SCHEDULE 31

Regulation 34

Amendment of the Making Available on the Market and Supervision of Transfers of Explosives Regulations (Northern Ireland) 2016

Introduction

1. The Making Available on the Market and Supervision of Transfers of Explosives Regulations (Northern Ireland) 2016 are amended as follows.

Commencement Information

I1 Sch. 31 para. 1 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 2

2.—(1) Regulation 2 (interpretation) is amended as follows—

(2) In paragraph (1)—

(a) omit the definition of "accreditation";

(b) omit the definition of "accreditation certificate";

(c) after the definition of "the 1993 Regulations" insert—

""approved body" has the meaning given to it in regulation 35 (approved bodies);";

(d) for the definition of "authorised representative" substitute—

""authorised representative" means—

(a) a person who—

(i) immediately before exit day was established in the United Kingdom or an EEA state; and was appointed by a manufacturer by written mandate to perform specified tasks for that manufacturer, in accordance with regulation 12, as it had effect immediately before exit day; and

(ii) on or after exit day continues to be so established and appointed by the manufacturer to perform those tasks; or

(b) a person who, on or after exit day is appointed in accordance with regulation 12;";

(e) omit the definition of "CE marking";

(f) omit the definition of "competent national authority";

(g) after the definition of "conformity assessment body" insert—

""declaration of conformity" means a declaration of conformity required to be drawn up in accordance with regulation 7;"

(h) after the definition of "the Department" insert—

""designated standard" has the meaning given to it in regulation 2A;";

(i) in the definition of "the Directive" at the end insert " (as it has effect immediately before exit day) ";

(j) omit the definition of "EU declaration of conformity";

(k) omit the definition of "harmonised standard";

(l) for the definition of "importer" substitute—

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

(a) is established in the United Kingdom; and

(b) places a civil explosive from a country outside the United Kingdom on the market;";

(m) in the definition of "making available on the market" for "an EEA state" substitute " the United Kingdom ";

(n) omit the definition of "notified body requirements";

(o) in the definition of "place on the market"—

(i) after "means" insert " , apart from in regulation 45A, ";

(ii) for "on the market in an EEA state" substitute " on the United Kingdom market ";

(p) for the definition of "relevant authority" substitute—

""relevant authority" means any public authority which has a function under these Regulations or a function under another enactment in relation to the security or traceability of civil explosives;" and

(q) after the definition of "transfer" insert—

""UK marking" means the marking in the form set out in Annex 2 of RAMS;

"UK national accreditation body" means the body appointed by the Secretary of State in accordance with Article 4 of RAMS;".

(3) Omit paragraph (3).

Commencement Information

I2 Sch. 31 para. 2 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of regulation 2A

3. After regulation 2 insert—

"**Interpretation: designated standard**

2A.—(1) Subject to paragraphs (6) and (7), "designated standard" means a technical specification which is—

(a) adopted by a recognised standardisation body for repeated or continuous application with which compliance is not compulsory; and

(b) designated by the Secretary of State by publishing the reference to the standard and maintaining that publication in a manner the Secretary of State considers appropriate.

(2) For the purposes of paragraph (1), a "technical specification" means a document that prescribes technical requirements to be fulfilled by a product, process, service or system and which lays down one or more of the following—

(a) the characteristics required of a product, including—

(i) levels of quality, performance, interoperability, environmental protection, health, safety or dimensions, and

(ii) the requirements applicable to the product as regards the name under which the product is sold, terminology, symbols, testing and test methods, packaging, marking or labelling and conformity assessment procedures;

(b) production methods and processes relating to the product, where these have an effect on the characteristics of the product.

(3) For the purposes of this regulation a "recognised standardisation body" means any one of the following organisations—

(a) the European Committee of Standardisation (CEN);

(b) the European Committee for Electrotechnical Standardisation (Cenlec);

(c) the European Telecommunications Standards Institute (ETSI);

(d) the British Standards Institution (BSI).

(4) When considering whether the manner of publication of a reference is appropriate in accordance with paragraph (1)(b), the Secretary of State must have regard to whether the publication will draw the standard to the attention of any person who may have an interest in the standard.

(5) Before publishing a reference to a technical specification adopted by the British Standards Institution, the Secretary of State must have regard to whether the technical specification is consistent with technical specifications adopted by the other recognised standardisation bodies.

(6) The Secretary of State may remove from publication the reference to a standard which has been published in accordance with paragraph (1)(b).

(7) Where the Secretary of State removes the reference to a standard from publication, that standard is no longer a designated standard.

(8) In this regulation, a reference to a "product" is a reference to a civil explosive.

(9) The Department may by regulations amend the list of recognised standardisation bodies in paragraph (3) to reflect any changes in the name or structure of those bodies made by the Secretary of State.

(10) Regulations made under paragraph (9) are subject to negative resolution.".

Commencement Information

I3 Sch. 31 para. 3 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 4

4.—(1) Regulation 4 (authorisation to transfer civil explosives) is amended as follows.

(2) In paragraph (1) omit "for the place where the transfer will terminate".

(3) In paragraph (2) for "relevant authority" substitute " relevant competent authority ".

(4) In paragraph (5), in both places where it appears, for "the area of the EEA States" substitute " the United Kingdom ".

(5) After paragraph (7) insert—

"(7A) A recipient competent authority document issued under this regulation may be granted for such period as the competent authority determines and may be revoked by notice in writing by that authority on grounds of safety or security.".

(6) For paragraph (8) substitute—

"(8) In this regulation—

(a) "competent authority" means the Chief Constable;

(b) "recipient competent authority document" means a document issued in accordance with this regulation by the competent authority; and

(c) "relevant competent authority" means—

(i) in respect of a transfer or part of a transfer which takes place within Northern Ireland, the Chief Constable; and

(ii) in respect of a transfer or part of a transfer which takes place in Great Britain, the body which discharges in Great Britain similar functions to those discharged by the Chief Constable under these Regulations in relation to Northern Ireland.".

(7) After paragraph (8) insert—

"(9) A transfer document issued under the Directive, which was valid immediately before exit day is deemed to be a valid recipient competent authority document for the purposes of this regulation after exit day, until such time as it expires or is withdrawn by a relevant competent authority.".

Commencement Information

I4 Sch. 31 para. 4 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 6

5. Regulation 6 (technical documentation and conformity assessment) is amended as follows—

(a) in paragraph (b)(i)—

(i) for "32(a)" substitute " 32(2)(a) ";

(ii) for "point 3(c) of Module B of Annex III to the Directive (as amended from time to time)" substitute " paragraph 2(2)(c) of Part 1 (Module B) of Schedule 5 ";

(b) in paragraph (b)(ii)—

(i) for "32(b)" substitute " 32(2)(b) ";

(ii) for "point 2 of Module G of Annex III to the Directive (as amended from time to time)" substitute " paragraph 46 of Part 6 (Module G) of Schedule 5 ".

