
STATUTORY INSTRUMENTS

2008 No. 1597

The Supply of Machinery (Safety) Regulations 2008

PART 1

Preliminary

Citation, commencement and revocation

1.—(1) These Regulations may be cited as the Supply of Machinery (Safety) Regulations 2008 and shall come into force on 29th December 2009.

(2) The Regulations listed in the first column of the table in Schedule 1 are revoked to the extent specified in the third column of that table.

Interpretation

2.—(1) In these Regulations—

- (a) references to “the Directive” are references to Directive [2006/42/EC](#) of the European Parliament and of the Council on machinery, and amending Directive [95/16/EC](#)(1); and
- (b) Annexes I to XI to the Directive are reproduced in Schedule 2 (with minor changes reflecting the Directive’s application to the EEA(2), and certain details of the Directive’s implementation in these Regulations – in particular, the use of certain defined terms and the adoption of gender neutral drafting), so that each Annex is a separate Part of that Schedule; accordingly, where reference is made to an Annex designated by a Roman numeral, the reference is to the Part of Schedule 2 designated by the corresponding Arabic numeral and reproducing the text of the Annex to the Directive designated by that Roman numeral in the Directive.

(2) In these Regulations—

“the 1974 Act” means the Health and Safety at Work etc Act 1974(3);

“the 1978 Order” means the Health and Safety at Work (Northern Ireland) Order 1978(4);

“the 1987 Act” means the Consumer Protection Act 1987(5);

“the 1992 Regulations” means the Supply of Machinery (Safety) Regulations 1992(6);

“applicable” means, in relation to the application of essential health and safety requirements to any machine, those essential health and safety requirements which are expressed in Annex I (Part 1 of Schedule 2) as applying either to all machinery or to machinery of a category to which that machine belongs or which has a characteristic that it shares;

(1) O.J. No. L 157, 9.6.2006, p.24, with corrigendum at O.J. No. L 76, 16.3.2007, p.35.

(2) By virtue of Decision No. 6/2007 of the EEA Joint Committee: O.J. No. L 209, 9.8.2007, p.8.

(3) 1974 c.37.

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

(5) 1987 c.43.

(6) S.I. 1992/3073, amended by S.I. 1994/2063, S.I. 2004/693 and S.I. 2005/831.

“authorised representative” means a person established in an EEA state who has received a written mandate from the manufacturer to perform, on the manufacturer’s behalf, all or part of the obligations and formalities imposed on manufacturers (either as “manufacturers” or “responsible persons”) by these Regulations or otherwise in connection with the Directive;

“CE marking” means a mark consisting of the symbol “CE” set out in the form shown in Annex III (Part 3 of Schedule 2);

“chains, ropes and webbing” has the meaning given in regulation 4(2)(e);

“Commission” means Commission of the European Communities;

“conformity assessment” means the assessment, in accordance with Annex VIII, IX or X (Part 8, Part 9 or Part 10 of Schedule 2), of whether machinery, or a representative model of machinery, satisfies the applicable requirements of these Regulations, and “conformity assessment procedure” means the procedures specified in any of those Annexes;

“enforcement authority” means—

- (a) in Great Britain, subject to sub-paragraph (b)—
 - (i) in relation to machinery and partly completed machinery for use at work, the Health and Safety Executive; and
 - (ii) in relation to any other machinery or partly completed machinery—
 - (aa) within each local weights and measures authority’s area, that authority; or
 - (bb) the Secretary of State;
- (b) the Office of Rail Regulation where, in Great Britain, the Health and Safety (Enforcing Authority for Railways and Other Guided Transport Systems) Regulations 2006⁽⁷⁾ make it the enforcing authority, within the meaning of section 18(7) of the 1974 Act, in relation to machinery for use in the operation of a railway, tramway or any other system of guided transport, as defined in those Regulations; and
- (c) in Northern Ireland—
 - (i) in relation to machinery and partly completed machinery for use at work, the Health and Safety Executive for Northern Ireland; and
 - (ii) in relation to any other machinery or partly completed machinery—
 - (aa) within each district council’s area, that council; or
 - (bb) the Secretary of State;

“essential health and safety requirements” means the requirements set out in Annex I (Part 1 of Schedule 2), sections 1 to 6, read in the light of the General Principles set out at the start of that Annex;

“follow”, in relation to a responsible person and a conformity assessment procedure, means the responsible person complying with the requirements which the conformity assessment procedure, as expressed in Annex VIII, IX or X (Part 8, Part 9 or Part 10 of Schedule 2), imposes on responsible persons;

“harmonised standard” means a non-binding technical specification adopted by the European Committee for Standardisation (CEN), the European Committee for Electrotechnical Standardisation (CENELEC) or the European Telecommunications Standards Institute (ETSI), on the basis of a remit issued by the Commission in accordance with the procedures laid down in Directive [98/34/EC](#) of the European Parliament and of the Council of 22 June 1998

