
STATUTORY INSTRUMENTS

2016 No. 315

**The Explosives Regulations 2014
(Amendment) Regulations 2016**

PART 2

AMENDMENT

Amendment of the Explosives Regulations 2014

3. The Explosives Regulations 2014(1) are amended as follows.
4. In regulation 2 (interpretation)—
 - (a) in paragraph (1) —
 - (i) after the definition of “the 2005 Regulations” insert—

““accreditation” has the meaning set out in point 10 of Article 2 of RAMS as amended from time to time;

“accreditation certificate” means a certificate, issued by the United Kingdom Accreditation Service (a company limited by guarantee incorporated in England and Wales under number 03076190) or a national accreditation body in another EEA state, attesting that a conformity assessment body meets the notified body requirements;”;
 - (ii) after the definition of “authorised defence site” insert—

““authorised representative” means a person established within an EEA state who has received a written mandate from the manufacturer to act on the manufacturer’s behalf in relation to specified tasks;”;
 - (iii) for the definition of “the CE marking” substitute—

““CE marking” means a marking which takes the form set out Annex II of RAMS as amended from time to time;”;
 - (iv) in the definition of “civil explosive”—
 - (aa) insert “or” after “any country;”;
 - (bb) omit “and” after “pyrotechnic article;”;
 - (cc) omit “an explosive which is used immediately at the place of manufacture;”;
 - (v) omit the definition of “the Civil Uses Directive”;
 - (vi) after the definition of “the Commission” insert—

““competent national authority” means an authority having responsibility for enforcing the law of an EEA state which implements the Directive;

“conformity assessment” means the process demonstrating whether the essential safety requirements relating to a civil explosive have been fulfilled;”;

“conformity assessment body” means a person who performs conformity assessment activities, including calibration, testing, certification and inspection;”;

(vii) after the definition of “desensitised explosive” insert—

““the Directive” means [Directive 2014/28/EU](#) of the European Parliament and of the Council on the harmonisation of the laws of the member States relating to the making available on the market and supervision of explosives for civil uses (recast)**(2)**;”;

(viii) for the definition of “distributor”, substitute—

““distributor” means a person in the supply chain, other than a manufacturer or an importer, who makes a civil explosive available on the market and “distributes” in relation to Part 11 and “distribution” in relation to Part 13 are to be construed accordingly”;

(ix) after the definition of “distributor” insert—

““economic operator” means a manufacturer, authorised representative, importer, distributor or any person who engages in the storage, use, transfer, import, export or trading of civil explosives;

“enforcing authority”, in relation to Part 13, means the Executive;

“essential safety requirements” means the requirements set out in Schedule 9 (essential safety requirements);

“EU declaration of conformity” means a declaration of conformity required to be drawn up in accordance with regulation 41 (EU declaration of conformity and CE marking);”;

(x) for the definition of “harmonised standard” substitute—

““harmonised standard” has the meaning set out in point 1(c) of Article 2 of Regulation (EU) 1025/2012 of the European Parliament and of the Council on European standardisation**(3)**, as amended from time to time;”;

(xi) after the definition of “holder” insert—

““importer”, in relation to civil explosives, means any person who—

(a) is established in an EEA state; and

(b) places a civil explosive from a third country on the market;”;

(xii) after the definition of “local authority” insert—

““making available on the market” means any supply for distribution, consumption or use on the market in an EEA state in the course of a commercial activity, whether in return for payment or free of charge, and related expressions must be construed accordingly;”;

(xiii) after the definition of “manufacture” insert—

““manufacturer”, in relation to civil explosives, means a person who—

(a) manufactures a civil explosive, or has a civil explosive designed or manufactured; and

(2) OJNo. L 96, 29.3.2014, p. 1.

(3) OJ No. L 316, 14.11.2012, p. 12.

