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STATUTORY INSTRUMENTS

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**1992 No. 3073**

**The Supply of Machinery (Safety) Regulations 1992**

**PART III**

**GENERAL REQUIREMENTS**

**General duty**

**11.**—(1) Subject to paragraph (3) below, no person shall supply relevant machinery unless the requirements of regulation 12 below are complied with in relation thereto.

(2) Where a person—

- (a) being the manufacturer of relevant machinery, himself puts that relevant machinery into service in the course of a business; or
- (b) having imported relevant machinery from a country or territory outside the Community, himself puts that relevant machinery into service in the course of a business,

for the purposes of these Regulations that person shall be deemed to have supplied that relevant machinery to himself.

(3) The requirements of paragraph (1) above do not apply in relation to supply by any person of relevant machinery which has previously been put into service in the Community.

**Requirements for supply of relevant machinery**

**12.**—(1) The requirements of this regulation are that—

- (a) the relevant machinery satisfies the relevant essential health and safety requirements;
- (b) the appropriate conformity assessment procedure in respect of the relevant machinery has been carried out by the responsible person in accordance with one of the procedures described in regulations 13, 14 and 15 below;
- (c) the responsible person, at his election, has issued either—
  - (i) an EC declaration of conformity in accordance with regulation 22 below; or
  - (ii) in the case of relevant machinery to which regulation 23 below applies, a declaration of incorporation in accordance with that regulation,in respect of the relevant machinery;
- (d) except in the case of relevant machinery to which regulation 23 below applies, the EC mark has been properly affixed by the responsible person to the relevant machinery in accordance with regulation 25 below; and
- (e) the relevant machinery is in fact safe.

(2) It is the responsibility of the manufacturer of relevant machinery to carry out the necessary research or tests on components, fittings or the completed machine to determine whether by its design or construction the machine is capable of being erected and put into service safely.

### *Conformity assessment procedures*

#### **Relevant machinery other than Schedule 4 machinery**

**13.—**(1) In the case of relevant machinery which is not Schedule 4 machinery the responsible person must draw up a technical file which comprises—

- (a) an overall drawing of the machinery together with drawings of the control circuits;
- (b) full detailed drawings, accompanied by any calculation notes, test results and such other data as may be required to check the conformity of the machinery with the essential health and safety requirements;
- (c) a list of:
  - (i) the essential health and safety requirements;
  - (ii) transposed harmonised standards;
  - (iii) standards; and
  - (iv) other technical specifications,which were used when the machinery was designed;
- (d) a description of methods adopted to eliminate hazards presented by the machinery;
- (e) if he so desires, any technical report or certificate obtained from a competent body or laboratory<sup>(1)</sup>;
- (f) if he declares conformity with a transposed harmonised standard which provides therefor, any technical report giving the results of tests carried out at his choice either by himself or by a competent body or laboratory; and
- (g) a copy of the instructions for the machinery drawn up in accordance with paragraph 1.7.4 of Schedule 3 hereto.

(2) For series manufacture, the responsible person must also have available documentation in respect of the internal measures that will be implemented to ensure that all the items of machinery so produced are in conformity with the provisions of the Machinery Directive.

(3) Where the file referred to in paragraph (1) above is drawn up in the United Kingdom it shall be in English always provided that the instructions for the machinery referred to in sub-paragraph (g) thereof shall be in such languages as are specified in paragraph 1.7.4(b) of Schedule 3 hereto.

#### **Schedule 4 machinery manufactured in accordance with transposed harmonised standards**

**14.—**(1) In the case of relevant machinery which is Schedule 4 machinery manufactured in accordance with transposed harmonised standards the responsible person must, at his election—

- (a) draw up and forward to an approved body for retention by that body a technical file;
- (b) submit the technical file referred to in paragraph (a) above to an approved body requesting—
  - (i) verification by that body that the transposed harmonised standards have been correctly applied; and
  - (ii) that the body draw up a certificate of adequacy for the file submitted in accordance with regulation 20 below; or
- (c) submit the technical file referred to in paragraph (a) above to an approved body together with an example of the relevant machinery for EC type-examination or, where appropriate,

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(1) A body or laboratory meeting the assessment criteria laid down in the relevant harmonised standards is presumed to be competent for the purposes of this regulation.

a statement as to where such an example might be examined, in accordance with regulation 21 below.