(7) [S.I. 2006/557](#), to which there are amendments not relevant to these Regulations.

laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services⁽⁸⁾;

“the Health and Safety Executive” (except where express reference is made to the Health and Safety Executive for Northern Ireland) means the Health and Safety Executive established under section 10 of the 1974 Act;

“the Health and Safety Executive for Northern Ireland” means the Health and Safety Executive for Northern Ireland established under Article 12 of the 1978 Order;

“interchangeable equipment” has the meaning given in regulation 4(2)(b);

“lifting accessory” has the meaning given in regulation 4(2)(d);

“machine” means an item of machinery;

“machinery” has the meaning given in regulation 4(3);

“manufacturer” means, in relation to machinery or partly completed machinery—

- (a) a person who designs or manufactures that machinery or partly completed machinery—
 - (i) with a view to its being placed on the market under that person’s own name or trademark; or
 - (ii) for that person’s own use in an EEA state; or
- (b) if there is no such person, the person who places that machinery or partly completed machinery on the market or puts it into service;

“notified body” means—

- (a) a UK notified body;
- (b) a person designated as a notified body for the purposes of the Directive by another EEA state and notified by that state to the Commission and the other EEA states under Article 14(1) of the Directive; or
- (c) a person recognised for the purpose of carrying out the functions of a notified body under the Directive under or by virtue of—
 - (i) a mutual recognition agreement relating to the Directive; or
 - (ii) a similar agreement (including a Protocol to a Europe Agreement, or another Agreement, on Conformity Assessment and Acceptance of Industrial Products), which has been concluded between the European Community and a state other than an EEA state;

“notified body criteria” has the meaning given in regulation 16(6);

“notified body designation” has the meaning given in regulations 16(2) and (4);

“official Community language” means an official language of an EEA state;

“partly completed machine” means an item of partly completed machinery;

“partly completed machinery” has the meaning given in regulation 6;

“place on the market” and related expressions have the meaning given in regulation 3;

“published harmonised standard” has the meaning given in regulation 7(4);

“put into service” and related expressions have the meaning given in regulation 3;

“removable mechanical transmission device” has the meaning given in regulation 4(2)(f);

“responsible person” means, in relation to machinery or partly completed machinery—

(8) O.J. No. L 204, 21.7.1998, p.37, as amended by Directives 98/48/EC (O.J. No. L 217, 5.8.1998, p.18) and 2006/96/EC (O.J. No. L 363, 20.12.2006, p.81).

- (a) the manufacturer of that machinery or partly completed machinery; or
- (b) the manufacturer's authorised representative;

“safe” means, in relation to machinery, that when it is properly installed and maintained, and used for the purposes for which it is intended, or under conditions which can reasonably be foreseen, it does not—

- (a) endanger the health of, or result in death or injury to, any person; or
- (b) where appropriate—
 - (i) endanger the health of, or result in death or injury to, domestic animals; or
 - (ii) endanger property;

“safety component” has the meaning given in regulation 4(2)(c);

“UK notified body” has the meaning given in regulation 16(3) and (4); and

“use at work” means, in relation to machinery or partly completed machinery, use or operation—

- (a) by persons at work (whether exclusively or not); or
- (b) otherwise than at work, in non-domestic premises made available to persons at a place where they may use the machinery or partly completed machinery provided for their use there,

and for these purposes, “at work” has the same meaning as it does under or by virtue of section 52 of the 1974 Act for the purposes of Part 1 of that Act.

Placing on the market and putting into service; supplies outside the EEA and showing at trade fairs not covered

3.—(1) In these Regulations, subject to paragraph (2)—

- (a) references to placing machinery or partly completed machinery on the market are references to making it available in an EEA state—
 - (i) for the first time;
 - (ii) with a view to distribution or use, whether by the person making it available or another; and
 - (iii) whether for reward or free of charge; and
- (b) references to putting any machinery or partly completed machinery into service are references to the first time that it is used for its intended purpose in an EEA state.

(2) For the purposes of these Regulations, machinery or partly completed machinery shall not be regarded as being placed on the market or put into service where—

- (a) it does not have affixed to it either the CE marking, or any inscription likely to be confused with the CE marking, and—
 - (i) it will not be put into service in an EEA state;
 - (ii) it is imported into an EEA state for re-export to a country which is not an EEA state; or
 - (iii) it is imported into an EEA state other than in the course of a business by a person who intends to use it other than in the course of a business; or
- (b) it is shown at a trade fair, exhibition or other similar demonstration; provided that, where any machinery or partly completed machinery which does not comply with the requirements of these Regulations which would apply to it but for this paragraph is shown at a trade fair, exhibition or other similar demonstration, the responsible person—

- (i) displays a notice in relation to it, stating that—
 - (aa) it does not comply with the requirements of these Regulations; and
 - (bb) it will not be made available until it does comply with those requirements;and
- (ii) takes adequate safety measures to ensure that it does not kill or injure any person.

