SCHEDULE 35

Amendment of Regulation (EU) 2016/425 and the Personal Protective Equipment (Enforcement) Regulations 2018

PART 2

Amendment of retained direct EU legislation

Amendment of Regulation (EU) 2016/425

3.—(1) Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment and repealing Council Directive 89/686/EEC is amended as follows.

(2) In Article 1, for "Union" substitute "United Kingdom".

(3) In Article 2(2)(d), for "Member States" substitute "the United Kingdom".

(4) In Article 3—

(a) in points (2) and (3), for "Union" substitute "United Kingdom";

(b) for point (5), substitute—

"(5) 'authorised representative' means—

(a) a person who—

(i) immediately before exit day, was established in the United Kingdom or an EEA state, and was appointed by a manufacturer by written mandate to perform specified tasks for that manufacturer, in accordance with Article 9 of Regulation 2016/425 (pre-exit); and

(ii) on or after exit day continues to be so established and appointed by the manufacturer to perform those tasks; or

(b) a person who, on or after exit day, is appointed in accordance with Article 9;";

(c) for point (6), substitute—

"(6) 'importer' means a person who—

(a) is established in the United Kingdom, and

(b) places PPE from a country outside the United Kingdom on the market;";

(d) omit points (10) to (12), and (17) and (18);

(e) after point (18), insert—

"(19) 'approved body' has the meaning given in Article 20;

(20) 'designated standard' has the meaning given in Article 7A;

(21) 'enforcement authority' means a person enforcing this Regulation under regulation 4 of the Personal Protective Equipment (Enforcement) Regulations 2018 (S.I. 2018/390);

(22) 'UK Marking' means the marking in the form published in accordance with Article 30(1) of Regulation (EC) 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) 339/93;

(23) 'UK national accreditation body' means the body appointed by the Secretary of State in accordance with Article 4 of Regulation (EC) 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) 339/93;

(24) 'Regulation 2016/425 (pre-exit)' means Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment and repealing Council Directive 89/686/EEC, as it had effect immediately before exit day;

(25) In this Regulation, references to "the market surveillance authority" are to be construed in accordance with regulation 3 of the Personal Protective Equipment (Enforcement) Regulations 2018.".

(5) Omit Article 6.

(6) In Article 7—

(a) for the heading, substitute—

"Making available, putting into service and exhibition at trade fairs, etc";

(b) in paragraph 1, for "Member States shall not impede" substitute "Nothing in this Regulation impedes";

(c) in paragraph 2, for "Member States shall not prevent" substitute "nothing in this Regulation prevents".

(7) After Article 7, insert—

"Article 7A

Designated standard

1. Subject to paragraphs 6 and 7, in this Regulation, a "designated standard" means a technical specification which is—

(a) adopted by a recognised standardisation body, for repeated or continuous application, with which compliance is not compulsory; and

(b) designated by the Secretary of State, by publishing the reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate.

2. For the purposes of paragraph 1, "technical specification" means a document that prescribes technical requirements to be fulfilled by a product, process, service or system and which lays down one or more of the following—

(a) the characteristics required of a product, including—

(i) levels of quality, performance, interoperability, environmental protection, health, safety or dimensions; and

(ii) the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures;

(b) production methods and processes relating to the product, where these have an effect on the characteristics of the product.

3. For the purposes of this Article, a "recognised standardisation body" means any one of the following organisations—

(a) the European Committee for Standardisation (CEN);

(b) the European Committee for Electrotechnical Standardisation (Cenelec);

(c) the European Telecommunications Standards Institute (ETSI);

(d) the British Standards Institution (BSI).

4. When considering whether the manner of publication of a reference is appropriate in accordance with paragraph 1(b), the Secretary of State must have regard to whether the publication will draw the standard to the attention of any person who may have an interest in the standard.

5. Before publishing the reference to a technical specification adopted by the British Standards Institution, the Secretary of State must have regard to whether the technical specification is consistent with technical specifications adopted by the other recognised standardisation bodies.