- (2) The technical file referred to in this regulation and regulation 15 below must include—
- (a) an overall drawing of the machinery together with drawings of the control circuits;
  - (b) full detailed drawings, accompanied by any calculation notes, test results and such other data as may be required to check the conformity of the machinery with the essential health and safety requirements;
  - (c) a description of methods adopted to eliminate hazards presented by the machinery, a list of transposed harmonised standards used and, in the case of relevant machinery to which regulation 15 below applies, a list of standards used;
  - (d) a copy of the instructions for the machinery drawn up in accordance with paragraph 1.7.4 of Schedule 3 hereto; and
  - (e) for series manufacture, the internal measures that will be implemented to ensure that all the items of machinery so produced are in conformity with the provisions of the Machinery Directive.

(3) The technical file referred to in this regulation and regulations 15 and 21(2) below must be drawn up in an official language of the member State in which the approved body is established (in the United Kingdom, English) or in such other language as is acceptable to the approved body, always provided that the instructions for the machinery referred to in paragraph 2(d) above shall be in such languages as are specified in paragraph 1.7.4(b) of Schedule 3 hereto.

#### **Schedule 4 machinery not manufactured in accordance with transposed harmonised standards**

- 15.** In the case of relevant machinery which is Schedule 4 machinery and—
- (a) which is not manufactured in accordance with transposed harmonised standards;
  - (b) which is only partly manufactured in accordance with transposed harmonised standards; or
  - (c) in respect of which there are no transposed harmonised standards,

the responsible person must submit a technical file, as described in regulation 14(2) above, to an approved body together with an example of the machinery for EC type examination or, where appropriate, a statement as to where such an example might be examined, in accordance with regulation 21 below.

#### **Modifications to relevant machinery**

**16.** Where the responsible person complies with one of the conformity assessment procedures referred to in regulation 14 or 15 above he must inform the approved body of any modifications, even of a minor nature, which he or, where the responsible person is not the manufacturer, the manufacturer has made or plans to make to the relevant machinery to which the technical file relates.

#### **Approved bodies**

**17.** For the purposes of these Regulations, an approved body is a body responsible for carrying out functions relating to the conformity assessment procedures set out in Article 8 of the Machinery Directive and described in regulations 14 and 15 above which has been—

- (a) appointed as a United Kingdom approved body pursuant to regulation 18 below; or
- (b) appointed by a member State other than the United Kingdom,

and in the case of either (a) or (b) above has been notified by the member State concerned to the Commission and the other member States pursuant to Article 9(1) of the Machinery Directive.

### **United Kingdom approved bodies**

**18.**—(1) The Secretary of State may from time to time appoint such qualified persons as he thinks fit to be United Kingdom approved bodies for the purposes of these Regulations.

(2) An appointment—

- (a) may relate to all descriptions of Schedule 4 machinery or such descriptions (which may be framed by reference to any circumstances whatsoever) of Schedule 4 machinery as the Secretary of State may from time to time determine;
- (b) may be made subject to such conditions as the Secretary of State may from time to time determine, and such conditions may include conditions which are to apply upon or following termination of the appointment;
- (c) shall, without prejudice to the generality of sub-paragraph (b) above, require that body, subject to paragraph (4) below—
  - (i) to acknowledge receipt of technical files submitted to it for retention pursuant to regulation 14(1)(a) above;
  - (ii) to carry out the required procedures in respect of the provision of certificates of adequacy at the request of responsible persons in accordance with regulation 20 below; and
  - (iii) to carry out EC type-examinations of examples of Schedule 4 machinery submitted to it or, where appropriate, made available for examination, in accordance with regulation 21 below;
- (d) shall be terminated—
  - (i) if it appears to the Secretary of State that the approved body is no longer a qualified person; or
  - (ii) upon 90 days' notice in writing to the Secretary of State, at the request of the approved body; and
- (e) may be terminated if it appears to the Secretary of State that any of the conditions of the appointment are not complied with.

(3) Subject to paragraph (2)(d) and (e) above, an appointment under this regulation may be for the time being or for such period as may be specified in the appointment.

(4) A United Kingdom approved body shall not be required to carry out the functions referred to in paragraph (2)(c) above where—

- (a) the documents submitted to it (other than the instructions for the machinery) in relation to carrying out such functions are not in English or another language acceptable to that 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 pursuant to regulation 19 below; or
- (c) the body reasonably believes that, having regard to the number of applications made to it in relation to its appointment under these Regulations which are outstanding, it will be unable to carry out the required work within 3 months of receiving the application.

(5) If for any reason the appointment of an approved body is terminated under this regulation, the Secretary of State may authorise another United Kingdom approved body to take over its functions in respect of such cases as he may specify.