PART 2

Application

Products to which Regulations apply; definition of “machinery”

- 4.—(1) These Regulations apply—
- (a) to products in respect of which the following conditions are satisfied—
 - (i) that they fall within one of the descriptions of products specified in paragraph (2);
 - (ii) that they do not fall within any of the categories of products specified in Schedule 3 as being products to which these Regulations do not apply;
 - (iii) that they are placed on the market or put into service on or after 29th December 2009; and
 - (iv) that these Regulations are not disapplied in respect of them by regulation 5; and
 - (b) to partly completed machinery, as defined in regulation 6.
- (2) The following descriptions of products are specified in this paragraph—
- (a) assemblies which fall within one of the following descriptions—
 - (i) an assembly, fitted with or intended to be fitted with a drive system other than directly applied human or animal effort, consisting of linked parts or components, at least one of which moves, and which are joined together for a specific application;
 - (ii) an assembly as referred to in sub-paragraph (i), missing only the components to connect it on site or to sources of energy and motion;
 - (iii) an assembly as referred to in sub-paragraph (i) or (ii), ready to be installed and able to function as it stands only if mounted on a means of transport, or installed in a building or structure;
 - (iv) assemblies of machinery as referred to in sub-paragraphs (i), (ii) and (iii) or partly completed machinery, which, in order to achieve the same end, are arranged and controlled so that they function as an integral whole;
 - (v) an assembly of linked parts or components, at least one of which moves and which are joined together, intended for lifting loads and whose only power source is directly applied human effort;
 - (b) devices which, after the putting into service of machinery or of a tractor, are assembled with that machinery or tractor by operators themselves in order to change its function or attribute a new function, in so far as they are not tools (“interchangeable equipment”);
 - (c) components—
 - (i) which serve to fulfil a safety function;
 - (ii) which are independently placed on the market;
 - (iii) the failure or malfunction of which endangers the safety of persons; and

- (iv) which are not necessary in order for the machinery to function, or for which other components which do not fall within sub-paragraphs (i) to (iii) may be substituted in order for the machinery to function, (“safety components”, examples of which are listed in Annex V (Part 5 of Schedule 2));
- (d) components or equipment (including slings and their components) which—
 - (i) are not attached to lifting machinery;
 - (ii) allow a load to be held;
 - (iii) are placed between the machinery and the load or on the load itself, or are intended to constitute an integral part of the load; and
 - (iv) are independently placed on the market (“lifting accessories”);
- (e) chains, ropes and webbing designed and constructed for lifting purposes as part of lifting machinery or lifting accessories (“chains, ropes and webbing”); and
- (f) removable components for transmitting power between self-propelled machinery or a tractor and another machine by joining them at the first fixed bearing (“removable mechanical transmission devices”) (when such components are placed on the market with a guard the components and the guard together shall be regarded as one product).

(3) Subject to paragraph (4), in these Regulations, the word “machinery” refers to products of any of the descriptions specified in paragraph (2) in respect of which the conditions specified in paragraph (1)(a)(ii), (iii) and (iv) are satisfied.

(4) Where an essential health and safety requirement is expressed to apply both to “machinery” generally and to a particular description of machinery referred to in paragraph (2)(b), (c), (d), (e) or (f), the general reference to “machinery” is to be understood—

- (a) as not referring to machinery of that particular description; and
- (b) as referring only to those descriptions of machinery referred to in paragraph (2) for which the hazard corresponding to that essential health and safety requirement exists when they are used under the conditions foreseen by the responsible person or in foreseeable abnormal situations.

Disapplication where more specific Community safety rules apply

5. These Regulations do not apply to a product if, or to the extent that, Community directives other than the Directive, which apply to it, make more specific provision than the Directive in connection with the hazards referred to in Annex I (Part 1 of Schedule 2).

Partly completed machinery

6.—(1) Subject to paragraph (2), provisions of these Regulations which refer to “partly completed machinery” apply to drive systems and other assemblies which—

- (a) are almost machinery;
- (b) cannot in themselves perform a specific application; and
- (c) are only intended to be incorporated into or assembled with other machinery or other partly completed machinery or equipment, thereby forming machinery.

(2) Paragraph (1) does not apply to assemblies of the kind described in paragraph (1) which—

- (a) are placed on the market before 29th December 2009; or

- (b) are only intended to be incorporated into or assembled with other products to form a product which falls within any of the categories of products specified in Schedule 3 as being products to which these Regulations do not apply.

PART 3

General prohibitions and obligations

Supply of machinery: general obligations and prohibition

7.—(1) No responsible person shall place machinery on the market or put it into service unless it is safe.