6. The Secretary of State may remove from publication the reference to a standard which has been published in accordance with paragraph 1(b).

7. Where the Secretary of State removes the reference to a standard from publication, that standard is no longer a designated standard.

8. In this Article, a reference to a "product" is a reference to PPE to which this Regulation applies.

9. The Secretary of State may, by regulations, amend paragraph 3 to reflect any changes in the name or structure of the recognised standardisation bodies.

10. Regulations made under paragraph 9 must be made by statutory instrument, subject to annulment in pursuance of a resolution of either House of Parliament.".

(8) In Article 8—

(a) in paragraph 2, in the second subparagraph (beginning "Where compliance of")—

(i) omit "EU";

(ii) for "CE" substitute "UK";

(b) in paragraph 3, omit "EU";

(c) in paragraph 4, for "harmonised" substitute "designated";

(d) in paragraph 6, for "market surveillance authorities" substitute "the market surveillance authority";

(e) in paragraph 7, for the words from "in a language" to the end, substitute "and that they are clear, legible and in easily understandable English";

(f) in paragraph 8, omit "EU" in both places;

(g) in paragraph 9, for the words from "competent national authorities" to "on the market", substitute "enforcement authority";

(h) in paragraph 10, for "a competent national authority" substitute "the enforcement authority".

(9) In Article 9—

(a) in paragraph 1, after "appoint" insert "a person established in the United Kingdom as their", and omit "an";

(b) in paragraph 2—

(i) in point (a)—

(aa) omit "EU" and "national";

(bb) for "authorities" substitute "authority";

(ii) in point (b), for "a competent national authority" substitute "the enforcement authority";

(iii) in point (c), for "competent national authorities" substitute "enforcement authority".

(10) In Article 10—

(a) in paragraph 2—

(i) in the first subparagraph (beginning "Before placing PPE"), for "CE" substitute "UK";

(ii) in the second subparagraph (beginning "Where an importer"), for "authorities" substitute "authority";

(b) in paragraph 3—

(i) omit the words from "or, where" to the end of the first sentence;

(ii) for "authorities" substitute "authority";

(iii) after "and market surveillance authorities" insert—

"The obligation set out in this paragraph 3 to indicate information on the PPE does not apply where—

(a) either—

(i) it is not possible to indicate that information on the PPE, or

(ii) the importer has imported the PPE from an EEA state and places it on the market within the period of 18 months beginning with exit day, and

(b) before placing the PPE on the market, the importer sets out the information referred to in this paragraph 3 on the packaging of the PPE or in a document accompanying the PPE.";

(c) in paragraph 4, for the words from "in a language which" to the end, substitute "and that they are clear, legible and in easily understandable English";

(d) in paragraph 7, for the words from "competent national authorities" to "available on the market" substitute "enforcement authority";

(e) in paragraph 8—

(i) omit "EU";

(ii) for "authorities" in the first place it occurs, substitute "authority";

(iii) for "those authorities" substitute "that authority";

(f) in paragraph 9, for "a competent national authority" substitute "the enforcement authority".

(11) In Article 11—

(a) in paragraph 2—

(i) in the first subparagraph (beginning "Before making PPE")—

(aa) for "CE" substitute "UK";

(bb) for the words from "in a language which" to "available on the market" substitute "and that they are clear, legible and in easily understandable English";

(ii) in the second subparagraph (beginning "Where a distributor"), for "authorities" at the end, substitute "authority";

(b) in paragraph 4, for the words from "competent national authorities" to "on the market" substitute "enforcement authority";

(c) in paragraph 5, for "a competent national authority" substitute "the enforcement authority".

(12) In Article 13, (in the first sentence), for "authorities" substitute "authority".

(13) For Article 14, substitute—

"Article 14

Presumption of conformity of PPE

1. PPE which is in conformity with a designated standard or part thereof shall be presumed to be in conformity with the essential health and safety requirements set out in Annex II covered by that standard or part thereof.