Commencement Information

I5 Sch. 31 para. 5 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 7

6. Regulation 7 (EU declaration of conformity and CE marking) is amended as follows—

(a) in the heading to that regulation—

(i) for "EU declaration" substitute " Declaration ";

(ii) for "CE" substitute " UK ";

(b) in paragraph (1)(a) omit "(EU declaration of conformity)";

(c) in paragraph (1)(b)—

(i) for "CE" substitute " UK ";

(ii) omit "(CE marking)";

(d) for paragraph (3) substitute—

"(3) Where a civil explosive is subject to more than one enactment requiring a declaration of conformity to be drawn up, the manufacturer must draw up a single declaration of conformity which identifies each enactment by its title.".

Commencement Information

I6 Sch. 31 para. 6 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 8

7. In regulation 8 (retention of technical documentation and EU declaration of conformity) and in the heading to that regulation omit "EU".

Commencement Information

I7 Sch. 31 para. 7 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 9

8. In regulation 9 (compliance procedures for series production), in paragraph (2)(b)—

(a) for "harmonised" substitute " designated ";

(b) omit "EU".

Commencement Information

I8 Sch. 31 para. 8 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 10

9. In regulation 10 (traceability of certain civil explosives excluded from the scope of regulations 4, 5 and 6 of the Identification and Traceability of Explosives Regulations (Northern Ireland) 2013 (ITOER (NI) 2013)) for paragraph (4) substitute—

"(4) For a civil explosive that is to be made available on the market in Northern Ireland the contact details referred to in paragraph (1) must be provided in English.".

Commencement Information

I9 Sch. 31 para. 9 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 11

10. For regulation 11 (instructions and safety information), substitute—

"**Instructions and safety information**

11.—(1) When placing a civil explosive on the market, a manufacturer must ensure that it is accompanied by instructions and safety information that are clear, legible and in easily understandable English.

(2) Any labelling on the civil explosive must be clear, legible and in easily understandable English.".

Commencement Information

I10 Sch. 31 para. 10 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 12

11. Regulation 12 (appointment of authorised representative by written mandate) is amended as follows—

(a) in paragraph (1) after "appoint a person" insert " established in the United Kingdom ";

(b) in paragraph (2)(a) omit "EU".

Commencement Information

I11 Sch. 31 para. 11 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 14

12. In regulation 14 (requirements which must be satisfied before an importer places a civil explosive on the market), in paragraph (1)(c)(i) for "CE" substitute " UK ".

Commencement Information

I12 Sch. 31 para. 12 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 16

13. In regulation 16 (information identifying importer)—

(a) after paragraph (1) insert—

"(1A) Paragraph (1) does not apply where the importer has imported the civil explosive from an EEA state **[**[F1]or Switzerland**]** and places it on the market within the period of eighteen months beginning with exit day, and before placing the civil explosive on the market, the importer sets out the information referred to in paragraph (1) in a document accompanying the civil explosive.";

(b) in paragraph (2) for "the market surveillance authority in the EEA State in which the civil explosive is to be made available to such end-users" substitute " a relevant authority ".

F1 Words in Sch. 31 para. 13(a) inserted (31.12.2020 immediately before IP completion day) by The Product Safety, Metrology and Mutual Recognition Agreement (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1246), regs. 1(3), **5**; 2020 c. 1, Sch. 5 para. 1(1)

Commencement Information

I13 Sch. 31 para. 13 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 17

14. For regulation 17 (instructions and safety information) substitute—

"**Instructions and safety information**

17. When placing a civil explosive on the market, an importer must ensure that it is accompanied by instructions and safety information that are clear, legible and in easily understandable English.".

Commencement Information

I14 Sch. 31 para. 14 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 18

15. In regulation 18 (retention of technical documentation and EU declaration of conformity), in the heading to that regulation and in paragraph (a), omit "EU".

Commencement Information

I15 Sch. 31 para. 15 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 19

16. In regulation 19 (duty to take action in respect of civil explosives placed on the market which are considered not to be in conformity), in paragraph (2) for "competent national authorities of any EEA State in which the manufacturer or importer made the civil explosive available on the market," substitute " market surveillance authority ".

Commencement Information

I16 Sch. 31 para. 16 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 20

17. In regulation 20 (provision of information and cooperation)—

(a) in each place where it occurs, for "a competent national authority" substitute " the market surveillance authority "; and

(b) in paragraph (1)(b) for "in a language which can be easily understood by the authority" substitute " in clear, legible and in easily understandable English ".

Commencement Information

I17 Sch. 31 para. 17 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 22

18. In regulation 22 (requirements which must be satisfied before a distributor makes a civil explosive available on the market), paragraph (1)(a) is amended as follows—

(a) in sub-paragraph (i) for "CE" substitute " UK "; and

(b) for sub-paragraph (iii) substitute—

"(iii) is accompanied by instructions and safety information that are clear, legible and in easily understandable English.".

Commencement Information

I18 Sch. 31 para. 18 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 24

19. In regulation 24 (duty to take action in respect of civil explosives made available on the market which are not in conformity), in paragraph (2) for "competent national authorities of any EEA State in which the distributor has made the civil explosive available on the market," substitute " market surveillance authority ".

Commencement Information

I19 Sch. 31 para. 19 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 25

20. In regulation 25 (provision of information and cooperation), in each place in which it occurs for "a competent national authority" substitute " the enforcing authority ".

Commencement Information

I20 Sch. 31 para. 20 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Revocation of regulation 28

21. Omit regulation 28 (translation of declaration of conformity).

Commencement Information

I21 Sch. 31 para. 21 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 30

22. In regulation 30 (prohibition on improper use of CE marking), in the heading and in each place in which it occurs, for "CE" substitute " UK ".

Commencement Information

I22 Sch. 31 para. 22 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of regulation 30A

23. After regulation 30 insert—

"**Obligations which are met by complying with obligations in the Directive**

30A.—(1) In this regulation—

(a) any reference to an Article or an Annex is a reference to an Article or an Annex of the Directive;

(b) "CE marking" has the meaning given to it in Article 2(24);

(c) "harmonised standard" has the meaning given to it in Article 2(16).

(2) Subject to paragraphs (6) and (7), paragraph (3) applies where, before placing a civil explosive on the market, the manufacturer—

(a) ensures that the civil explosive has been designed and manufactured in accordance with the essential safety requirements set out in Annex II;

(b) ensures that the relevant conformity assessment procedures that apply to that civil explosive in accordance with Article 20 have been carried out;

(c) draws up the technical documentation referred to in Annex III;

(d) ensures that the technical documentation and other records and correspondence relating to the conformity assessment procedures are prepared in or translated into English;

(e) affixes a CE marking, in accordance with Articles 22 and 23(1) to (5);

(f) draws up an EU declaration of conformity, in accordance with Article 21; and

(g) ensures that the EU declaration of conformity is prepared in or translated into English.