(2) Before machinery is placed on the market or put into service, the responsible person must—

- (a) ensure that the applicable essential health and safety requirements are satisfied in respect of it;
- (b) ensure that the technical file is compiled and made available in accordance with the requirements of Annex VII (Part 7 of Schedule 2), part A;
- (c) provide, in particular, the information necessary to operate it safely, such as instructions;
- (d) follow, as appropriate—
 - (i) the conformity assessment procedure prescribed by regulation 10;
 - (ii) one of the conformity assessment procedures prescribed by regulation 11; or
 - (iii) one of the conformity assessment procedures prescribed by regulation 12;
- (e) draw up the EC declaration of conformity in accordance with the requirements of Annex II (Part 2 of Schedule 2), section A, part 1, and ensure that—
 - (i) a copy of it accompanies the machinery; and
 - (ii) the original is retained in accordance with the requirements of Annex II, part 2, first paragraph; and
- (f) affix the CE marking to the machinery—
 - (i) visibly, legibly and indelibly; and
 - (ii) as prescribed in Annex III (Part 3 of Schedule 2).

(3) In order to comply with the requirements of paragraphs (1) and (2), a responsible person must carry out, or procure the carrying out of, all the necessary research and tests on components, fittings or the completed machinery to determine whether, by its design and construction, it is capable of being assembled and put into service safely.

(4) For the purposes of paragraph (2)(a), machinery which is manufactured in conformity with a harmonised standard, the references to which have been published in the *Official Journal of the European Union* (a “published harmonised standard”) shall be presumed to comply with the essential health and safety requirements covered by that standard.

(5) Where—

- (a) the conformity assessment procedure specified in regulations 11(2)(b) and 12(2)(a) has been followed; and
- (b) a type-examination certificate has been issued,

in respect of machinery, the manufacturer must comply with the ongoing obligations of manufacturers prescribed in Annex IX (Part 9 of Schedule 2), point 9, in respect of that machinery.

(6) Where—

- (a) the conformity assessment procedure specified in regulations 11(2)(c) and 12(2)(b) has been followed; and
- (b) a quality system has been approved,

in respect of machinery, the manufacturer must comply with the ongoing obligations of manufacturers prescribed in Annex X (Part 10 of Schedule 2) in respect of that machinery.

Supply of partly completed machinery: general obligations and prohibition

8.—(1) Before partly completed machinery is placed on the market, the responsible person must ensure that—

- (a) the relevant technical documentation is prepared and made available in accordance with the requirements of Annex VII (Part 7 of Schedule 2), part B;
- (b) assembly instructions are prepared in accordance with Annex VI (Part 6 of Schedule 2);
- (c) a declaration of incorporation has been drawn up in accordance with Annex II (Part 2 of Schedule 2), part 1, section B, and that—
 - (i) a copy of it accompanies the machinery; and
 - (ii) the original is retained in accordance with Annex II, part 2, second paragraph.

(2) The assembly instructions and the declaration of incorporation shall accompany partly completed machinery until it is incorporated into machinery.

(3) After partly completed machinery is incorporated into machinery its assembly instructions and declaration of incorporation shall form part of the technical file for that machinery.

(4) In order to comply with the requirements of paragraph (1), a responsible person must carry out, or procure the carrying out of, all the necessary research and tests on components, fittings or the partly completed machinery to determine whether, by its design and construction, it is capable of being assembled and used safely.

Putting machinery into service

9. A person who is not a responsible person shall not put machinery into service unless it satisfies the applicable essential health and safety requirements and is safe.

Conformity assessment procedures

Machinery not referred to in Annex IV

10. If machinery falls within a category which is not referred to in Annex IV (Part 4 of Schedule 2), the responsible person shall follow the conformity assessment procedure with internal checks on the manufacture of machinery prescribed in Annex VIII (Part 8 of Schedule 2) in respect of it.

Annex IV machinery manufactured fully in accordance with published harmonised standards and fully covered by such standards

11.—(1) This regulation applies to machinery—

- (a) which falls within a category which is referred to in Annex IV (Part 4 of Schedule 2); and
- (b) in respect of which both of the following conditions are satisfied—
 - (i) that the machinery is manufactured in accordance with published harmonised standards; and

(ii) that the published harmonised standards in accordance with which it is manufactured cover all the applicable essential health and safety requirements.

(2) Where this regulation applies, the responsible person shall follow one of the following conformity assessment procedures—

- (a) the conformity assessment procedure with internal checks on the manufacture of machinery prescribed in Annex VIII (Part 8 of Schedule 2); or
- (b) the EC type-examination procedure prescribed in Annex IX (Part 9 of Schedule 2) and the internal checks on the manufacture of machinery prescribed in Annex VIII, point 3; or
- (c) the full quality assurance procedure prescribed in Annex X (Part 10 of Schedule 2).

