STATUTORY INSTRUMENTS

2016 No. 315

The Explosives Regulations 2014 (Amendment) Regulations 2016

PART 2

AMENDMENT

Amendment of the Explosives Regulations 2014

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.

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 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 subparagraph (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;
 - (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."