(3) Where this paragraph applies—

(a) the requirements of regulations 5, 6, 7(1) and 7(3) are to be treated as being satisfied;

(b) regulations 7(2), 8, 9(2), 12(2) and 30 apply subject to the modifications in paragraph (10); and

(c) Schedule 2 paragraph 12 does not apply.

(4) Subject to paragraphs (6) and (7), paragraph (5) applies where, before placing a civil explosive on the market, the importer ensures that—

(a) the relevant conformity assessment procedures that apply to that explosive in accordance with Article 20 have been carried out;

(b) the manufacturer has drawn up the technical documentation referred to in Annex III; and

(c) the civil explosive bears the CE marking referred to in Article 23.

(5) Where this paragraph applies—

(a) the requirements of regulation 14(1)(a) to (c) are to be treated as being satisfied; and

(b) regulations 13, 15(1), 18 and 26 apply subject to the modifications in paragraph (10).

(6) This paragraph applies where there is no designated standard or part of a designated standard which corresponds exactly to a harmonised standard or part of a harmonised standard referred to in Article 19.

(7) Where paragraph (6) applies paragraphs (2)(b) and (4)(a) are to be treated as requiring the manufacturer to carry out one of the conformity assessment procedures set out in Article 20.

(8) Paragraph (9) applies where, before making a civil explosive available on the market, a distributor ensures that the civil explosive bears the CE marking referred to in Article 23.

(9) Where this paragraph applies—

(a) regulation 22(1)(a)(i) is to be treated as being satisfied; and

(b) regulations 23(1) and 26 apply subject to the modifications in paragraph (10).

(10) The modifications referred to in sub-paragraphs (3)(b), (5)(b) and (9)(b) are that—

(a) any reference to "declaration of conformity" is to be read as a reference to the EU declaration of conformity;

(b) any reference to "UK marking" is to be read as a reference to the CE marking;

(c) any reference to "essential safety requirements" is to be read as a reference to the essential safety requirements referred to in Annex II;

(d) any reference to "designated standard" is to be read as a reference to a harmonised standard;

(e) any reference to "relevant conformity assessment procedure" is to be read as a reference to the relevant conformity assessment procedures referred to in Article 20;

(f) any reference to "technical documentation" is a reference to the technical documentation referred to in Annex III.

Conformity assessment procedure obligation which is met by complying with the Directive

30B.—(1) In this regulation any reference to an Article or an Annex is a reference to an Article or an Annex of the Directive.

(2) Paragraph (3) applies where, prior to the manufacture of a civil explosive, the manufacturer ensures that the conformity assessment procedure that applies to that explosive in accordance with Article 20(a) has been carried out.

(3) Where this paragraph applies—

(a) any reference to "relevant conformity assessment procedure" in regulations 6(a), 7(1), 14(1)(a), 30(1)(b), 33(b) and 34(3) are to be read as including the conformity assessment procedure referred to in Article 20(a) of the Directive; and;

(b) any reference to "technical documentation" in regulations 6(b), 8, 14(1)(b), 18(b), and in Schedule 2 Part 1 paragraph 12(1)(d) and Schedule 5 is to be read as including the technical documentation relating to the design of the civil explosive referred to in Annex III.".

Commencement Information

I23 Sch. 31 para. 23 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 31

24. In regulation 31 (presumption of conformity), paragraph (1) is amended as follows—

(a) for "harmonised" substitute " designated "; and

(b) omit "the reference to which has been published in the Official Journal of the European Union,".

Commencement Information

I24 Sch. 31 para. 24 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 32

25. For regulation 32 (conformity assessment procedures) substitute—

"**Conformity assessment procedures**

32.—(1) Assessment of conformity of a civil explosive is carried out by an approved body in accordance with the procedures set out in Schedule 5.

(2) For the assessment of conformity of a civil explosive, the manufacturer must follow one of the following procedures set out in Schedule 5—

(a) in Part 1 of Schedule 5, Type examination carried out by an approved body (Module B), and, at the choice of the manufacturer, one of the following procedures—

(i) in Part 2 of Schedule 5, conformity to type based on internal production control plus supervised product checks at random intervals (Module C2);

(ii) in Part 3 of Schedule 5, conformity to type based on quality assurance of the production process (Module D);

(iii) in Part 4 of Schedule 5, conformity to type based on product quality assurance (Module E);

(iv) in Part 5 of Schedule 5, conformity to type based on product verification (Module F);

(b) in Part 6 of Schedule 5, conformity based on unit verification (Module G).".

Commencement Information

I25 Sch. 31 para. 25 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 33

26. Regulation 33 (EU declaration of conformity) is amended as follows—

(a) in the heading for "EU declaration" substitute " Declaration ";

(b) in the opening words omit "EU";

(c) in paragraph (b) for "Annex III to the Directive (as amended from time to time)" substitute " Schedule 5 ";

(d) in paragraph (c) for "Annex IV to the Directive (as amended from time to time)" substitute " Schedule 6 ".

Commencement Information

I26 Sch. 31 para. 26 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to regulation 34

27. Regulation 34 (CE marking) is amended as follows—

(a) in the heading for "CE" substitute " UK ";

(b) in paragraph (1) for "CE" substitute " UK ";

(c) in paragraph (2) for "CE" in both places it appears, substitute " UK ";

(d) in paragraph (3)—

(i) for "CE" substitute " UK ";

(ii) for "notified" substitute " approved ";

(e) in paragraph (4) for "notified" in each place it appears, substitute " approved ";

(f) in paragraph (5) for "CE" substitute " UK ".

Commencement Information

I27 Sch. 31 para. 27 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to Part 3, Sub-Part C

28. For Part 3, Sub-Part C (NOTIFICATION OF CONFORMITY ASSESSMENT BODIES) substitute—

"SUB-PART C: APPROVAL OF CONFORMITY ASSESSMENT BODIES

Approved bodies

35.—(1) An approved body is a conformity assessment body which—

(a) has been approved by the Secretary of State pursuant to the procedure set out in regulation 36 (approval of conformity assessment bodies); or

(b) immediately before exit day was a notified body in respect of which the Secretary of State had taken no action under regulation 41(1) or (2) as they had effect immediately before exit day to suspend or withdraw the body's status as a notified body.

(2) Paragraph (1) has effect subject to regulation 39 (restriction, suspension or withdrawal of approval).