2. The presumption in paragraph 1 is rebuttable.".

(14) In Article 15—

(a) in the heading, and in paragraphs 1, 2 and 4, omit "EU";

(b) in paragraph 2, for the words from "translated into the language" to the end, substitute "in English";

(c) for paragraph 3, substitute—

"**3.** Where PPE is subject to more than one enactment requiring a declaration of conformity, the manufacturer must draw up a single declaration of conformity which identifies each enactment by its title.".

(15) In Article 16, and in the heading to that Article, for "CE" substitute "UK".

(16) In Article 17—

(a) in paragraphs 1 to 4, and in the heading, for "CE" substitute "UK";

(b) in paragraph 3, for "notified", in both places, substitute "approved";

(c) in paragraph 4, for "notified" substitute "approved";

(d) omit paragraph 5.

(17) In Article 19(b) and (c), omit "EU".

(18) In the heading to Chapter V for "Notification" substitute "Approval".

(19) For Article 20, substitute—

"Article 20

Approved bodies

1. An approved body is a conformity assessment body which—

(a) has been approved by the Secretary of State pursuant to the procedure set out in Article 21 (approval of conformity assessment bodies); or

(b) immediately before exit day was a notified body in respect of which the Secretary of State had taken no action under Article 30 of Regulation 2016/425 (pre-exit), to suspend or withdraw the body's status as a notified body.

2. Paragraph 1 has effect subject to Article 30 (restriction, suspension or withdrawal of approval).

3. In this Chapter—

"notified body" means a body which—

(a) the Secretary of State had, before exit day, notified to the European Commission and the member States of the European Union in accordance with Article 20 of Regulation 2016/425 (pre-exit); and

(b) in respect of which no objections had been raised, as referred to in Article 28(5) of Regulation 2016/425 (pre-exit);

"approved body requirements" means the requirements set out in Article 24.".

(20) For Article 21, substitute—

"Article 21

Approval of conformity assessment bodies

1. The Secretary of State may approve only those conformity assessment bodies that qualify for approval.

2. A conformity assessment body qualifies for approval if the first and second conditions below are met.

3. The first condition is that the conformity assessment body has applied to the Secretary of State to become an approved body and that application is accompanied by—

(a) a description of—

(i) the conformity assessment activities that the conformity assessment body intends to carry out;

(ii) the conformity assessment procedure in respect of which the conformity assessment body claims to be competent;

(iii) the category of PPE in respect of which the conformity assessment body claims to be competent; and

(b) either—

(i) an accreditation certificate; or

(ii) the documentary evidence necessary for the Secretary of State to verify, recognise and regularly monitor the conformity assessment body's compliance with the approved body requirements.

4. The second condition is that the Secretary of State is satisfied that the conformity assessment body meets the approved body requirements.

5. For the purposes of paragraph 4, the Secretary of State may accept an accreditation certificate provided in accordance with paragraph 3(b), as sufficient evidence that the conformity assessment body meets the approved body requirements.

6. When deciding whether to approve a conformity assessment body that qualifies for approval, the Secretary of State may—

(a) have regard to any other matter which appears to the Secretary of State to be relevant; and

(b) set conditions that the conformity assessment body must meet.

7. For the purposes of this Article, "accreditation certificate" means a certificate issued by the UK national accreditation body, attesting that a conformity assessment body meets the approved body requirements.".

(21) For Article 22, substitute—

"Article 22

UK national accreditation body

The Secretary of State may authorise the UK national accreditation body to carry out the following activities on behalf of the Secretary of State—

(a) assessing whether a conformity assessment body meets the approved body requirements;

(b) monitoring approved bodies in accordance with Article 23; and

(c) compiling and maintaining the register of approved bodies, in accordance with Article 29.".

(22) For Article 23 substitute—

"Article 23

Monitoring obligations

The Secretary of State must monitor each approved body with a view to verifying that the body—

(a) continues to meet—

(i) the approved body requirements; and

(ii) any conditions set by the Secretary of State under Article 21(6)(b); and

(b) carries out its functions in accordance with this Regulation.".

