served by—

- (i) delivering it to that person in person;
- (ii) leaving it at the person's proper address; or
- (iii) sending it by post or electronic means to that person's proper address.

(4) In the case of a body corporate, a document may be served on a director of that body.

(5) In the case of a partnership, a document may be served on a partner or person having control or management of the partnership business.

(15) 1995 c.46.

(6) If a person has specified an address in the United Kingdom (other than that person's proper address) at which that person or someone on that person's behalf will accept service, that address must also be treated as that person's proper address.

(7) For the purposes of this regulation "proper address" means—

(a) in the case of a body corporate or its director—

(i) the registered or principal office of that body; or

(ii) the email address of the secretary or clerk of that body;

(b) in the case of a partnership, a partner or person having control or management of the partnership business—

(i) the principal office of the partnership; or

(ii) the email address of a partner or a person having that control or management;

(c) in any other case, a person's last known address, which includes an email address.

(8) In this regulation, "partnership" includes a Scottish partnership.

Appeals against notices

13.—(1) An application for an order to vary the terms of, or set aside, a notice served under regulation 5 (enforcement powers) or 12 (Article 38 notices) may be made—

(a) by the economic operator on whom the notice has been served; and

(b) in the case of a notice other than a recall notice, by a person having an interest in the PPE in respect of which the notice has been served.

(2) An application must be made before the end of the period of 21 days beginning with the day on which the notice was served.

(3) The appropriate court may only make an order setting aside a notice served under regulation 5 or 12 if satisfied—

(a) that no contravention of EU Regulation 2016/425 or these Regulations has occurred; or

(b) that the enforcement authority failed to comply with Article 14 (presumption of conformity of PPE) when serving the notice.

(4) On an application to vary the terms of the notice, the appropriate court may vary the terms of the notice as it considers appropriate.

(5) In this regulation—

(a) "the appropriate court" is to be determined in accordance with regulation 14; and

(b) "notice" means—

(i) a notice served under regulation 12;

(ii) a prohibition notice, a notice to warn or a suspension notice served in accordance with Schedule 1; or

(iii) a compliance notice, a withdrawal notice, or a recall notice served in accordance with Schedule 4.

Appropriate court for appeals against notices etc and further appeals

14.—(1) In England and Wales, or Northern Ireland, the appropriate court for the purposes of regulation 13 is—

(a) the court in which proceedings have been brought for an offence under regulation 7 (offences);

- (b) an employment tribunal seized of appeal proceedings against a notice which relates to PPE which has been served under or by virtue of paragraph 1 of Schedule 2;
 - (c) an industrial tribunal seized of appeal proceedings against a notice which relates to PPE which has been served under or by virtue of paragraph 1 of Schedule 3 (enforcement powers of the Health and Safety Executive for Northern Ireland under the 1978 Order); or
 - (d) in any other case, a magistrates' court in England and Wales, or Northern Ireland.
- (2) In Scotland the appropriate court for the purposes of regulation 13 is—
- (a) the sheriff of a sheriffdom in which the person making the appeal resides or, as the case may be, has a registered or principal office; or
 - (b) an employment tribunal seized of appeal proceedings against a notice which relates to PPE which has been served under or by virtue of paragraph 1 of Schedule 2.
- (3) A person aggrieved by an order made by a magistrates' court in England and Wales, or Northern Ireland, pursuant to an application under regulation 13, or by a decision of such a court not to make such an order, may appeal against that order or decision—
- (a) in England and Wales, to the Crown Court;
 - (b) in Northern Ireland, to the county court.

Compensation

15.—(1) Where an enforcement authority other than the Health and Safety Executive, the Health and Safety Executive of Northern Ireland or the Office for Nuclear Regulation, serves a relevant notice in respect of PPE, that authority is liable to pay compensation to a person having an interest in the PPE in respect of any loss or damage caused by reason of the notice if both conditions mentioned in paragraph (2) are met.

- (2) The conditions are that—
- (a) the PPE in respect of which the relevant notice was served neither—
 - (i) presents a risk; nor
 - (ii) contravenes any requirement of EU regulation 2016/425; and
 - (b) any neglect or default on the part of the economic operator was not the reason for service of the relevant notice.

(3) In this regulation, “relevant notice” means a suspension, withdrawal or recall notice as referred to in regulation 13(5)(b).

Recovery of expenses of enforcement

16.—(1) This regulation applies where a person commits an offence under regulation 7 (offences).

(2) The court may (in addition to any other order it may make as to costs or expenses) order the person to reimburse the enforcement authority for any expenditure which the authority has reasonably incurred in investigating the offence.

Action by enforcement authority

17.—(1) An enforcement authority may itself take any action which an economic operator could have been required to take by a notice served under regulation 5 (enforcement powers) where the conditions for serving such a notice are met and either—

- (a) the enforcement authority has been unable to identify any economic operator on whom to serve such a notice; or

- (b) the economic operator on whom such a notice has been served has failed to comply with it.
- (2) If the enforcement authority has taken action under paragraph (1) following the failure of an economic operator to comply with a notice, the authority may recover from that person as a civil debt any costs or expenses incurred by the enforcement authority in taking the action.
- (3) A civil debt recoverable under paragraph (2) may be recovered summarily—
 - (a) in England and Wales, by way of a complaint pursuant to section 58 of the Magistrates’ Courts Act 1980;
 - (b) in Northern Ireland, in proceedings under Article 62 of the Magistrates’ Court (Northern Ireland) Order 1981.

PART 3

Miscellaneous

Review and consequential amendments

- 18.**—(1) The Secretary of State must—
- (a) carry out a review of the regulatory provision contained in these Regulations; and
 - (b) publish a report setting out the conclusions of that review.
- (2) In carrying out the review the Secretary of State must, so far as is reasonable, have regard to how EU Regulation 2016/425 (which is enforced and supplemented by means of these Regulations) is executed and enforced in other member States.
- (3) The first report must be published before the end of the period of five years beginning with the day on which these Regulations come into force.
- (4) Subsequent reports under this regulation are to be published at intervals not exceeding five years.
- (5) Section 30(4) of Small Business, Enterprise and Employment Act 2015⁽¹⁶⁾ requires that the reports published under this regulation must, in particular—
- (a) set out the objectives intended to be achieved by the regulatory provision referred to in paragraph (1)(a),
 - (b) assess the extent to which those objectives are achieved,
 - (c) assess whether those objectives remain appropriate, and
 - (d) if those objectives remain appropriate, assess the extent to which they could be achieved in another way which involves less onerous regulatory provision.
- (6) In this regulation, “regulatory provision” has the same meaning as in sections 28 to 32 of the 2015 Act (see section 32 of that Act).
- 19.** Schedule 5 (consequential amendments) makes amendments to legislation which are consequential to these Regulations (subject to regulation 2(4)).

(16) 2015 c.26.

20th March 2018

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