- (b) markets that civil explosive under that person’s name or trade mark or uses it for their own purposes;
“market surveillance authority” means the Executive”;
- (xiv) after the definition of “mine” insert—
““mobile explosives manufacturing unit” means a moveable unit, whether mounted on a vehicle or not, for manufacturing and charging explosives from dangerous goods that are not explosives, with the unit consisting of various tanks, bulk containers and related equipment.”;
- (xv) after the definition “new nuclear build site” insert—
““notified body requirements” means the requirements set out in Schedule 15 (notified body requirements);”;
- (xvi) after the definition of “percussion caps” insert—
““place on the market” means the first making available on the market in an EEA state, and related expressions must be construed accordingly;”;
- (xvii) after the definition of “pyrotechnic substance” insert—
““RAMS” means 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) No 339/93(4);
“recall” means taking any measure aimed at achieving the return of a civil explosive that has already been made available to the end-user and related expressions must be construed accordingly;”;
- (xviii) after the definition of “recipient competent authority document” insert—
““relevant conformity assessment procedure” means a conformity assessment procedure referred to in regulation 66 (conformity assessment procedures);”;
- (xix) after the definition of “substance” insert—
““technical documentation” has the meaning given in regulation 40(b) (technical documentation and conformity assessment);
“technical specification” means a document that prescribes technical requirements to be fulfilled by a civil explosive;”;
- (xx) after the definition of “wholly-owned subsidiary” insert—
““withdraw”, when used in relation to a civil explosive, means taking any measure aimed at preventing a civil explosive in the supply chain from being made available on the market and related expressions must be construed accordingly.”; and
- (b) after paragraph (11), insert—
 - “(12) In Part 13, “risk” means a risk, other than a minimal risk, which—
 - (a) could arise from lawful and readily predictable human behaviour; and
 - (b) may result in—
 - (i) harm to the health or safety of any person;
 - (ii) unintended damage to property; or
 - (iii) unintended harm to the environment.

(13) Until the entry into force of any amendment made to Annex II (technical regulations, standards, testing and certification) to the EEA Agreement by a Decision of the EEA Joint Committee⁽⁵⁾, inserting a reference to the Directive⁽⁶⁾ into that Annex, references in regulations 2(1) and 8 and Part 13 and its related Schedules to, as the case may be, “an EEA state”, “another EEA state”, “the EEA state”, “other EEA state” or “other EEA states” are to be construed as referring to, respectively, “a member State”, “another member State”, “the member State”, “other member State” and “other member States”.

5. In regulation 3 (application and extent)—

(a) for paragraph (4), substitute—

“(4) Subject to the following provisions of this regulation, these Regulations apply—

(a) within Great Britain, and

(b) except for regulations 4, 5, 31 and 32, outside Great Britain as sections 1 to 59 and 80 to 82 of the 1974 Act apply by virtue of the Health and Safety at Work etc. Act 1974 (Application outside Great Britain) order 2013(7).”;

(b) in paragraph (14), for “39 to 42” substitute “39 to 77”;

(c) in paragraph (15), after sub-paragraph (a), insert—

“(aa) an explosive manufactured at a blasting site that is loaded immediately after being produced;”;

(d) omit paragraphs (16) to (18).

6. In regulation 8 (authorisation to transfer civil explosives), in paragraph (9)—

(a) in sub-paragraph (a)(ii), for “Article 9 of the Civil Uses Directive” substitute “Article 11 of the Directive”; and

(b) in sub-paragraph (b), for “Article 9.3, 9.5 or 9.6 of the Civil Uses Directive” substitute “Article 11.2, 11.4 or 11.6 of the Directive”.

7. For Part 13 (placing on the market of civil explosives), substitute—

“PART 13

SUB-PART A: MAKING AVAILABLE ON THE MARKET – OBLIGATIONS OF ECONOMIC OPERATORS, SUB-PART B: CONFORMITY ASSESSMENT BODIES, SUB-PART C: NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

SUB-PART A: MAKING AVAILABLE ON THE MARKET – OBLIGATIONS OF ECONOMIC OPERATORS

MANUFACTURERS

Design and manufacture in accordance with essential safety requirements

39. Before placing a civil explosive on the market or using it for their own purposes, a manufacturer must ensure that it has been designed and manufactured in accordance with the essential safety requirements.

(5) The EEA Joint Committee is established by Article 92 of the EEA Agreement.