(23) In Article 24—

(a) for the heading, substitute—

"Approved body requirements";

(b) in paragraph 1, for "notification" substitute "approval";

(c) in paragraph 2, for "under the national law of a Member State" substitute "in the United Kingdom";

(d) in paragraphs 4 (in the second subparagraph), and 7(a), for "notified" substitute "approved";

(e) in paragraph 6—

(i) for "notified", in the first two places where it occurs, substitute "approved";

(ii) in point (b), for "a notified body" substitute "an approved body";

(f) in paragraph 7(c)—

(i) for "harmonised" substitute "designated";

(ii) for "Union harmonisation legislation and of national legislation" substitute "this Regulation and any other relevant United Kingdom legislation";

(g) in paragraph 9, for "liability is assumed by the Member State in accordance with national law, or the Member State itself" substitute "the Secretary of State";

(h) in paragraph 10—

(i) for "national" substitute "United Kingdom";

(ii) for "competent authorities of the Member State in which its activities are carried out" substitute "enforcement authority";

(i) in paragraph 11—

(i) for "the notified" substitute "any approved";

(ii) for "under Article 36" substitute "by the Secretary of State".

(24) For Article 25, substitute —

"Article 25

Presumption of conformity of approved bodies

1. Where a conformity assessment body demonstrates its conformity with the criteria laid down in a designated standard (or part of such a standard), the Secretary of State must presume that the conformity assessment body meets the approved body requirements covered by that standard (or the part of that standard).

2. The presumption in paragraph 1 is rebuttable.".

(25) For Article 26, substitute—

"Article 26

Subsidiaries of, and subcontracting by approved bodies

1. An approved body may subcontract specific conformity assessment activities, or use a subsidiary to carry out such activities provided—

(a) the body is satisfied that the subcontractor or subsidiary meets the approved body requirements;

(b) the body has informed the Secretary of State that it is satisfied that the subcontractor or subsidiary meets those requirements; and

(c) the economic operator for whom the activities are to be carried out has consented to the activities being carried out by that person.

2. The approved body which subcontracts specific conformity assessment activities or uses a subsidiary to carry out such activities remains responsible for the proper performance of those activities (irrespective of where the subcontractor or subsidiary is established).

3. Where an approved body subcontracts, or uses a subsidiary to carry out, a specific conformity assessment activity, the approved body must, for a period of 10 years beginning on the day on which the activity is first carried out, keep available for inspection by the Secretary of State all relevant documentation concerning—

(a) the assessment of the qualifications of the subcontractor or the subsidiary; and

(b) the conformity assessment activity carried out by the subcontractor or subsidiary.

4. In this Article, "subsidiary" has the meaning given to it by section 1159 of the Companies Act 2006(**1**).".

(26) Omit Articles 27 and 28.

(27) For Article 29, substitute—

"Article 29

Identification numbers and register of approved bodies

1. The Secretary of State must—

(a) assign an approved body identification number to each approved body; and

(**1**) 2006 c.46.

(b) compile and maintain a register of—

(i) approved bodies;

(ii) their approved body identification numbers;

(iii) the activities for which they have been approved; and

(iv) any restrictions on those activities.

2. The register referred to in paragraph 1 must be made publicly available.".

(28) For Article 30, substitute—

"Article 30

Restriction, suspension or withdrawal of approval

1. Where the Secretary of State determines that an approved body—

(a) no longer meets an approved body requirement, or

(b) is failing to fulfil its obligations under these Regulations, other than a condition referred to in Article 21(6)(b),

the Secretary of State must restrict, suspend or withdraw the body's status as an approved body under Article 21.

2. Where the Secretary of State determines that an approved body no longer meets a condition referred to in Article 21(6)(b), the Secretary of State may restrict, suspend or withdraw the body's status as an approved body under Article 21.

3. In deciding what action to take under paragraph 1 or 2, the Secretary of State must have regard to the seriousness of the non-compliance.