(3) In this Sub-Part—

"notified body" means a body—

(a) which the Secretary of State had before exit day notified to the European Commission and to the other EEA states, in accordance with Article 24 of the Directive; and

(b) in respect of which no objections had been raised, as referred to in regulation 35(1)(b), as it had effect immediately before exit day;

"approved body requirements" means the requirements set out in Schedule 3.

Approval of conformity assessment bodies

36.—(1) The Secretary of State may approve only those conformity assessment bodies that qualify for approval.

(2) A conformity assessment body qualifies for approval if the first and second condition are met.

(3) The first condition is that the conformity assessment body has applied to the Secretary of State to become an approved body and that 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 procedure in respect of which the conformity assessment body claims to be competent;

(iii) the civil explosives in respect of which the conformity assessment body claims to be competent; and

(b) either—

(i) an accreditation certificate; or

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

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

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

(6) When deciding whether to approve a conformity assessment body that qualifies for approval, 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) For the purposes of this regulation, "accreditation certificate" means a certificate, issued by the UK national accreditation body, attesting that a conformity assessment body meets the approved body requirements.

Presumption of conformity of approved bodies

37.—(1) Where a conformity assessment body demonstrates its conformity with the criteria laid down in a designated standard (or part of such standard), the Secretary of State is to presume that the conformity assessment body meets the approved body requirements covered by that standard (or part of that standard).

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

Monitoring

38. The Secretary of State must monitor each approved body with a view to verifying that the body—

(a) continues to meet the approved body requirements;

(b) meets any conditions set—

(i) in accordance with regulation 36(6)(b); or

(ii) in the case of an approved body which was a notified body immediately before exit day, in accordance with conditions set under regulation 36(6)(b) as it applied immediately before exit day; and

(c) carries out its functions in accordance with these Regulations.

Restriction, suspension or withdrawal of approval

39.—(1) Where the Secretary of State determines that an approved body—

(a) no longer meets an approved body requirement; or

(b) is failing to fulfil its obligations under these Regulations, other than a condition referred to in regulation 38(b),

the Secretary of State must restrict, suspend or withdraw the body's status as an approved body under regulation 35 (approved bodies).

(2) Where the Secretary of State determines that an approved body no longer meets a condition referred to in regulation 38(b), the Secretary of State may restrict, suspend or withdraw the body's status as an approved body under regulation 35.

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

(4) Before taking action under paragraph (1) or (2), the Secretary of State must—

(a) give notice in writing to the approved body of the proposed action and the reasons for it;

(b) give the approved body an opportunity to make representations to the Secretary of State regarding the proposed action within a reasonable period from the date of the notice; and

(c) consider any such representations.

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

(a) transfer its files relating to the activities it has undertaken as an approved body to another approved body or to the Secretary of State; or

(b) keep its files relating to the activities it has undertaken as an approved body available for the Secretary of State and market surveillance authority for a period of 10 years from the date they were created.

(6) The activities undertaken as an approved body referred to in paragraph (5) include any activities that the body has undertaken as a notified body.

Operational matters in relation to approved bodies

40.—(1) Subject to the terms of its appointment, an approved body must carry out the conformity assessment activities and procedures—

(a) in respect of which the body's approval was given under regulation 36; or

(b) in respect of which the body's notification as a notified body was made.

(2) Where an approved body carries out a conformity assessment procedure, it must do so in accordance with Schedule 4 (operational obligations of approved bodies).

(3) An approved body must make provision for a manufacturer to be able to make an appeal against a refusal by the approved body—

(a) to issue a Type examination certificate referred to in Schedule 5 (conformity assessment procedures); or

(b) to affix, or cause to be affixed, the body's identification number pursuant to regulation 34 (UK marking).

Subsidiaries and contractors

41.—(1) An approved body may subcontract specific conformity assessment activities or use a subsidiary to carry out such activities provided—

(a) the body is satisfied that the subcontractor or subsidiary meets the approved body requirements;

(b) the body has informed the Secretary of State that it is satisfied that the subcontractor or subsidiary meets those requirements; and

(c) the economic operator for whom the activities are to be carried out has consented to the activities being carried out by that person.

(2) The approved body which subcontracts specific conformity assessment activities or uses a subsidiary to carry out such activities remains responsible for the proper performance of those activities (irrespective of where the subcontractor or subsidiary is established).

(3) Where an approved body subcontracts, or uses a subsidiary to carry out, a specific conformity assessment activity, the approved body must, for a period of 10 years beginning on the day on which the activity is first carried out, keep available for inspection by the Secretary of State all relevant documentation concerning—

(a) the assessment of the qualifications of the subcontractor or the subsidiary; and

(b) the conformity assessment activity carried out by the subcontractor or subsidiary.

(4) In this regulation "subsidiary" has the meaning given to it in section 1159 of the Companies Act 2006 [M1].

Register of approved bodies

42.—(1) The Secretary of State must—

(a) assign an approved body identification number to each approved body; and

(b) compile and maintain a register of—

(i) approved bodies;

(ii) their approved body identification numbers;

(iii) the activities for which they have been approved; and

(iv) any restrictions on those activities.

(2) The register referred to in paragraph (1) must be made publicly available.

UK national accreditation body

43. The Secretary of State may authorise the UK national accreditation body to carry out the following activities on behalf of the Secretary of State—

(a) assessing whether a conformity assessment body meets the approved body requirements;

(b) monitoring approved bodies in accordance with regulation 38; and

(c) compiling and maintaining the register of approved bodies, in accordance with regulation 42.".

Commencement Information

I28 Sch. 31 para. 28 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M1 2006 c.46.

Transitional provision in relation to EU Exit

29. After regulation 45 (transitional provisions) insert—

"**Transitional provision in relation to EU Exit**

45A.—(1) In this regulation—

"pre-exit period" means the period beginning with 20th April 2016 and ending immediately before exit day;

"product" means a civil explosive to which these Regulations apply.

(2) Subject to paragraph (3), where a product was made available on the market during the pre-exit period, despite the amendments made by Schedule 31 to the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 [M2], any obligation to which a

person was subject under these Regulations as they had effect immediately before exit day, continues to have effect as it did immediately before exit day, in relation to that product.

(3) Paragraph (2) does not apply to—

(a) any obligation of any enforcing authority to inform the European Commission or the member States of any matter; or

(b) any obligation to take action outside of the market in respect of that product.

(4) Where during the pre-exit period—

(a) a product has not been placed on the market; and

(b) a manufacturer has taken any action under regulation 6 as it had effect immediately before exit day in relation to that product,

that action has effect as if it had been done under regulation 6 as it had effect on and after exit day.".

Commencement Information

I29 Sch. 31 para. 29 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M2 S.I. 2019/696.

Amendment to Schedule 1

30. In Schedule 1 at the beginning omit "(This Schedule reproduces, with minor modifications, the provision of Annex II to the Directive)".