(6) Directive 2014/28/EU is a recast of, and replaces, Council Directive 1993/15/EC of 5th April 1993 (OJ No. L121, 15.5.93, p.20) which applied in relation to the EEA by virtue of Decision No. 7/94 of 21st March 1994 of the EEA Joint Committee amending Protocol 47 and certain Annexes to the EEA Agreement (OJ No. L160, 28.6.1994, p.1). Directive 2014/28/EU is referred to in its heading as being a text with EEA relevance.

(7) S.I. 2013/240.

Technical documentation and conformity assessment

40. Before placing a civil explosive on the market, or using it for their own purposes, a manufacturer must, in respect of that civil explosive—

- (a) have a relevant conformity assessment procedure carried out; and
- (b) draw up the technical documentation referred to —
 - (i) for a civil explosive in respect of which the conformity assessment procedure in regulation 66(a) is being carried out, in point 3(c) of Module B of Annex III to the Directive as amended from time to time;
 - (ii) for a civil explosive in respect of which the conformity assessment procedure in regulation 66(b) is being carried out, in point 2 of Module G of Annex III to the Directive as amended from time to time.

EU declaration of conformity and CE marking

41.—(1) Where the conformity of a civil explosive with the essential safety requirements has been demonstrated by a relevant conformity assessment procedure, the manufacturer must, before placing the civil explosive on the market or using it for their own purposes—

- (a) draw up a declaration of conformity in accordance with regulation 67 (EU declaration of conformity); and
- (b) affix the CE marking in accordance with regulation 68 (CE marking).

(2) The manufacturer must keep the EU declaration of conformity up to date.

(3) Where a civil explosive is subject to more than one EU instrument requiring a declaration of conformity to be drawn up, the manufacturer must draw up a single declaration of conformity, which —

- (a) identifies the EU instruments; and
- (b) includes references to the publication of those EU instruments in the Official Journal of the European Union.

Retention of technical documentation and EU declaration of conformity

42. A manufacturer must keep the technical documentation and the EU declaration of conformity drawn up in respect of a civil explosive for a period of 10 years beginning on the day on which the civil explosive is placed on the market.

Compliance procedures for series production

43.—(1) A manufacturer of civil explosives which are manufactured by series production must ensure that, before placing such a civil explosive on the market, procedures are in place to ensure that any civil explosive so manufactured will be in conformity with this Part.

(2) In doing so, the manufacturer must take adequate account of —

- (a) any change in the design or characteristics of the civil explosive; and
- (b) any change in a harmonised standard or in another technical specification by reference to which the EU declaration of conformity was drawn up.

Traceability of certain civil explosives excluded from the scope of regulations 33, 34 and 36

44.—(1) A manufacturer of a civil explosive which is excluded from the scope of regulations 33, 34 and 36 by virtue of regulation 3(15), must, before placing such a civil explosive on the market—

- (a) ensure that it bears a type, batch or serial number or other element allowing its identification, and
- (b) indicate on the civil explosive—
 - (i) any of—
 - (aa) the manufacturer’s name;
 - (ab) registered trade name; or
 - (ac) trade mark; and
 - (ii) a single postal address at which they can be contacted.

(2) Where the small size, shape or design of the civil explosive does not allow the information specified in paragraph (1)(a) to be indicated on it, the manufacturer must ensure that such information is indicated on its packaging or in a document accompanying the civil explosive.

(3) Where it is not possible to indicate the information specified in paragraph (1)(b) on the civil explosive, the manufacturer must indicate that information on the packaging or in a document accompanying the civil explosive.

(4) The contact details referred to in paragraph (1) must be provided in a language which can be easily understood by end-users and the competent national authority in the EEA state in which the civil explosive is to be made available to such end-users.

Instructions and safety information

45.—(1) When placing a civil explosive on the market, a manufacturer must ensure that it is accompanied by instructions and safety information in a language which can be easily understood by end-users in the EEA state in which the civil explosive is to be made available to such end users.

(2) When the civil explosive is being made available to end-users in the United Kingdom, the language which can easily be understood by end-users is English.