Annex IV machinery not manufactured fully in accordance with published harmonised standards or not fully covered by such standards

12.—(1) This regulation applies to machinery—

- (a) which falls within a category which is referred to in Annex IV (Part 4 of Schedule 2); and
- (b) in respect of which any of the following conditions is satisfied—
 - (i) that the machinery is not manufactured in accordance with the published harmonised standards which relate to it; or
 - (ii) that the machinery is only partly manufactured in accordance with the published harmonised standards which relate to it; or
 - (iii) that the published harmonised standards in accordance with which the machinery is manufactured do not cover all the applicable essential health and safety requirements; or
 - (iv) that no harmonised standards exist for the machinery.

(2) Where this regulation applies, the responsible person shall follow one of the following conformity assessment procedures—

- (a) the EC type-examination procedure prescribed in Annex IX (Part 9 of Schedule 2) and the internal checks on the manufacture of machinery prescribed in Annex VIII (Part 8 of Schedule 2), point 3; or
- (b) the full quality assurance procedure prescribed in Annex X (Part 10 of Schedule 2).

PART 4

CE Marking

CE-marked machinery to be taken to comply with Regulations

13.—(1) Unless there is evidence to the contrary—

- (a) an enforcement authority;
- (b) the Secretary of State (where the Secretary of State is not an enforcement authority); and
- (c) any court or tribunal of competent jurisdiction which is called upon to decide a matter which involves the application of these Regulations,

shall presume that machinery which bears the CE marking and is accompanied by an EC declaration of conformity which complies with Annex II (Part 2 of Schedule 2), part 1, section A complies with these Regulations.

(2) The failure or refusal by a responsible person, in response to a duly reasoned request from an enforcement authority, to make the technical file or a copy of it available in accordance with Annex VII (Part 7 of Schedule 2), part A, point 2 shall be reasonable grounds for the authority—

- (a) to doubt the conformity of machinery with the essential health and safety requirements, in accordance with Annex VII, part A, point 3; or
- (b) to doubt the conformity of partly completed machinery with the essential health and safety requirements, in accordance with Annex VII, part B, last paragraph,

and it may make such use of its powers under Schedule 5 as is appropriate in the light of such doubts.

Machinery covered by more than one Directive

14.—(1) Subject to paragraph (2), where machinery falls within the scope of a Community directive other than the Directive (“the other Directive”), the affixing of the CE marking indicates that the relevant requirements of the other Directive are also satisfied.

(2) Where—

- (a) the other Directive includes a provision allowing the responsible person to choose, during a transitional period that has not ended, the system to be applied;
- (b) the responsible person takes advantage of this option; and
- (c) the particulars of the other Directive which the responsible person has chosen to apply, as published in the *Official Journal of the European Union*, are given in the EC declaration of conformity,

the affixing of the CE marking indicates that the machinery conforms only to the provisions of the other Directive which the responsible person has chosen to apply.

Protection of CE marking

15.—(1) No person shall affix the CE marking to machinery which does not comply with these Regulations.

(2) No person shall affix to machinery any marking, sign or inscription which is likely to mislead any other person as to the meaning or form of the CE marking (or both).

(3) Other markings may be affixed to machinery which bears the CE marking only if the visibility, legibility or meaning of the CE marking is not impaired as a result.

PART 5

Notified bodies

Designation and monitoring of UK notified bodies

16.—(1) The Secretary of State may designate a person to carry out conformity assessment.

(2) Except as provided in paragraph (4), any such designation (a “notified body designation”) shall be made in accordance with paragraphs (5) to (9) of this regulation.

(3) A person in respect of whom—

- (a) a notified body designation has been made under this regulation; and
- (b) whose designation has been notified by the Secretary of State to the Commission and the other EEA states under Article 14(1) of the Directive,

is a “UK notified body” to the extent that that designation remains in effect.

(4) If a person holds an appointment as a United Kingdom approved body under the 1992 Regulations which has been notified to the Commission and the other EEA states under Article 9(1) of Directive 98/37/EC and has not been terminated—

(a) the appointment—

- (i) is a “notified body designation” for the purposes of these Regulations; and
- (ii) shall be varied in accordance with regulation 17 to the extent that it is necessary or expedient to vary it to take account of the repeal of Directive 98/37/EC and the revocation of the 1992 Regulations and their replacement by the Directive and these Regulations; and

(b) that person is a “UK notified body” to the extent that the appointment remains in effect.

(5) Except where paragraph (4) applies, any person wishing to be a UK notified body must apply to the Secretary of State for designation under this regulation.

(6) A notified body designation shall not be made unless the Secretary of State is satisfied that the person in respect of whom it is to be made meets the criteria specified in Annex XI (Part 11 of Schedule 2) (the “notified body criteria”).

(7) A person who meets the assessment criteria laid down in a published harmonised standard shall be presumed to meet that part of the notified body criteria which corresponds to the criteria in that standard.

(8) A notified body designation—

- (a) shall be in writing;
- (b) shall specify the conformity assessment procedures that the person designated may carry out;
- (c) may relate to all the categories of machinery listed in Annex IV (Part 4 of Schedule 2) or to such of those categories as are specified in the designation;
- (d) may designate a person for a specified period; and
- (e) may be made subject to such other conditions as are specified in the designation, including conditions which are to apply upon or following termination of the designation.