4. Before taking action under paragraph 1 or 2, the Secretary of State must—

(a) give notice in writing to the approved body of the proposed action and the reasons for it;

(b) give the approved body an opportunity to make representations to the Secretary of State regarding the proposed action within a reasonable period from the date of the notice; and

(c) consider any such representations made by the approved body.

5. Where the Secretary of State has taken action in respect of an approved body under paragraph 1 or 2, or where an approved body has ceased its activity, the approved body must, at the request of the Secretary of State—

(a) transfer its files relating to the activities it has undertaken as an approved body to another approved body or to the Secretary of State; or

(b) keep its files relating to the activities it has undertaken as an approved body available for inspection by the Secretary of State and market surveillance authority for a period of 10 years from the date they were created.

6. The activities undertaken as an approved body referred to in paragraph 5 include any activities that the body has undertaken as a notified body.".

(29) Omit Article 31.

(30) In Article 32—

(a) in the heading, and in paragraph 5, for "notified" substitute "approved";

(b) in paragraph 1, for "Notified" substitute "Approved";

(c) after paragraph 1 insert—

"**1A.** Subject to the terms of its appointment and to paragraph 3, an approved body must carry out the conformity assessment activities and procedures, in respect of which—

(a) the body's approval was given under Article 21; or

(b) the body's notification as a notified body was made.";

(d) in paragraphs 3 and 4, for "a notified" substitute "an approved";

(e) in paragraph 3 for "harmonised" substitute "designated".

(31) In Article 33—

(a) for "Notified" substitute "Approved"; and

(b) in the heading, for "notified" substitute "approved".

(32) In Article 34—

(a) in the heading, for "notified" substitute "approved";

(b) in paragraph 1—

(i) for—

(aa) "Notified" substitute "Approved";

(bb) "notifying authority" substitute "Secretary of State";

(ii) in point (b), for "notification" substitute "their approval";

(iii) in point (c), for "market surveillance authorities" substitute "the market surveillance authority";

(iv) in point (d), for "notification" substitute "approval";

(c) in paragraph 2—

(i) for "Notified" in the first place it occurs, substitute "Approved";

(ii) for "the other bodies notified" substitute "other approved bodies".

(33) Omit Article 35 and 36.

(34) For the heading to Chapter VI, substitute—

"MARKET SURVEILLANCE AND CONTROL OF PPE ENTERING THE UNITED KINGDOM MARKET".

(35) In Article 37—

(a) for the heading, substitute—

"Market surveillance and control of PPE entering the United Kingdom market";

(b) for "Article 15(3) and Articles 16 to 29" substitute "Articles 15(3), 16 to 22 and 26 to 29".

(36) In Article 38—

(a) in the heading, omit "at national level";

(b) in paragraph 1—

(i) in the first subparagraph (beginning "Where the market")—

(aa) for "authorities of one Member State have" substitute "authority has";

(bb) for "they" substitute "the authority";

(cc) in the last sentence, for "authorities" substitute "authority",

(ii) in the second subparagraph (beginning "Where, in the course of the evaluation")—

(aa) for "authorities find" substitute "authority finds";

(bb) for "they" in both places, substitute "the authority";

(iii) in the third subparagraph (beginning "The market surveillance authorities")—

(aa) for "authorities", substitute "authority";

(bb) for "notified" substitute "approved";

(c) omit paragraph 2;

(d) in paragraph 3, omit "throughout the Union";

(e) in paragraph 4—

(i) in the first subparagraph (beginning "Where the relevant")—

(aa) for "authorities", substitute "authority";

(bb) omit "provisional";

(cc) for "their national market" substitute "the market";

(ii) omit the second subparagraph (beginning "The market surveillance authorities shall");

(f) omit paragraphs 5 to 8.

(37) Omit Article 39.

(38) In Article 40—

(a) in paragraph 1, for "a Member State" substitute "the enforcement authority";

(b) in paragraph 2, omit "throughout the Union";

(c) omit paragraphs 3 to 5.