(3) The instructions and safety information, as well as any labelling, must be clear and understandable.

AUTHORISED REPRESENTATIVES

Appointment of authorised representative by written mandate

46.—(1) A manufacturer may, by written mandate, appoint a person as their authorised representative to perform specified tasks on the manufacturer’s behalf.

(2) The mandate must allow the authorised representative to do at least the following in relation to a civil explosive covered by the mandate—

- (a) perform the manufacturer’s obligations under regulation 42 (retention of technical documentation and EU declaration of conformity); and
- (b) perform the manufacturer’s obligations under regulation 54 (provision of information and cooperation).

(3) A manufacturer must not delegate the performance of their functions under regulation 39 (design and manufacture in accordance with essential safety requirements) and regulation 40 (technical documentation and conformity assessment) to an authorised representative.

(4) An authorised representative must comply with all the duties imposed on the manufacturer in relation to each obligation under this Part that the authorised representative is appointed by the manufacturer to perform and, accordingly—

- (a) as far as those duties are concerned, references in this Part (except in this regulation) to the manufacturer are to be taken as including a reference to the authorised representative; and
- (b) if the authorised representative contravenes or fails to comply with any of those duties, the authorised representative may be proceeded against as though the authorised representative were the manufacturer.

(5) A manufacturer who has appointed an authorised representative to perform on their behalf an obligation under this Part remains responsible for the proper performance of that obligation.

IMPORTERS

Prohibition on placing on the market civil explosives which are not in conformity

47. An importer must not place a civil explosive on the market unless it is in conformity with the essential safety requirements.

Requirements which must be satisfied before an importer places a civil explosive on the market

48.—(1) Before placing a civil explosive on the market, an importer must ensure that—

- (a) a relevant conformity assessment procedure has been carried out by the manufacturer;
- (b) the manufacturer has drawn up the technical documentation;
- (c) the civil explosive—
 - (i) bears the CE marking; and
 - (ii) is accompanied by the required documents; and
- (d) the manufacturer has complied with the requirements, where applicable, set out in regulation 44 (traceability of certain civil explosives excluded from the scope of regulations 33, 34 and 36) to the extent not already covered by sub-paragraph (c) (ii).

(2) In paragraph (1)(c)(ii), “required documents” means any documents that are required to be provided with the civil explosive pursuant to—

- (a) regulation 44(2) and (3); and
- (b) regulation 45.

Prohibition on placing on the market civil explosives considered not to be in conformity with the essential safety requirements

49.—(1) Where an importer considers, or has reason to believe, that a civil explosive is not in conformity with the essential safety requirements, the importer must not place the civil explosive on the market.

(2) Where the civil explosive presents a risk, the importer must inform the manufacturer and the market surveillance authority of that risk.

Information identifying importer

50.—(1) Before placing a civil explosive on the market, an importer must indicate on the civil explosive—

- (a) any of—
 - (i) the name;
 - (ii) registered trade name; or
 - (iii) registered trade mark of the importer; and
- (b) a postal address at which the importer can be contacted.

(2) The information specified in paragraph (1) must be in a language which can be easily understood by end-users and the competent national authority in the EEA state in which the civil explosive is to be made available to such end-users.

(3) Where it is not possible to indicate the information specified in paragraph (1) on the civil explosive, the importer must indicate that information—

- (a) on the packaging; or
- (b) in a document accompanying the civil explosive.

Instructions and safety information

51.—(1) When placing a civil explosive on the market, an importer must ensure that it is accompanied by instructions and safety information in a language which can be easily understood by end-users in the EEA state in which the civil explosive is to be made available to such end-users.

(2) Where the civil explosive is being made available to end-users in the United Kingdom, the language which can be easily understood by end-users is English.

Retention of technical documentation and EU declaration of conformity

52. An importer must, for a period of 10 years beginning on the day on which the civil explosive is placed on the market—

- (a) keep a copy of the EU declaration of conformity at the disposal of the market surveillance authority; and
- (b) ensure that the technical documentation can be made available to that authority, upon request.

