
STATUTORY INSTRUMENTS

2018 No. 390

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

PART 2

Market Surveillance and Enforcement

Designation of market surveillance authorities

- 3.—(1) The market surveillance authority is—
- (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 ^{M1});
 - (b) an authorised defence site (within the meaning given in regulation 2(1) of the Health and Safety (Enforcing Authority) Regulations 1998 ^{M2}); or
 - (c) a new nuclear build site (within the meaning given in regulation 2A of those Regulations ^{M3}).

Marginal Citations

M1 2013 c.32.

M2 S.I. 1998/494 amended by S.I. 2014/469. There are other amendments not relevant to these Regulations.

M3 Regulation 2A was inserted by S.I. 2014/469 and amended by S.I. 2015/51 (regulation 38, Schedule 5).

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).

Notification to the Secretary of State of enforcement action etc **E+W+S**

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, ^{F1}in accordance with Chapter 6].

Extent Information

- E1** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F1** Words in [reg. 6](#) substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 35 para. 1\(5\)](#) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2, 3](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

Notification to the Secretary of State of enforcement action etc **N.I.**

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 ^{F5}... member States.

Extent Information

- E4** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

- F5** Word in [reg. 6](#) omitted (N.I.) (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), [reg. 1\(b\)](#), [Sch. 17 para. 1\(2\)](#)

[^{F2}Information obligations

6A.—(1) Nothing in EU Regulation 2016/425 requires any market surveillance authority or the Secretary of State to inform the Commission or member States of any matter in relation to PPE on the market of Great Britain only.]

Textual Amendments

- F2** [Reg. 6A](#) inserted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), [reg. 1\(b\)](#), [Sch. 17 para. 1\(3\)](#)

Offences **E+W+S**

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 [^{F3}UK] marking); and
- (f) Article 17 (rules and conditions for affixing the [^{F3}UK] 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.

Extent Information

E2 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F3 Word in [reg. 7\(1\)](#) substituted (E.W.S.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 35 para. 1\(6\)](#) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2, 3](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#)

Modifications etc. (not altering text)

- C1** [Reg. 7\(1\)](#) modified (W.) (31.12.2020) by [The Personal Protective Equipment \(Temporary Arrangements\) \(Coronavirus\) \(Wales\) Regulations 2020 \(S.I. 2020/1489\)](#), [regs. 1\(1\), 4\(1\)](#) (with [reg. 4\(4\)](#))
- C2** [Reg. 7\(1\)](#) modified (E.) (31.12.2020) by [The Personal Protective Equipment \(Temporary Arrangements\) \(Coronavirus\) \(England\) Regulations 2020 \(S.I. 2020/1484\)](#), [regs. 1\(1\), 4\(1\)](#) (with [reg. 4\(4\)](#))
- C3** [Reg. 7\(1\)](#) modified (S.) (1.2.2021) by [The Personal Protective Equipment \(Temporary Arrangements\) \(Coronavirus\) \(Scotland\) Regulations 2021 \(S.S.I. 2021/50\)](#), [regs. 1, 4\(1\)](#) (with [reg. 4\(4\)](#))
- C4** [Reg. 7\(3\)](#) modified (E.) (31.12.2020) by [The Personal Protective Equipment \(Temporary Arrangements\) \(Coronavirus\) \(England\) Regulations 2020 \(S.I. 2020/1484\)](#), [regs. 1\(1\), 4\(2\)\(3\)](#) (with [reg. 4\(4\)](#))
- C5** [Reg. 7\(3\)](#) modified (W.) (31.12.2020) by [The Personal Protective Equipment \(Temporary Arrangements\) \(Coronavirus\) \(Wales\) Regulations 2020 \(S.I. 2020/1489\)](#), [regs. 1\(1\), 4\(2\)\(3\)](#) (with [reg. 4\(4\)](#))
- C6** [Reg. 7\(3\)](#) modified (S.) (1.2.2021) by [The Personal Protective Equipment \(Temporary Arrangements\) \(Coronavirus\) \(Scotland\) Regulations 2021 \(S.S.I. 2021/50\)](#), [regs. 1, 4\(2\)\(3\)](#) (with [reg. 4\(4\)](#))

Offences **N.I.**

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.

Extent Information

- E5** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

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 ^{M4} (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).

Marginal Citations

M4 1995 c.46.

Written notice under Article 38 and service of documents **N.I.**

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 [^{F4}in Northern Ireland]; 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.

(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.

Extent Information

- E3** This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

- F4** Words in [reg. 12\(1\)\(b\)](#) inserted (N.I.) (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment\) \(Northern Ireland\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1112\)](#), [reg. 1\(b\)](#), [Sch. 17 para. 1\(4\)](#)

Written notice under Article 38 and service of documents **E+W+S**

12.—(1) In a case falling within Article 38 (procedure ^{F6}... 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.

(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.

Extent Information

- E6** This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

- F6** Words in [reg. 12\(1\)](#) omitted (E.W.S.) (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), [reg. 1](#), [Sch. 35 para. 1\(7\)](#) (as amended by [S.I. 2020/676](#), [regs. 1\(1\), 2, 3](#)); [2020 c. 1](#), [Sch. 5 para. 1\(1\)](#)

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.

Changes to legislation:

There are currently no known outstanding effects for the The Personal Protective Equipment (Enforcement) Regulations 2018, PART 2.