Commencement Information

I30 Sch. 31 para. 30 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendments to Schedule 2

31. Schedule 2 is amended as follows—

(a) in paragraph 2 for "the Directive" substitute " these Regulations ";

(b) omit paragraph 4(c);

(c) in paragraph 9(2) for "notified body" substitute " approved body ";

(d) omit paragraph 9(4);

(e) omit paragraph 9(7);

(f) in paragraph 9(8)—

(i) for "The notices in sub-paragraphs (6) and (7)" substitute " The notice in sub-paragraph (6) ";

(ii) in head (f)(ii) for "harmonised" substitute " designated ";

(g) in paragraph 9(10) for "competent national authority" substitute " relevant authority ";

(h) omit paragraph 10 (EU safeguarding procedures);

(i) omit paragraph 11(3);

(j) in paragraph 11(4) for "The notices referred to in sub-paragraphs (2) and (3)" substitute " The notice referred to in sub-paragraph (2) ";

(k) in paragraph 12—

(i) in sub-paragraphs (1)(a), (1)(b) and (1)(c), for "CE marking" substitute " UK marking " in each place it appears;

(ii) in sub-paragraph (1)(b) for "a notified body" substitute " an approved body ";

(iii) in sub-paragraph (1)(b) "the notified body" substitute "the approved body"; and

(iv) in sub-paragraph (1)(c) for "EU declaration of conformity" substitute " declaration of conformity " in each place it appears.

Commencement Information

I31 Sch. 31 para. 31 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendment to Schedule 3

32. Schedule 3 is amended as follows—

(a) in the heading, for "Notified" substitute " Approved ";

(b) in paragraph 8 for "notified" substitute " approved ";

(c) in paragraph 11(c)—

(i) for "harmonised" substitute " designated ";

(ii) omit "and of the Directive";

(d) in paragraph 17—

(i) for "notified" substitute " approved ";

(ii) for "under the Directive" substitute " by the Secretary of State ".

Commencement Information

I32 Sch. 31 para. 32 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Amendments to Schedule 4

33. Schedule 4 is amended as follows—

(a) in the heading for "Notified" substitute " Approved ";

(b) in paragraph 1, for "A notified" substitute " An approved ";

(c) in paragraph 2, for "A notified" substitute " An approved ";

(d) in paragraph 3, for "A notified" substitute " An approved ";

(e) in paragraph 4, for "A notified" substitute " An approved ";

(f) in paragraph 5—

(i) for "a notified" substitute " an approved ";

(ii) for "harmonised" substitute " designated ";

(g) in paragraph 6, for "a notified" substitute " an approved ";

(h) in paragraph 7, for "notified" substitute " approved " in both places it appears;

(i) in paragraph 8, for "a notified" substitute " an approved ";

(j) in paragraph 9, for "notified" substitute " approved ";

(k) in paragraph 10—

(i) for "A notified" substitute " An approved ";

(ii) in sub-paragraph (b)—

(aa) for "notification" in the first place it appears substitute " approval ";

(bb) in the second place it appears omit "(notification)";

(iii) in sub-paragraph (d) for "notification" substitute " approval ";

(l) in paragraph 11, for "A notified" substitute " An approved ";

(m) in paragraph 12—

(i) for "A notified" substitute " An approved ";

(ii) for "notified under the Directive" substitute " approved under these Regulations ";

(n) in paragraph 13—

(i) for "A notified" substitute " An approved ";

(ii) for "any notified body" substitute " any approved body ";

(iii) for "under the Directive" substitute " by the Secretary of State ".

Commencement Information

I33 Sch. 31 para. 33 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Insertion of Schedule 5 and Schedule 6

34. After Schedule 4 insert—

"SCHEDULE 5 Regulation 32

CONFORMITY ASSESSMENT PROCEDURES

PART 1

TYPE EXAMINATION (MODULE B)

1.—(1) Type examination (Module B) is a conformity assessment procedure in which an approved body examines the technical design of an explosive and verifies and attests that the technical design of the explosive meets the requirements of these Regulations that apply to it.

(2) Type examination must be carried out as an assessment of the adequacy of the technical design of the explosive through—

(a) examination of the technical documentation and supporting evidence referred to in paragraph 2; and

(b) examination of a specimen of the production envisaged which is representative of the complete product (combination of production type and design type).

2.—(1) A manufacturer must lodge an application for Type examination (Module B) with an approved body of the manufacturer's choice.

(2) The application must include—

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, the name and address of the authorised representative;

(b) a written declaration that the same application has not been lodged with any other approved body;

(c) the technical documentation;

(d) the specimens representative of the production envisaged, and any further specimens requested by the approved body if needed for carrying out the test programme;

(e) the supporting evidence for the adequacy of the technical design solution; this supporting evidence must—

(i) mention any documents that have been used, in particular where the relevant designated standards have not been applied in full;

(ii) include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on the manufacturer's behalf and under the manufacturer's responsibility.

3. The technical documentation referred to in paragraph 2(2)(c) must—

(a) make it possible to assess the explosive's conformity with the applicable requirements of these Regulations and must include an adequate analysis and assessment of any risks;

(b) specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the explosive;

(c) contain, wherever applicable, at least the following elements—

(i) a general description of the explosive;

(ii) conceptual design and manufacturing drawings and schemes of components, sub-assemblies and circuits;

(iii) descriptions and explanations necessary for the understanding of those drawings and schemes and the operation of the explosive;

(iv) a list of the designated standards applied in full or in part (where applicable specifying the parts which have been applied);

(v) where designated standards have not been applied, descriptions of the solutions adopted to meet the essential safety requirements, including a list of other relevant technical specifications applied to meet the essential safety requirements;

(vi) the results of design calculations made and examinations carried out;

(vii) test reports.

4.—(1) The approved body must examine the technical documentation and supporting evidence in respect of an explosive to assess the adequacy of the technical design of the explosive.

(2) For each of the specimens examined, the approved body must—

(a) verify that the specimen—

(i) has been manufactured in conformity with the technical documentation;

(ii) identifies the elements which have been designed in accordance with the applicable provisions of the relevant designated standards, as well as the elements which have been designed in accordance with other relevant technical specifications;

(b) carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant designated standards, these have been applied correctly;

(c) carry out, or arrange the carrying out of, appropriate examinations and tests to check whether, where the solutions in the relevant designated standards have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential safety requirements;

(d) agree with the manufacturer on a location where the examinations and tests will be carried out.

5. The approved body must draw up an evaluation report that records the activities undertaken in accordance with paragraph 4 and their outcomes and, without prejudice to the approved body's obligations in relation to the Secretary of State, the approved body may disclose the content of that report, in full or in part, only with the agreement of the manufacturer.