MANUFACTURERS AND IMPORTERS

Duty to take action in respect of civil explosives placed on the market which are considered not to be in conformity

53.—(1) A manufacturer or importer who considers, or has reason to believe, that a civil explosive which they have placed on the market is not in conformity with this Part must immediately take the corrective measures necessary to—

- (a) bring the civil explosive into conformity;
- (b) withdraw the civil explosive; or
- (c) recall the civil explosive.

(2) Where the civil explosive presents a risk, the manufacturer or importer must immediately inform the market surveillance authority, and the competent national authorities of any other EEA state in which the manufacturer or importer made the civil explosive available on the market, of the risk, giving details of—

- (a) the respect in which the civil explosive is considered not to be in conformity with this Part; and
- (b) any corrective measures taken.

Provision of information and cooperation

54.—(1) A manufacturer or importer must, further to a reasoned request from the market surveillance authority, provide the authority with the information and documentation necessary to demonstrate that the civil explosive is in conformity with this Part—

- (a) in paper or electronic form; and
- (b) in a language which can be easily understood by the authority.

(2) A manufacturer or importer must, at the request of the market surveillance authority, cooperate with the authority on any action taken to—

- (a) evaluate a civil explosive in accordance with paragraph 8 of Schedule 12 (evaluation of civil explosive presenting a risk);
- (b) eliminate the risks posed by a civil explosive which the manufacturer or importer has placed on the market.

DISTRIBUTORS

Duty to act with due care

55. When making a civil explosive available on the market, a distributor must act with due care to ensure that it is in conformity with this Part.

Requirements which must be satisfied before a distributor makes a civil explosive available on the market

56.—(1) Before making a civil explosive available on the market, the distributor must verify that—

- (a) the civil explosive—
 - (i) bears the CE marking;
 - (ii) is accompanied by the required documents;

- (iii) is accompanied by instructions and safety information in a language which can be easily understood by end-users in the EEA state in which the civil explosive is to be made available;
 - (b) the manufacturer has complied with the requirements, where applicable, set out in regulation 44 (traceability of certain civil explosives excluded from the scope of regulations 33, 34 and 36) to the extent not already covered by sub-paragraph (a)(ii); and
 - (c) the importer has complied with the requirements set out in regulation 50 (information identifying importer) to the extent not already covered by sub-paragraph (a)(ii).
- (2) In paragraph (1)(a)(ii), “required documents” means the documents that are required to be provided with the civil explosive pursuant to—
- (a) regulation 44(2) and (3); and
 - (b) regulation 50(3).

Prohibition on making available on the market where civil explosive considered not to be in conformity with the essential safety requirements

57.—(1) Where a distributor considers, or has reason to believe, that a civil explosive is not in conformity with the essential safety requirements, the distributor must not make the civil explosive available on the market.

- (2) Where the civil explosive presents a risk, the distributor must inform the following persons of the risk—
- (a) the manufacturer or the importer; and
 - (b) the market surveillance authority.

Duty to take action in respect of civil explosives made available on the market which are not in conformity

58.—(1) A distributor who considers, or has reason to believe, that a civil explosive which the distributor has made available on the market is not in conformity with this Part must make sure that the necessary corrective measures are taken to—

- (a) bring that civil explosive into conformity;
- (b) withdraw the civil explosive; or
- (c) recall the civil explosive.

(2) Where the civil explosive presents a risk, the distributor must immediately inform the market surveillance authority, and the competent national authorities of the other EEA states in which the distributor has made the civil explosive available on the market, of that risk, giving details of—

- (a) the respect in which the civil explosive is considered not to be in conformity with this Part; and
- (b) any corrective measures taken.

Provision of information and cooperation

59.—(1) A distributor must, further to a reasoned request from the enforcing authority, provide the authority with the information and documentation, in paper or electronic form, necessary to demonstrate that the civil explosive is in conformity with this Part.

- (2) A distributor must, at the request of the enforcing authority, cooperate with the authority on any action taken to—
- (a) evaluate a civil explosive in accordance with paragraph 8 of Schedule 12 (evaluation of civil explosives presenting a risk); and
 - (b) eliminate the risks posed by a civil explosive which the distributor has made available on the market.