(6) In this regulation—

“qualified person” means a person (which may include the Secretary of State) who meets the minimum criteria; and

“minimum criteria” means the criteria set out in Annex VII of the Machinery Directive (minimum criteria to be taken into account by member States for the notification of bodies)(2).

## **Fees**

**19.**—(1) Without prejudice to the power of the Secretary of State, where he is a United Kingdom approved body, to charge fees pursuant to regulations made under section 56 of the Finance Act 1973(3) and subject to paragraph (2) below, a United Kingdom approved body other than the Secretary of State may charge such fees in connection with, or incidental to, carrying out its duties in relation to the functions referred to in regulation 18(2)(c) above as it may determine; provided that such fees shall not exceed the sum of the following—

- (a) the costs incurred or to be incurred by the approved body in performing the relevant function; and
- (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) The power in paragraph (1) above includes the power to require the payment of fees or a reasonable estimate thereof in advance of carrying out the work requested by the responsible person.

## **Certificate of adequacy**

**20.**—(1) A certificate of adequacy is a document drawn up by an approved body to which a technical file as described in regulation 14(2) above has been submitted in which that body certifies that—

- (a) the transposed harmonised standards have been correctly applied in respect of the design and construction of the relevant machinery to which the file relates; and
- (b) the file contains all the necessary information.

(2) A United Kingdom approved body to which such a file has been submitted by a responsible person as described in regulation 14(1)(b) above shall, if satisfied in respect of the matters referred to in paragraph (1)(a) and (b) above, draw up a certificate of adequacy in respect of the file, and send a copy thereof to the responsible person.

(3) If the United Kingdom approved body is not so satisfied, it shall—

- (a) give the responsible person the opportunity, within a reasonable period, of making representations as to why it should not refuse to draw up a certificate of adequacy for the file; and
- (b) if, after considering any representations made pursuant to sub-paragraph (a) above, it remains unsatisfied in respect of the matters referred to in paragraph (1)(a) and (b) above, it shall—
  - (i) refuse to draw up a certificate of adequacy for the file;

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(2) Approved bodies meeting the assessment criteria laid down in the relevant harmonised standards are presumed to meet the minimum criteria.

(3) 1973 c. 51.

- (ii) notify its decision in writing to the responsible person who submitted the file stating the grounds on which such refusal is based; and
- (iii) at the same time inform all other approved bodies of such decision.

(4) Where the United Kingdom approved body which has drawn up a certificate of adequacy for a technical file is notified, pursuant to regulation 16 above, by the responsible person who submitted the file of a modification which he or, where the responsible person is not the manufacturer, the manufacturer has made, or plans to make, to the relevant machinery to which the file relates, the United Kingdom approved body shall examine such modification and—

- (a) if it is satisfied that the requirements of paragraph (1)(a) and (b) above are or, as the case may be, would be met in respect of the relevant machinery so modified, it shall notify the responsible person in writing that the certificate of adequacy remains valid; or
- (b) if it is not so satisfied it shall notify the responsible person in writing that the certificate of adequacy for the file does not or would not, as the case may be, remain valid in respect of the relevant machinery as modified stating the grounds on which such decision was based.

### **EC type-examination**

**21.**—(1) EC type-examination is the procedure whereby an approved body ascertains and certifies that an example of relevant machinery satisfies those provisions of the Machinery Directive which apply to it.

(2) An application for EC type-examination by a responsible person (in this regulation referred to as the applicant) to a United Kingdom approved body shall—

- (a) specify—
  - (i) the name and address of the applicant; and
  - (ii) the place of manufacture of the machinery to which the application relates; and
- (b) be accompanied by—
  - (i) a technical file for the machinery as described in regulation 14(2) above; and
  - (ii) an example of the machinery or, where appropriate, a statement as to where such an example might be examined.

(3) The United Kingdom approved body to which such application is made shall satisfy itself that the technical file contains all the necessary information.

(4) The United Kingdom approved body shall also—

- (a) examine and perform such tests as it considers appropriate on the example; and
- (b) if satisfied that—
  - (i) the example has been manufactured in conformity with the technical file and may safely be used under its intended working conditions;
  - (ii) the standards or transposed harmonised standards, as the case may be, if used, have been properly applied; and
  - (iii) the example complies with the relevant essential health and safety requirements,draw up and forward to the applicant an EC type-examination certificate which shall state the conclusions of the EC type-examination, indicate any conditions to which the issue of the certificate is subject and shall be accompanied by the descriptions and drawings necessary to identify the example to which the certificate relates.