6.—(1) Where the type meets the applicable requirements of these Regulations, the approved body must issue a Type examination certificate to the manufacturer, which must contain—

(a) the name and address of the manufacturer;

(b) the conclusions of the examination;

(c) the conditions (if any) for its validity;

(d) the necessary data for the identification of the approved type;

(e) all relevant information to allow the conformity of manufactured explosives with the examined type to be evaluated and to allow for in-service control.

(2) The Type examination certificate referred to in sub-paragraph (1)—

(a) may have one or more annexes attached;

(b) must be accompanied by the descriptions and drawings necessary for identification of the approved type.

(3) Where the type does not satisfy the applicable requirements of these Regulations, the approved body must refuse to issue a Type examination certificate and must inform the applicant accordingly, giving detailed reasons for its refusal.

7. An approved body must keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of these Regulations, and must determine whether such changes require further investigation and, if so, the approved body must inform the manufacturer accordingly.

8. A manufacturer must inform the approved body that holds the technical documentation relating to the Type examination certificate of all modifications to the approved type that may affect the conformity of the explosive with the essential safety

requirements or the conditions for validity of that certificate; such modifications require additional approval in the form of an addition to the original Type examination certificate.

9.—(1) Each approved body must inform the Secretary of State of all Type examination certificates and any additions thereto which it has issued or withdrawn, and must, periodically or upon request, make available to the Secretary of State the list of such certificates and any additions thereto refused, suspended or otherwise restricted.

(2) Each approved body must inform the other approved bodies of all Type examination certificates and any additions thereto which it has refused, withdrawn, suspended or otherwise restricted, and must, upon request, inform the other approved bodies of such certificates and additions thereto which it has issued.

(3) The other approved bodies and the Secretary of State may obtain from the approved body a copy of—

(a) the Type examination certificates and additions thereto;

(b) the technical documentation and the results of the examinations carried out by the approved body.

(4) An approved body must keep a copy of the Type examination certificate, its annexes and additions, as well as the file containing the technical documentation including the documentation submitted by the manufacturer, until the expiry of the validity of that certificate.

(5) A manufacturer must keep a copy of the Type examination certificate, its annexes and additions together with the technical documentation at the disposal of the relevant authority for 10 years beginning on the day on which the explosive has been placed on the market.

10. A manufacturer's authorised representative (if any) may lodge the application referred to in paragraph 2 and fulfil the obligations set out in paragraphs 8 and 9(5), provided that they are specified in the mandate by which they were appointed under regulation 12.

PART 2

CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED PRODUCT CHECKS AT RANDOM INTERVALS (MODULE C2)

11. Conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) is the part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 12 to 14, and it is solely the manufacturer's responsibility to ensure and declare that the explosives concerned are in conformity with the type described in the Type examination certificate and satisfy the requirements of these Regulations that apply to them.

Manufacturing

12. A manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured explosives with the type described in the Type examination certificate and with the requirements of these Regulations that apply to them.

Product checks

13.—(1) The approved body chosen by the manufacturer must carry out product checks or have them carried out at random intervals determined by that body, in order to verify the quality of the internal checks on the explosive, taking into account, amongst other things, the technological complexity of the explosives and the quantity of production.

(2) The approved body must ensure that—

(a) it takes an adequate sample of the final product on site before its placing on the market; and

(b) the sample is examined and appropriate tests as identified by the relevant parts of the designated standards, or equivalent tests set out in other relevant technical specifications, are carried out to check the conformity of the explosive with the type described in the Type examination certificate and with the relevant requirements of these Regulations.

(3) Where a sample does not conform to the acceptable quality level, the approved body must take appropriate measures.

(4) The acceptance sampling procedure to be applied is intended to determine whether the manufacturing process of the explosive performs within acceptable limits, with a view to ensuring conformity of the explosive.

(5) The manufacturer must, under the responsibility of the approved body, affix the approved body's identification number during the manufacturing process.

UK marking and declaration of conformity

14.—(1) A manufacturer must affix the UK marking to each individual explosive that is in conformity with the type described in the Type examination certificate and which satisfies the applicable requirements of these Regulations.

(2) A manufacturer must draw up a written declaration of conformity for each explosive type and keep it at the disposal of the relevant authority for 10 years beginning on the day on which the explosive has been placed on the market; the declaration of conformity must identify the explosive type for which it has been drawn up.

(3) A copy of the declaration of conformity must be made available to the relevant authority upon request.

Authorised representative

15. A manufacturer's obligations set out in paragraph 14 may be fulfilled by the manufacturer's authorised representative (if any), on the manufacturer's behalf and under the manufacturer's responsibility, provided that they are specified in the mandate by which they were appointed under regulation 12.

PART 3

CONFORMITY TO TYPE BASED ON QUALITY ASSURANCE OF THE PRODUCTION PROCESS (MODULE D)

16. Conformity to type based on quality assurance of the production process (Module D) is a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 17 and 23, and it is solely the manufacturer's responsibility to ensure and declare that the explosives concerned are in conformity with the type described in the

Type examination certificate and satisfy the requirements of these Regulations that apply to them.

Manufacturing

17. A manufacturer must operate an approved quality system for production, final product inspection and testing of the explosives specified in paragraph 18, and which is subject to surveillance as specified in paragraph 22.

Quality system

18.—(1) A manufacturer must lodge an application for assessment of the manufacturer's quality system with an approved body of the manufacturer's choice.

(2) The application must include—

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, the name and address of the authorised representative;

(b) a written declaration that the same application has not been lodged with any other approved body;

(c) all relevant information for the explosive category envisaged;

(d) the documentation concerning the quality system;

(e) the technical documentation of the approved type and a copy of the Type examination certificate.

19.—(1) The quality system must ensure that the explosives are in conformity with the type described in the Type examination certificate and comply with the requirements of these Regulations that apply to them.

(2) All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions.

(3) The quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records and must, in particular, contain an adequate description of—

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;

(b) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

(c) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(d) quality records, such as inspection reports and test data, calibration data, and qualification reports on the personnel concerned;

(e) the means of monitoring the achievement of the required product quality and the effective operation of the quality system.

20.—(1) The approved body must assess the quality system to determine whether it satisfies the requirements referred to in paragraph 19 and, where applicable, it must presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant designated standard.

(2) The audit team appointed by the approved body to carry out the audit in sub-paragraph (1) ("the audit") must have experience in quality management systems, with at least one member of the team having experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of these Regulations.

(3) The audit must include an assessment visit to the manufacturer's premises.

(4) The audit team must review the technical documentation referred to in paragraph 18(2)(e) to verify the manufacturer's ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the explosive with those requirements.

(5) The decision of the approved body must be notified to the manufacturer and must contain the conclusions of the audit and a reasoned assessment of the decision.