IMPORTERS AND DISTRIBUTORS

Storage and transport

60. Each importer and distributor must ensure that, while a civil explosive is their responsibility, its storage or transport conditions do not jeopardise its conformity with the essential safety requirements.

Cases in which obligations of manufacturers apply to importers and distributors

61. An economic operator (“A”) who would, but for this regulation, be considered an importer or distributor, is to be considered a manufacturer for the purposes of this Part and is subject to the obligations of a manufacturer under this Part, where A—

- (a) places a civil explosive on the market under A’s own name or trademark; or
- (b) modifies a civil explosive already placed on the market in such a way that it may affect whether the civil explosive is in conformity with this Part.

ALL ECONOMIC OPERATORS

Translation of declaration of conformity

62.—(1) Before making a civil explosive available on the market, an economic operator must ensure that the EU declaration of conformity is prepared in, or translated into, the language required by the EEA state in which it is to be made available on the market.

(2) Where the civil explosive is to be made available on the market in the United Kingdom, the language required is English.

Identification of economic operators

63.—(1) This regulation applies in relation to civil explosives excluded from the scope of regulations 33, 34 and 36 by virtue of regulation 3(15).

(2) An economic operator (“E”) who receives a request from the market surveillance authority before the end of the relevant period, must, within such period as the authority may specify, identify to the market surveillance authority—

- (a) any economic operator who has supplied E with a civil explosive to which this regulation applies; and
 - (b) any economic operator to whom E has supplied a civil explosive to which this regulation applies.
- (3) The relevant period is—
- (a) for information under paragraph (2)(a), a period of 10 years beginning on the day on which E was supplied with the civil explosive;

- (b) for information under paragraph (2)(b), a period of 10 years beginning on the day on which E supplied the civil explosive.

Prohibition on improper use of CE marking

64.—(1) An economic operator must not affix the CE marking to a civil explosive unless—

- (a) that economic operator is the manufacturer; and
- (b) the conformity of the civil explosive with the essential safety requirements has been demonstrated by a relevant conformity assessment procedure.

(2) An economic operator must not affix to a civil explosive a marking (other than the CE marking) which purports to attest that the civil explosive is in conformity with the essential safety requirements.

(3) An economic operator must not affix to a civil explosive a marking, sign or inscription which is likely to mislead any other person as to the meaning or form of the CE marking.

(4) An economic operator must not affix to a civil explosive any other marking if the visibility, legibility and meaning of the CE marking would be impaired as a result.

SUB-PART B: CONFORMITY ASSESSMENT

Presumption of conformity

65.—(1) A civil explosive which is in conformity with a harmonised standard, or part of such a standard, the reference to which has been published in the Official Journal of the European Union is to be presumed to be in conformity with the essential safety requirements covered by that standard, or that part of that standard.

- (2) The presumption in paragraph (1) is rebuttable.

Conformity assessment procedures

66. For the assessment of conformity of a civil explosive, the manufacturer must follow one of the following procedures referred to in Annex III to the Directive as amended from time to time—

- (a) EU-type examination carried out by a notified body (Module B), and, at the choice of the manufacturer, one of the following procedures—
 - (i) conformity to type based on internal production control plus supervised product checks at random intervals (Module C2);
 - (ii) conformity to type based on quality assurance of the production process (Module D);
 - (iii) conformity to type based on product quality assurance (Module E);
 - (iv) conformity to type based on product verification (Module F);
- (b) conformity based on unit verification (Module G).

EU declaration of conformity

67. The EU declaration of conformity for a civil explosive must—

- (a) state that the fulfilment of the essential safety requirements has been demonstrated in respect of the civil explosive;

- (b) contain the elements specified in Annex III to the Directive, as amended from time to time, for the relevant conformity assessment procedure followed in respect of the civil explosive; and
- (c) have the model structure set out in Annex IV to the Directive, as amended from time to time.

CE marking

68.—(1) The CE marking must be affixed visibly, legibly and indelibly to the civil explosive.