(5) The United Kingdom approved body shall, if so requested, taking the necessary measures to guarantee confidentiality, supply to the Secretary of State a copy of the EC type-examination

certificate, a copy of the technical file and copies of the reports on the examinations and tests that it has carried out in relation to that application.

(6) If the United Kingdom approved body is not satisfied that the requirements of paragraphs (3) and (4)(b) above are met and is minded to refuse to issue an EC typeexamination certificate, it shall—

- (a) inform the applicant in writing of the reasons why it proposes to refuse to issue an EC type-examination certificate;
- (b) give the applicant the opportunity, within a reasonable period, of making representations as to why it should not be refused; and
- (c) if, after considering any representations made pursuant to sub-paragraph (b) above, it remains unsatisfied in respect of the requirements of paragraphs (3) and (4)(b) above, it shall—
  - (i) notify its decision in writing to the applicant stating the grounds on which the refusal is based; and
  - (ii) at the same time inform all other approved bodies of such decision.

(7) Where the United Kingdom approved body which has issued an EC type-examination certificate in respect of an example of relevant machinery to an applicant is notified, pursuant to regulation 16 above, by that person of a modification which he or, where that person is not the manufacturer, the manufacturer has made, or plans to make, to the relevant machinery to which that example relates, the United Kingdom approved body shall examine such modification and—

- (a) if it is satisfied that the relevant machinery as modified does, or would, as the case may be, conform sufficiently with the example as to the matters referred to in paragraph (4)(b) above, it shall notify the applicant in writing that the EC type-examination certificate is or would be, as the case may be, valid in respect of the relevant machinery as modified for the purposes of issuing EC declarations of conformity in accordance with regulation 22(5) below; or
- (b) if it is not so satisfied it shall notify the applicant in writing that the EC typeexamination certificate is not, or would not be, as the case may be, a valid certificate in respect of the relevant machinery as modified for the abovementioned purposes stating the grounds on which such decision was based.

#### *Declaration and marking procedures*

### **EC declaration of conformity**

**22.**—(1) Drawing up an EC declaration of conformity is the procedure whereby the responsible person declares in respect of each item of relevant machinery which he supplies in the Community that that particular item of relevant machinery complies with all the essential health and safety requirements applying to it.

(2) An EC declaration of conformity must—

- (a) state the business name and full address of—
  - (i) the responsible person; and
  - (ii) where that person is not the manufacturer, of the manufacturer;
- (b) contain a description of the machinery to which the declaration relates which, without prejudice to the generality of the foregoing, includes, in particular—
  - (i) its make;
  - (ii) type; and
  - (iii) serial number;

- (c) indicate all relevant provisions with which the machinery complies;
  - (d) state in the case of relevant machinery in relation to which an EC typeexamination certificate has been issued the name and address of the approved body which issued the certificate and the number of such certificate;
  - (e) state in the case of relevant machinery in respect of which a technical file as described in regulation 14(2) above has been drawn up the name and address of the approved body to which the file has been sent or which has drawn up a certificate of adequacy for the file, as the case may be;
  - (f) specify (as appropriate) the transposed harmonised standards used;
  - (g) specify (as appropriate) the national standards and any technical specifications used; and
  - (h) identify the person authorised to sign the declaration on behalf of the responsible person.
- (3) An EEC declaration of conformity must be—
- (a) drawn up in the same language as the instructions for the machinery are drawn up as specified in paragraph 1.7.4(b) of Schedule 3 hereto; and
  - (b) typed or written by hand in block capitals.
- (4) In the case of relevant machinery in respect of which the responsible person has carried out one of the conformity assessment procedures described in regulations 13, 14(1)(a) or 14(1)(b) above, the responsible person must state in the EC declaration of conformity that the item of machinery to which the declaration relates complies with the relevant essential health and safety requirements.
- (5) In the case of relevant machinery in respect of which the responsible person has carried out the conformity assessment procedure described in regulation 14(1)(c) or 15 above and an EC type-examination certificate has been issued in respect of an example of that machinery, and such certificate remains valid, the responsible person must state that the item of machinery in respect of which the declaration is made conforms with the example to which that certificate relates.
- (6) For the purposes of these Regulations, the requirement in paragraph (2)(c) above shall be satisfied where the EC declaration of conformity specifies the Machinery Directive and any other Community Directives with which the relevant machinery complies.