21.—(1) A manufacturer must—

(a) fulfil the obligations arising out of the quality system as approved and maintain it in an adequate and efficient state; and

(b) keep the approved body that has approved the quality system informed of any intended change to the quality system.

(2) Where the approved body is notified by a manufacturer of any proposed change to the quality system the approved body must—

(a) evaluate such proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in paragraph 19 or whether a reassessment is necessary; and

(b) notify the manufacturer of its decision and, that notification must contain the conclusions of the examination and a reasoned assessment of the decision.

Surveillance under the responsibility of the approved body

22.—(1) The approved body must carry out surveillance, the purpose of which is to ensure that a manufacturer fulfils the obligations arising out of the approved quality system.

(2) A manufacturer must, for assessment purposes, allow the approved body access to the manufacture, inspection, testing and storage sites and must provide the approved body with all necessary information including, in particular—

(a) the quality system documentation;

(b) the quality records, such as inspection reports and test data, calibration data, and qualification reports on the personnel concerned.

(3) The approved body must carry out periodic audits to ensure that a manufacturer maintains and applies the quality system and, following each audit, must provide the manufacturer with an audit report.

(4) The approved body may pay unexpected visits to a manufacturer; during such visits the approved body may, if necessary, carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly; and following such a visit the approved body must provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

UK marking and declaration of conformity

23.—(1) A manufacturer must affix the UK marking, and, under the responsibility of the approved body referred to in paragraph 18(1), the latter's identification number to each

individual explosive that is in conformity with the type described in the Type examination certificate and which satisfies the applicable requirements of these Regulations.

(2) A manufacturer must draw up a written declaration of conformity for each explosive type and keep it at the disposal of the relevant authority for 10 years beginning on the day on which the explosive has been placed on the market; the declaration of conformity must identify the explosive type for which it has been drawn up.

(3) A copy of the declaration of conformity must be made available to the relevant authority upon request.

24. A manufacturer must, for a period of 10 years beginning on the day on which the explosive has been placed on the market, keep at the disposal of the relevant authority—

(a) the documentation referred to in paragraph 18(2);

(b) any information relating to the change referred to in paragraph 21(1)(b) and 21(2), as approved;

(c) the decisions and reports of the approved body referred to in paragraphs 21, 22(3) and 22(4).

25. Each approved body must inform the Secretary of State of quality system approvals issued or withdrawn and must, periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.

26. Each approved body must inform other approved bodies of quality system approvals which it has refused, suspended, withdrawn or otherwise restricted, and, upon request, of quality system approvals which it has issued.

Authorised representative

27. A manufacturer's obligations set out in paragraphs 18(1), 18(2), 21(1)(b), 21(2), 23 and 24 may be fulfilled by the manufacturer's authorised representative (if any), on the manufacturer's behalf and under the manufacturer's responsibility, provided that they are specified in the mandate by which they were appointed under regulation 12.

PART 4

CONFORMITY TO TYPE BASED ON PRODUCT QUALITY ASSURANCE (MODULE E)

28. Conformity to type based on product quality assurance (Module E) is that part of a conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 29 and 34, and it is solely manufacturer's responsibility to ensure and declare that the explosives concerned are in conformity with the type described in the Type examination certificate and satisfy the requirements of these Regulations that apply to them.

Manufacturing

29. A manufacturer must operate an approved quality system for final product inspection and testing of the explosives concerned as specified in paragraphs 30 and 31 and, which must be subject to surveillance as specified in paragraph 33.

Quality system

30.—(1) A manufacturer must lodge an application for assessment of the manufacturer's quality system with an approved body of the manufacturer's choice for the explosives concerned.

(2) The application must include—

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, the name and address of the authorised representative;

(b) a written declaration that the same application has not been lodged with any other approved body;

(c) all relevant information for the explosive category envisaged;

(d) the documentation concerning the quality system;

(e) the technical documentation of the approved type and a copy of the Type examination certificate.

(3) The quality system must ensure compliance of the explosives with the type described in the Type examination certificate and with the applicable requirements of these Regulations.

(4) All the elements, requirements and provisions adopted by the manufacturer must be documented in a systematic and orderly manner in the form of written policies, procedures and instructions; this quality system documentation must permit a consistent interpretation of the quality programmes, plans, manuals and records and, it must, in particular, contain an adequate description of—

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to product quality;

(b) the examinations and tests that will be carried out after manufacture;

(c) the quality records, such as inspection reports and test data, calibration data and qualification reports on the personnel concerned;

(d) the means of monitoring the effective operation of the quality system.

31.—(1) The approved body must assess the quality system to determine whether it satisfies the requirements referred to in paragraph 30(3) and (4) and, where applicable, it must presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of a relevant designated standard.

(2) The audit team, appointed by the approved body to carry out the audit under sub-paragraph (1) (“the audit”) must have experience in quality management systems and have at least one member with experience of evaluation in the relevant product field and product technology concerned, and knowledge of the applicable requirements of these Regulations.

(3) The audit must include an assessment visit to the manufacturer's premises.

(4) The audit team must review the technical documentation referred to in paragraph 30(2)(e), in order to verify the manufacturer's ability to identify the relevant requirements of these Regulations and to carry out the necessary examinations with a view to ensuring compliance of the explosive with those requirements.

(5) The decision of the approved body must be notified to the manufacturer and, the notification must contain the conclusions of the audit and the reasoned assessment for the decision.

32.—(1) A manufacturer must—

(a) fulfil the obligations arising out of the quality system as approved and maintain it in an adequate and efficient state; and

(b) keep the approved body that has approved the quality system informed of any intended change to the quality system.

(2) Where the approved body is notified by a manufacturer of any proposed change to the quality system the approved body must—

(a) evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in paragraph 30(3) and (4) or whether a reassessment is necessary; and

(b) notify the manufacturer of its decision and, that notification must contain the conclusions of the examination and the reasoned assessment for the decision.

Surveillance under the responsibility of the approved body

33.—(1) The approved body must carry out surveillance, the purpose of which is to ensure that a manufacturer fulfils the obligations arising out of the approved quality system.

(2) A manufacturer must, for assessment purposes, allow the approved body access to the manufacture, inspection, testing and storage sites and must provide it with all necessary information, in particular—

(a) the quality system documentation;

(b) the quality records, such as inspection reports and test data, calibration data and qualification reports on the personnel concerned.

(3) The approved body must carry out periodic audits to ensure that a manufacturer maintains and applies the quality system and, following each audit, must provide the manufacturer with an audit report.

(4) The approved body may pay unexpected visits to the manufacturer; during such visits the approved body may carry out product tests, or have them carried out, in order to verify that the quality system is functioning correctly and, following such a visit, the approved body must provide the manufacturer with a visit report and, if tests have been carried out, a test report.