(2) Where it is not possible or warranted, on account of the nature of the civil explosive, to affix the CE marking in accordance with paragraph (1), the CE marking must be affixed to—

- (a) the packaging; and
- (b) the accompanying documents.

(3) The CE marking must be followed by the identification number of the notified body which carried out the relevant conformity assessment procedure for the civil explosive, where that body is involved in the production control phase.

(4) The identification number of the notified body must be affixed—

- (a) by the notified body itself; or
- (b) under the instructions of the notified body, by the manufacturer or the manufacturer's authorised representative.

(5) In the case of a civil explosive—

- (a) manufactured for the manufacturer's own use;
- (b) transported and delivered unpackaged or in a mobile explosives manufacturing unit for its direct unloading into the blast-hole; or
- (c) manufactured at the blasting site which is loaded immediately after being produced,

the CE marking must be affixed to the accompanying documents.

SUB-PART C: NOTIFICATION OF CONFORMITY ASSESSMENT BODIES

Notified bodies

69.—(1) For the purposes of this Part, a notified body is a conformity assessment body—

- (a) which has been notified to the European Commission and to the other EEA states—
 - (i) under regulation 70 (notification); or
 - (ii) by the Secretary of State, before 20th April 2016, in accordance with Article 24 of the Directive, as amended from time to time; and
- (b) in respect of which no objections are raised by the European Commission or the other EEA states—
 - (i) within two weeks of a notification, where an accreditation certificate is used; or
 - (ii) within two months of a notification, where accreditation is not used.

(2) Paragraph (1) has effect subject to regulation 75 (changes to notifications).

Notification

70.—(1) The Secretary of State must notify to the European Commission and the other EEA states only those conformity assessment bodies that qualify for notification.

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

(3) The first condition is that the conformity assessment body makes an application to the Secretary of State for notification and that the 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 module for which the conformity assessment body claims to be competent; and

(iii) the civil explosive for which the conformity assessment body claims to be competent; and either

(b) an accreditation certificate; or

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

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

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

(6) When deciding whether to notify a conformity assessment body that qualifies for notification to the European Commission and the other EEA states, 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) The Secretary of State must inform the European Commission of the United Kingdom's procedures for the assessment and notification of conformity assessment bodies, and any changes to those procedures.

Presumption of conformity of notified bodies

71.—(1) Where a conformity assessment body demonstrates its conformity with the criteria laid down in a harmonised standard (or part of such a standard), the reference of which has been published in the Official Journal of the European Union, the Secretary of State is to presume that the conformity assessment body meets the notified body requirements covered by that standard (or part of that standard).

(2) The presumption in paragraph (1) is rebuttable.

Contents of notification

72. A notification under regulation 70 must include—

(a) details of—

- (i) the conformity assessment activities in respect of which the conformity assessment body has made its application for notification;
 - (ii) the conformity assessment module in respect of which the conformity assessment body has made its application for notification; and
 - (iii) the civil explosive in respect of which the conformity assessment body has made its application for notification; and either
- (b) an accreditation certificate; or
 - (c) documentary evidence which attests to—
 - (i) the conformity assessment body's competence; and
 - (ii) the arrangements in place to ensure that the conformity assessment body will be monitored regularly and will continue to meet the notified body requirements.

Monitoring

73.—(1) The Secretary of State must monitor each notified body with a view to verifying that the notified body—

- (a) continues to meet the notified body requirements;
- (b) meets any conditions set in accordance with regulation 70(6)(b); and
- (c) carries out its functions in accordance with these Regulations.

(2) The Secretary of State must inform the European Commission of the United Kingdom's procedures for the monitoring of notified bodies, and any changes to those procedures.

United Kingdom Accreditation Service

74. The Secretary of State may authorise the United Kingdom Accreditation Service (a company limited by guarantee incorporated in England and Wales under number 03076190) to carry out the following activities on behalf of the Secretary of State—

- (a) assessing whether a conformity assessment body meets the notified body requirements; and
- (b) monitoring notified bodies in accordance with regulation 73.

Changes to notifications

75.—(1) Where the Secretary of State determines that a notified body no longer meets a notified body requirement, or that it is failing to fulfil any of its obligations under these Regulations other than conditions set in accordance with regulation 70(6)(b), the Secretary of State must restrict, suspend or withdraw the body's status as a notified body under regulation 69.