(9) In making a notified body designation the Secretary of State may have regard (in addition to the notified body criteria) to any other matter which appears to the Secretary of State to be relevant.

(10) The Secretary of State shall, from time to time, publish a list of UK notified bodies, identifying, in the case of each UK notified body, the description of machinery for which that notified body is designated.

(11) The Secretary of State shall, from time to time, carry out an inspection of each UK notified body with a view to verifying that it—

- (a) meets the notified body criteria;
- (b) complies with any condition to which its designation is subject; and
- (c) complies with these Regulations.

(12) A UK notified body shall comply with any request of the Secretary of State to provide information relevant to determining its compliance with the notified body criteria, these Regulations, or any condition to which its designation is subject.

Duration, variation and termination of designations

17.—(1) A notified body designation which does not designate a person as a UK notified body for a specified period shall have effect until such time as it is terminated under paragraph (4).

(2) A notified body designation which designates a person as a UK notified body for a specified period shall expire in accordance with its terms unless the period so specified is extended or shortened under paragraph (3) before the date on which it had been due to expire.

(3) The Secretary of State may vary any aspect of a notified body designation if—

- (a) the UK notified body so requests; or
- (b) it appears to the Secretary of State necessary or expedient to do so.

(4) The Secretary of State may terminate a notified body designation—

- (a) on the expiry of 90 days' notice in writing at the request of the UK notified body;
- (b) if it appears to the Secretary of State that any condition of the designation is not complied with; or
- (c) if the Secretary of State considers that the UK notified body no longer satisfies the notified body criteria.

(5) Where the Secretary of State is minded to vary a notified body designation in accordance with paragraph (3)(b), or to terminate a notified body designation under paragraph (4)(b) or (c), the Secretary of State shall—

- (a) give notice in writing to the UK notified body of the proposed variation or termination and the reasons for it, stating that the UK notified body has 21 days from the date of the notice in which to make representations to the Secretary of State in respect of the proposed variation or termination; and
- (b) consider any representations received from the UK notified body in accordance with the notice.

(6) If a notified body designation is terminated under paragraph (4), the Secretary of State may, by notice in writing—

- (a) authorise another UK notified body to take over the functions of the UK notified body whose designation has been terminated in respect of such cases as are specified in the notice; and
- (b) give such directions as the Secretary of State considers appropriate (either to the UK notified body whose designation has been terminated or to another UK notified body) in respect of a UK notified body's files or any other matter which the Secretary of State considers expedient for the purposes of ensuring that another notified body carries out the functions of a notified body for the existing customers of the notified body whose designation has been terminated.

Functions of UK notified bodies

18.—(1) Subject to the terms of their notified body designations and paragraph (2), UK notified bodies shall carry out the functions of notified bodies specified in Annexes IX and X (Parts 9 and 10 of Schedule 2).

(2) A UK notified body shall not be obliged to carry out these functions where—

- (a) the documents submitted to it in relation to the carrying out of any such function (other than the instructions for the machinery) are not in English or another language acceptable to the body;
- (b) the responsible person has not submitted with its application the amount of the fee which the body requires to be submitted with the application; or
- (c) the body reasonably believes that, having regard to the number of outstanding applications made to it in relation to its appointment under these Regulations, it will be unable to carry out the required work within 3 months of receiving the application.

(3) If, having issued a certificate to a responsible person under Annex IX or an approval to a manufacturer under Annex X, a UK notified body finds—

- (a) that the manufacturer has, after the issue of that certificate or approval, failed to satisfy applicable requirements of these Regulations in respect of the machinery to which the certificate or approval relates (whether or not such failure is continuing); or
- (b) that the certificate or approval should not have been issued,

it shall proceed in accordance with paragraph (4).

(4) Where paragraph (3) applies, the UK notified body concerned shall—

- (a) consider—
 - (i) what corrective action, if any, the manufacturer should take in the light of its findings; and
 - (ii) whether, and, if so, on what terms, the certificate or approval should be suspended, withdrawn, or made subject to restrictions;
- (b) send to the manufacturer a notice in writing, setting out the conclusions it has provisionally reached under paragraph (a), and the reasons for those conclusions, and invite the manufacturer to respond to them within such reasonable period of time as is specified in the notice;
- (c) make a decision on the matters specified in paragraph (a), including provision for the suspension or withdrawal of a certificate or approval, or making it subject to restrictions, if it considers the taking of any such action appropriate, having regard to—
 - (i) the manufacturer's response;
 - (ii) the principle of proportionality; and
 - (iii) paragraph (6); and
- (d) communicate the decision, with a detailed statement of the reasons for it, to the manufacturer.

