
STATUTORY INSTRUMENTS

2008 No. 1597

The Supply of Machinery (Safety) Regulations 2008

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.