(2) With the consent of a notified body, or where the Secretary of State determines that a notified body no longer meets a condition set in accordance with regulation 70(6)(b), the Secretary of State may restrict, suspend or withdraw the body's status as a notified body under regulation 69.

(3) In deciding what action is required under paragraph (1) or (2), the Secretary of State must have regard to the seriousness of the failure.

(4) Where the Secretary of State takes action under paragraph (1) or (2), the Secretary of State must immediately inform the European Commission and the other EEA states.

(5) Where the Secretary of State has taken action in respect of a notified body under paragraph (1) or (2), or where a notified body has ceased its activity, the notified body must, at the request of the Secretary of State—

- (a) transfer its files relating to the activities it has undertaken as a notified body to another notified body or to the Secretary of State; or
- (b) keep its files relating to the activities it has undertaken as a notified body available for the Secretary of State and the market surveillance authority for a period of ten years from the date they were created.

Operational obligations of notified bodies

76. When a notified body carries out a relevant conformity assessment procedure, it must do so in accordance with Schedule 16 (operational obligations of notified bodies).

Subsidiaries and contractors

77.—(1) Where a notified body subcontracts specific conformity assessment activities, or has such activities carried out by a subsidiary, the activities are only to be treated as having been carried out by a notified body for the purposes of regulation 66 (conformity assessment procedures) where the conditions in paragraphs (2) and (3) are met.

(2) The notified body must—

- (a) ensure that the subcontractor or subsidiary meets the notified body requirements; and
- (b) inform the Secretary of State accordingly.

(3) The notified body must have obtained the agreement of the client to the use of a subcontractor or subsidiary.

(4) Where a notified body subcontracts specific conformity assessment activities, or has such activities carried out by a subsidiary, the notified body must for a period of at least 10 years, beginning on the day on which the activities are carried out, keep at the disposal of the Secretary of State the documentation concerning—

- (a) the assessment of the qualifications of the subcontractor or the subsidiary; and
- (b) the conformity assessment activities carried out by the subcontractor or subsidiary.

(5) When monitoring a notified body in accordance with regulation 73, the Secretary of State must treat the notified body as responsible for the tasks performed by a subcontractor or subsidiary, wherever the subcontractor or subsidiary is established.”.

8. In Part 14—

- (a) re-number regulations 43 and 44 as, respectively, regulations 78 and 79; and
- (b) for regulation 45 and its chapeau, substitute—

“Enforcement in relation to regulation 8 and Part 13, market surveillance and further matters

80. Schedule 12, which makes provision as to—

- (a) enforcement in relation to regulation 8 and Part 13;
- (b) market surveillance in relation to that Part;
- (c) compliance, withdrawal and recall notices; and

(d) a defence of due diligence, appeals against notices and further provisions in relation to enforcement;

has effect.”.

9. In Part 15—

- (a) re-number regulation 46 as regulation 81 and, in paragraph (4) of that regulation, for “and 38 to 42” substitute “, 38 and Part 13”; and
- (b) re-number regulations 47, 48 and 49 as, respectively, regulations 82, 83 and 84.

10. In Schedule 9 (essential safety requirements)—

- (a) in the bracketed passage after the Schedule heading, for “Annex I to the Civil Uses Directive”, substitute “Annex II to the Directive”;
- (b) in paragraph 4(k), omit “in the official language or languages of the recipient EEA state”; and
- (c) in paragraph (i) of paragraph 5(b), for “and other fuses” substitute “, other fuses and shock tubes”.

11. Schedule 10 (conformity marking) is omitted.

12. In Schedule 11, in paragraph 15, for sub-paragraph (1), substitute—

“(1) The Executive is the enforcing authority for regulation 8, Part 13 and paragraph 18 of Schedule 12.”.

13. For Schedule 12, substitute the schedule contained in Schedule 1 to these Regulations.

14. After Schedule 14, insert Schedules 15 and 16 which are contained in Schedule 2 to these Regulations.