### **Declaration of incorporation**

- 23.—(1) This regulation applies in the case of relevant machinery which—
- (a) is intended for—
    - (i) incorporation into other machinery; or
    - (ii) assembly with other machinery,to constitute relevant machinery;
  - (b) cannot function independently; and
  - (c) is not interchangeable equipment.
- (2) A declaration of incorporation is a document whereby a responsible person declares the matters referred to in paragraph (1)(a) above and which includes the particulars set out in paragraph (3) below.
- (3) A declaration of incorporation must—
- (a) state the name and address of the responsible person;
  - (b) contain a description of the machinery or machinery parts;
  - (c) state in the case of relevant machinery in respect of which an EC typeexamination certificate has been issued the name and address of the approved body which issued the certificate and the number of such certificate;



- (d) state in the case of relevant machinery in respect of which a technical file as described in regulation 14(2) above has been drawn up the name and address of the approved body to which the file has been sent or which has drawn up a certificate of adequacy for the file, as the case may be;
- (e) specify the transposed harmonised standards (if any) used;
- (f) state that the machinery (to which the declaration of incorporation relates) must not be put into service until the relevant machinery into which it is to be incorporated has been declared in conformity with the provisions of the Machinery Directive; and
- (g) identify the person signing the declaration of incorporation.

### **Retention of documentation**

24.—(1) A responsible person who issues EC declarations of conformity or declarations of incorporation, as the case may be, in the United Kingdom shall retain on his premises the technical file or a copy of the technical file submitted to an approved body, as the case may be, which relates to the relevant machinery in respect of which such declarations are made so that such file is available to the enforcement authorities for a period of 10 years beginning with the date on which the last unit of relevant machinery to which the file relates is produced.

(2) Nothing in paragraph (1) above shall require the responsible person to keep the documents comprising a technical file available as a permanent file provided that all the required documents are individually available and can be assembled into a technical file.

(3) For the avoidance of doubt, it is hereby declared that for the purposes of enforcing these Regulations a technical file is a document or record and shall be construed accordingly in any of the statutory provisions applied to these Regulations pursuant to Schedule 6 hereto.

### **The EC mark**

25.—(1) For the purposes of these Regulations, the EC mark shall be regarded as properly affixed to relevant machinery if—

- (a) the responsible person who affixes the EC mark to the relevant machinery has issued an EC declaration of conformity in respect thereof;
- (b) the EC mark is affixed to the relevant machinery in a distinct, visible, legible and indelible manner; and
- (c) in the case of relevant machinery which is the subject of Community Directives other than the Machinery Directive, the requirements of those other Directives have also been complied with in respect of the relevant machinery.

(2) No person shall affix the EC mark to any relevant machinery unless that machinery—

- (a) satisfies the relevant essential health and safety requirements; and
- (b) is safe.

(3) No mark or inscription which is capable of being confused with the EC mark shall be affixed to relevant machinery.

(4) A person who supplies relevant machinery which does not bear the EC mark shall, at the request of an enforcement authority, or of an officer of such an authority, give any information which he has, or which is available to him, concerning the date when the relevant machinery was first supplied in the Community and explain (so far as he is able) why the machinery does not bear that mark.

### *Supplementary provisions*

#### **Conditions for relevant machinery being taken to comply with the relevant essential health and safety requirements**

**26.**—(1) Subject to paragraph (2) below, relevant machinery which is accompanied by an EC declaration of conformity and to which the EC mark is affixed shall be taken to comply with the relevant essential health and safety requirements, unless there are reasonable grounds for suspecting that it does not so comply.

(2) Paragraph (1) above does not apply—

- (a) in relation to an enforcement authority where the responsible person fails or refuses to make available to the enforcement authority the technical file or a copy thereof pursuant to regulation 24(1) above; or
- (b) in the case of relevant machinery—
  - (i) which is resupplied in the circumstances described in regulation 11(3) above; and
  - (ii) to which the EC mark is indelibly affixed.

#### **Judicial review of decisions of approved bodies**

**27.**—(1) A person aggrieved by a decision of an approved body under regulation 20(3)(b), 20(4)(b), 21(6)(c) or 21(7)(b) shall, at the same time as he is notified of the decision, be given information about the judicial remedies available to him.

(2) That information shall include—

- (a) a brief statement of the procedure by which judicial review may be applied for in accordance with Rules of Court (or, in Northern Ireland, with rules of court made, or having effect as if made, under section 55 of the Judicature (Northern Ireland) Act 1978(4)); and
- (b) the information that in England and Wales or in Northern Ireland, an application for leave to apply to the Court for judicial review shall be made promptly and in any event within three months from the date when grounds for the application first arose unless the court considers that there is good reason for extending the period within which the application shall be made.