(39) In Article 41—

(a) in paragraph 1—

(i) in the first sentence, for "a Member State" substitute "the enforcement authority";

(ii) in points (a) and (b), for "CE" substitute "UK";

(iii) in point (c), for "notified" substitute "approved";

(iv) in point (d), omit "EU";

(b) in paragraph 2, for "Member State concerned" substitute "enforcement authority".

(40) For Article 42 substitute—

"Article 42

Regulation making powers

1. In order to take into account technical progress and knowledge or new scientific evidence with respect to the category of a specific risk, the Secretary of State may, by regulations, amend Annex I by reclassifying the risk from one category to another.

2. Regulations made under paragraph 1 must be made by statutory instrument, subject to annulment in pursuance of a resolution of either House of Parliament.

3. Any power to make regulations under this Article includes power to make—

(a) different provision for different purposes;

(b) consequential, supplementary, transitional or transitory provision or savings.".

(41) Omit Articles 43 to 46.

(42) For Article 47, substitute—

"Article 47

Transitional provision in relation to EU exit

1. In this Article, "pre-exit period" means the period beginning with 21 April 2018 and ending immediately before exit day.

2. Subject to paragraph 3, where PPE was made available on the market during the pre-exit period, despite the amendments made by Schedule 35 of the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019(**2**), any obligation to which a person was subject under Regulation 2016/425 (pre-exit), continues to have effect as it did immediately before exit day, in relation to that PPE.

3. Paragraph 2 does not apply to—

(a) any obligation of the enforcement authority to inform the European Commission or the member States of any matter, or

(b) any obligation to take action outside of the United Kingdom in relation to that PPE.

4. Where during the pre-exit period—

(a) PPE has not been placed on the market; and

(b) a manufacturer has taken any action under Article 8(2) of Regulation 2016/425 (pre-exit) with respect to carrying out the applicable conformity assessment procedure referred to in Article 19 of that Regulation,

that action has effect as if it had been done under Article 8(2) of this Regulation (with respect to carrying out the applicable conformity assessment procedure referred to in Article 19 of this Regulation).".

(43) Omit Article 48.

(44) After Article 48, omit—

(a) the words "This Regulation shall be binding" to the end;

(b) "Done at Strasbourg, 9 March 2016";

(c) the signatory text.

(45) In Annex II (Essential Health and Safety Requirements)—

(a) in paragraph 1.4—

(i) in point (i), for "Union harmonisation" substitute "relevant United Kingdom";

(ii) in point (j), for "notified" substitute "approved";

(iii) in point (k), for "harmonised" substitute "designated";

(iv) in point (l), omit "EU";

(v) in the sentence after point (l), (beginning "The information referred"), omit "EU".

(b) in paragraph 2.12—

(i) in the first subparagraph, (beginning "Where PPE bears")—

(aa) omit "harmonised";

(bb) for the words from "a language easily" to the end, substitute "English";

(**2**) S.I. 2019/XXXX.

(c) in paragraph 3.5, for "by Directive 2003/10/EC of the European Parliament and of the Council" substitute "in the Control of Noise at Work Regulations 2005 (S.I. 2005/1643) and the Control of Noise at Work Regulations (Northern Ireland) 2006 (S.R. 2006 No.1)"(**3**).

(46) In Annex III—

(a) in point (f), for "harmonised" in both places, substitute "designated";

(b) in point (g), for "harmonised" substitute "designated".

(47) In Annex IV—

(a) in the heading to paragraph 4—

(i) for "CE" substitute "UK";

(ii) omit "EU";

(b) in paragraph 4.1, for "CE" substitute "UK";

(c) in paragraph 4.2, omit "EU", in each place it occurs.