(5) Where a UK notified body, acting under paragraph (4)—

- (a) suspends or withdraws a certificate, or makes it subject to restrictions; or
- (b) considers that action by an enforcement authority may prove necessary in connection with the machinery which is the subject of its decision,

it shall communicate its decision under that paragraph to the enforcement authorities and the Secretary of State (if the Secretary of State is not an enforcement authority in relation to the machinery concerned).

(6) In making a decision under paragraph (4), a UK notified body shall not suspend or withdraw a certificate or approval, or make it subject to restrictions, if the manufacturer has ensured compliance with the applicable requirements of these Regulations by means of appropriate corrective measures.

(7) An appeal may be made in accordance with the provisions of Schedule 4—

- (a) by a manufacturer who is aggrieved by a decision which a UK notified body has made under paragraph (4); or
- (b) by a responsible person who is aggrieved by a decision of a UK notified body—
 - (i) not to issue a type-examination certification pursuant to Annex IX (Part 9 of Schedule 2), point 5; or
 - (ii) in relation to a quality system which is notified to a responsible person pursuant to Annex X (Part 10 of Schedule 2), point 2.3.

Fees

19.—(1) A UK notified body may charge such fees in connection with, or incidental to, carrying out its functions under regulation 18 as it may determine; provided that such fees shall not exceed the sum of—

- (a) the costs incurred or to be incurred by the body in performing the relevant functions; plus
- (b) an amount on account of profit which is reasonable in the circumstances having regard to—
 - (i) the character and extent of the work done or to be done by the body on behalf of the responsible person; and
 - (ii) the commercial rate normally charged on account of profit for that work or similar work.

(2) A UK notified body may require the payment of fees or a reasonable estimate of fees in advance of carrying out the work required by the responsible person.

PART 6**Enforcement****General duties and powers of enforcement authorities**

20. Schedule 5, which makes provision about the general duties and powers of enforcement authorities, shall have effect.

Non-compliance with CE marking requirements

21.—(1) For the purposes of this regulation, a product is deficient as regards CE marking—

- (a) if it is not subject to the Directive, but the CE marking is affixed to it pursuant to the Directive; or
- (b) if it is machinery and—
 - (i) the CE marking is not affixed to it;
 - (ii) it is not accompanied by a copy of the EC declaration of conformity; or
 - (iii) the CE marking is affixed to it but it does not conform to the relevant provisions of these Regulations; or
 - (iv) a marking other than the CE marking, which is prohibited by regulation 15(2) or (3), is affixed to it.

(2) Where an enforcement authority has reasonable grounds for suspecting that a product is deficient as regards CE marking, but does not have reasonable grounds for suspecting that it is not safe, the enforcement authority may take action under the following provisions as they are applied by Schedule 5—

- (a) in the case of the Health and Safety Executive or the Office of Rail Regulation, section 20 of the 1974 Act;
- (b) in the case of the Health and Safety Executive for Northern Ireland, Article 22 of the 1978 Order; and
- (c) in the case of any other enforcement authority, section 29 of the 1987 Act,

but no other action may be taken pursuant to Schedule 5 and no proceedings may be brought pursuant to regulation 22 in respect of that product until the enforcement authority has served on the

responsible person a notice in writing in accordance with paragraph (3) and the responsible person has failed to comply with its requirements.

(3) Where an enforcement authority has reasonable grounds for considering that a product is deficient as regards CE marking, it may serve a notice on the responsible person which—

- (a) identifies the product concerned;
- (b) states that the enforcement authority considers that it is deficient as regards CE marking and the reasons why the authority considers that this is the case;
- (c) requires the responsible person to take (or refrain from taking) specified action within a specified period to bring the deficiency to an end; and
- (d) warns the responsible person that if the deficiency continues beyond the period specified in the notice, further action may be taken under these Regulations.

(4) In any proceedings under regulation 22 in respect of a person's alleged failure to comply with a notice under paragraph (3), an enforcement authority must show that the product concerned was deficient as regards CE marking at the time when the notice was served.

Offences and penalties

22.—(1) A person who contravenes or fails to comply with—

- (a) a requirement of regulations 7, 8, 9, 10, 11, 12 or 15; or
- (b) a requirement under regulation 21(3)(c) of a notice served under regulation 21(3);

is guilty of an offence.

(2) Subject to paragraph (3), a person guilty of an offence under paragraph (1) shall be liable—

- (a) on summary conviction, to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding three months or to both; and
- (b) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both.

(3) A person who is guilty of an offence as a result of having contravened or failed to comply with—

- (a) regulation 7(2)(b), (e) or (f);
- (b) regulation 8;
- (c) regulation 15; or
- (d) a requirement under regulation 21(3)(c) of a notice served under regulation 21(3);

shall be liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Defence of due diligence

23.—(1) Subject to the following provisions of this regulation, in proceedings for an offence under these Regulations, a person who is shown to have taken all reasonable steps and exercised all due diligence to avoid committing the offence shall have a defence.

(2) Where, in any proceedings against a person for such an offence, the defence provided by paragraph (1) involves an allegation that the commission of the offence was due to—

- (a) the act or default of another; or
- (b) reliance on information given by another,

such a defence shall not, without leave of the court, be relied on unless, not later than seven clear days before the hearing of the proceedings (or, in Scotland, the trial diet), that person has served a notice in accordance with paragraph (3) on the person bringing the proceedings.

(3) A notice under this regulation shall give such information identifying or assisting in the identification of the person who committed the act or default or gave the information as is in the possession of the person serving the notice at the time it is served.

(4) A person shall not be entitled to rely on the defence provided by paragraph (1) by reason of that person's reliance on information supplied by another, unless it is shown that it was reasonable in all the circumstances for that person to have relied on the information, having regard in particular to—

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

Liability of persons other than the principal offender

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

(2) Where a body corporate commits an offence and it is proved that the offence was committed—

- (a) with the consent or connivance of an officer of the body corporate; or
- (b) as a result of the negligence of an officer of the body corporate,

the officer, as well as the body corporate, shall be guilty of the offence.

(3) In paragraph (2), a reference to an officer of a body corporate includes a reference to—

- (a) a director, manager, secretary or other similar officer of the body corporate;
- (b) a person purporting to act as a director, manager, secretary or other similar officer; and
- (c) if the affairs of the body corporate are managed by its members, a member.

(4) In this regulation, references to a “body corporate” include references to a partnership in Scotland, and in relation to such partnership, any reference to a director, manager, secretary or other similar officer of a body corporate is a reference to a partner.

PART 7

Miscellaneous

Amendment of the Lifts Regulations 1997

25. The amendments to the Lifts Regulations 1997⁽⁹⁾ specified in Schedule 6 shall have effect.

Other amendments

26. The amendments specified in Schedule 7 shall have effect.

Consequential disapplication of domestic health and safety law

27.—(1) Subject to paragraph (3), any requirement which—

- (a) is imposed by or under any of the enactments (relating to various aspects of the safety of machinery) specified in paragraph (2); and

(9) [S.I. 1997/831](#), amended by [S.I. 2004/693](#) and [S.I. 2005/831](#).

(b) but for this paragraph, would have to be satisfied by or in respect of machinery if it is to be lawfully placed on the market or put into service,
is disapplied.

(2) The enactments specified in this paragraph are—

- (a) section 83 of the Mines and Quarries Act 1954⁽¹⁰⁾;
- (b) section 85(1) of the Mines Act (Northern Ireland) 1969⁽¹¹⁾;
- (c) regulation 3(3) of the Coal and Other Mines (Locomotives) Regulations 1956⁽¹²⁾;
- (d) regulation 52 of the Miscellaneous Mines (General) Regulations 1956⁽¹³⁾;
- (e) regulation 11 of the Coal Mines (Firedamp Drainage) Regulations 1960⁽¹⁴⁾;
- (f) in the Docks Regulations 1988⁽¹⁵⁾—
 - (i) regulation 13(1)(a), (b), and (c);
 - (ii) the words “or assembled” in regulation 13(1)(d); and
 - (iii) regulations 13(2)(b), (c) and (d);
- (g) in the Docks Regulations (Northern Ireland) 1989⁽¹⁶⁾—
 - (i) regulation 13(1)(a), (b), and (c);
 - (ii) the words “or assembled” in regulation 13(1)(d); and
 - (iii) regulations 13(2)(b), (c) and (d);
- (h) regulation 26 of the Electricity at Work Regulations 1989⁽¹⁷⁾;
- (i) regulation 26 of the Electricity at Work Regulations (Northern Ireland) 1991⁽¹⁸⁾; and
- (j) regulations 4 to 8 of the Boulby Mine (Storage and Battery Locomotives) Special Regulations 1972⁽¹⁹⁾.

(3) This regulation does not affect the application of the enactments listed in paragraph (2) to machinery after it has been placed on the market or put into service.

Time-limited derogation for impact machinery

28. These Regulations shall not have effect in relation to—

- (a) portable cartridge-operated fixing machinery; or
- (b) other impact machinery,

before 29 June 2011, but shall have effect in relation to such machinery from that date.

⁽¹⁰⁾ 1954 c.70.

⁽¹¹⁾ 1969 c.6.

⁽¹²⁾ S.I. 1956/1771.

⁽¹³⁾ S.I. 1956/1778.

⁽¹⁴⁾ S.I. 1960/1015.

⁽¹⁵⁾ S.I. 1988/1655.

⁽¹⁶⁾ S.R. 1989 No. 320.

⁽¹⁷⁾ S.I. 1989/635.

⁽¹⁸⁾ S.R. 1991 No. 13.

⁽¹⁹⁾ S.I. 1972/472.

19th June 2008

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and Consumer Affairs,
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