(48) In Annex V—

(a) in the heading, and in the headings to paragraphs 3, 4, 6 and 7, omit "EU";

(b) in paragraph 1, for "a notified" substitute "an approved";

(c) in paragraphs 1, 2, 3, 6.2, 6.3, 7.7, and 9, omit "EU";

(d) in paragraphs 7.2, 7.4, 7.5, 7.6, and 8, omit "EU", in each place it occurs;

(e) in paragraphs 4, 6.1, 6.2, 6.4, 7.2 and 7.7, for "notified" substitute "approved";

(f) in paragraph 3, 5, 7.1, 7.4, 7.5, 7.6 and 8, for "notified", in each place it occurs, substitute "approved";

(g) in paragraph 4, for "harmonised", in each place it occurs, substitute "designated";

(h) in paragraph 5, for "notifying authorities" substitute "Secretary of State";

(i) in paragraphs 6.1 and 6.4, for "an EU" substitute "a";

(j) in paragraph 6.2(e) and 7.6(b), for "harmonised" substitute "designated";

(k) in paragraph 8—

(i) in the first subparagraph (beginning "Each notified body shall inform its notifying"), for "its notifying authority", in both places, substitute "the Secretary of State";

(ii) in the third subparagraph (beginning "The Commission")—

(aa) for "The Commission, the Member States", substitute "The Secretary of State";

(bb) for "On a reasoned request, the Commission and the Member States may" substitute "The Secretary of State may on request".

(49) In Annex VI—

(a) in paragraphs 1 and 2, and in the heading to paragraph 3, omit "EU";

(b) in paragraph 3, omit "EU", in each place it occurs;

(c) in paragraph 3.1 and in the heading to paragraph 3, for "CE" substitute "UK";

(50) In Annex VII—

(**3**) These Regulations implement, as respects Great Britain and Northern Ireland, Directive 2003/10/EC of the European Parliament and of the Council on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise), (OJ No L42, 15.2.2003, p 38). There are amendments not relevant to this instrument.

(a) in paragraphs 1, 2, 4.1, 4.2, 4.3, 4.4, 4.6 and 6.1, and in the heading to paragraph 6, omit "EU";

(b) in paragraph 3, in each place it occurs—

(i) for "notified" substitute "approved";

(ii) omit "EU";

(c) in paragraphs 4.1, 4.2, 4.3, 4.4, 4.6, 5.1 and 6.1, for "notified" substitute "approved";

(d) in paragraph 4.3, for "harmonised" substitute "designated";

(e) in paragraph 4.6, for "notifying authority" substitute "Secretary of State";

(f) in paragraph 5.3, for "notified", in both places, substitute "approved";

(g) in the heading to paragraph 6, and in paragraph 6.1, for "CE" substitute "UK";

(h) in paragraph 6.2, omit "EU", in each place it occurs.

(51) In Annex VIII—

(a) in paragraphs 1, 3.2, 3.6 and 5.1, and in the heading to paragraph 5, omit "EU";

(b) in paragraphs 3.1 and 5.2, omit "EU", in each place it occurs;

(c) in paragraphs 3.3, 4.2, 4.3, 5.1 and 6, and in the heading to paragraph 4, for "notified" substitute "approved";

(d) in paragraphs 3.1, 3.5, 3.6, 4.4 and 7, for "notified", in each place it occurs, substitute "approved";

(e) in paragraph 3.3, for "harmonised" substitute "designated";

(f) in the heading to paragraph 5, and in paragraph 5.1, for "CE" substitute "UK";

(g) in paragraph 5.2—

(i) in the first subparagraph (beginning "The manufacturer shall"), for "national authorities" substitute "enforcement authority";

(ii) in the second subparagraph (beginning "A copy of"), for "relevant authorities" substitute "enforcement authority";

(h) in paragraph 6, for "national authorities" substitute "enforcement authority";

(i) in paragraph 7, for "its notifying authority", in both places, substitute "the Secretary of State".

(52) In Annex IX—

(a) in the heading, omit "EU";

(b) in paragraph 5, for "Union harmonisation legislation" substitute "statutory requirements";

(c) in paragraph 6, for "harmonised" substitute "designated";

(d) in paragraphs 7 and 8, for "notified" substitute "approved";

(e) in paragraph 7, omit "EU" in both places it occurs.