UK marking and declaration of conformity

34.—(1) A manufacturer must affix the UK marking and, under the responsibility of the approved body referred to in paragraph 30(1), the latter's identification number to each individual explosive that is in conformity with the type described in the Type examination certificate and satisfies the applicable requirements of these Regulations.

(2) A manufacturer must draw up a written declaration of conformity for each explosive type and keep it at the disposal of the relevant authority for 10 years beginning on the day on which the explosive has been placed on the market.

(3) A copy of the declaration of conformity must be made available to the relevant authority upon request.

35. A manufacturer must, for a period of 10 years, beginning on the day on which the explosive has been placed on the market, keep at the disposal of the relevant authority—

(a) the documentation referred to in paragraph 30(1) and 30(2);

(b) the information relating to the change referred to in paragraph 32, as approved;

(c) the decisions and reports of the approved body referred to in paragraphs 32(2), 33(3) and 33(4).

36.—(1) Each approved body must inform the Secretary of State of quality system approvals issued or withdrawn, and must, periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.

(2) Each approved body must inform the other approved bodies of quality system approvals which it has refused, suspended or withdrawn, and, upon request, of quality system approvals which it has issued.

Authorised representative

37. A manufacturer's obligations set out in paragraphs 30(1), 30(2), 32(1)(b), 34 and 35 may be fulfilled by the manufacturer's authorised representative (if any), on the manufacturer's behalf and under the manufacturer's responsibility, provided that they are specified in the mandate by which they were appointed under regulation 12.

PART 5

CONFORMITY TO TYPE BASED ON PRODUCT VERIFICATION (MODULE F)

38. Conformity to type based on product verification (Module F) is the part of a conformity assessment procedure whereby a manufacturer fulfils the obligations laid down in paragraphs 39, 42(1) and 43, and it is solely the manufacturer's responsibility to ensure and declare that the explosives concerned, which have been subject to examinations and tests under paragraph 40, are in conformity with the type described in the Type examination certificate and satisfy the requirements of these Regulations that apply to them.

Manufacturing

39. A manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured explosives with the approved type described in the Type examination certificate and with the requirements of these Regulations that apply to them.

Verification

40.—(1) An approved body chosen by the manufacturer must carry out appropriate examinations and tests in order to check the conformity of the explosives with the approved type described in the Type examination certificate and with the appropriate requirements of these Regulations.

(2) The examinations and tests to check the conformity of the explosives with the appropriate requirements must be carried out, at the choice of the manufacturer, either—

(a) by examination and testing of every product as specified in paragraph 41; or

(b) by examination and testing of the explosives on a statistical basis as specified in paragraph 42.

Verification of conformity by examination and testing of every product

41.—(1) All explosives must be individually examined and appropriate tests in the relevant designated standard or equivalent tests in other relevant technical specifications must be carried out in order to verify conformity with the approved type described in the

Type examination certificate and with the appropriate requirements of these Regulations; in the absence of such a designated standard, the approved body concerned must decide on the appropriate tests to be carried out.

(2) The approved body must issue a certificate of conformity in respect of the examinations and tests carried out, and must affix its identification number to each approved explosive or have it affixed under its responsibility.

(3) A manufacturer must keep the certificates of conformity available for inspection by the relevant authority for 10 years beginning on the day on which the explosive has been placed on the market.

Statistical verification of conformity

42.—(1) A manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of each lot produced, and must present the manufacturer's explosives for verification in the form of homogeneous lots.

(2) The approved body must take a random sample from each lot; all explosives in a sample must be individually examined and appropriate tests set out in the relevant designated standards, or equivalent tests set out in other relevant technical specifications, must be carried out in order to verify their conformity with the approved type described in the Type examination certificate and with the applicable requirements of these Regulations and to determine whether the lot is accepted or rejected; in the absence of such a designated standard, the approved body concerned must decide on the appropriate tests to be carried out.

(3) If a lot is accepted, all explosives of the lot must be considered approved, except for those explosives from the sample that have been found not to satisfy the tests.

(4) The approved body must issue a certificate of conformity in respect of the examinations and tests carried out, and must affix its identification number to each approved explosive or have it affixed under its responsibility.

(5) A manufacturer must keep the certificates of conformity at the disposal of the relevant authority for 10 years beginning on the day on which the explosive has been placed on the market.

(6) If a lot is rejected, the approved body, or enforcing authority, must take appropriate measures to prevent the placing on the market of that lot and, in the event of the frequent rejection of lots the approved body may suspend statistical verification and take appropriate measures.

UK marking and declaration of conformity

43.—(1) A manufacturer must affix the UK marking, and, under the responsibility of the approved body referred to in paragraph 40(1), the latter's identification number to each individual explosive confirming that the explosive is in conformity with the approved type described in the Type examination certificate and that it satisfies the applicable requirements of these Regulations.

(2) A manufacturer must draw up a written declaration of conformity for each explosive type and keep it at the disposal of the relevant authority for 10 years beginning on the day on which the explosive has been placed on the market and, such a declaration of conformity must identify the explosive type for which it has been drawn up.

(3) A copy of the declaration of conformity must be made available to the relevant authority upon request.

(4) If the approved body referred to in paragraph 40(1) agrees, and under its responsibility, the manufacturer may affix the approved body's identification number to the explosives.

(5) If the approved body referred to in paragraph 40(1) agrees and under its responsibility, a manufacturer may affix the approved body's identification number to the explosives during the manufacturing process.

Authorised representative

44. A manufacturer's obligations under this Part of this Schedule may be fulfilled by the manufacturer's authorised representative (if any), on the manufacturer's behalf and under the manufacturer's responsibility, provided that they are specified in the mandate by which they were appointed under regulation 12, but an authorised representative may not fulfil the manufacturer's obligations set out in paragraphs 39 and 42(1).

PART 6

CONFORMITY BASED ON UNIT VERIFICATION (MODULE G)

45. Conformity based on unit verification (Module G) is the conformity assessment procedure whereby a manufacturer fulfils the obligations laid down in paragraphs 46, 47 and 49, and it is solely the manufacturer's responsibility to ensure and declare that the explosive concerned, which has been subject to the provisions of paragraph 48, is in conformity with the requirements of these Regulations that apply to it.

Technical documentation

46.—(1) A manufacturer must establish the technical documentation and make it available to the approved body referred to in paragraph 48; the documentation must make it possible to assess the explosive's conformity with the relevant requirements and must include an adequate analysis and assessment of any risks.

(2) The technical documentation must specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the explosive and, wherever applicable, the technical documentation must contain at least the following elements—

(a) a general description of the explosive;

(b) conceptual design and manufacturing drawings and schemes of components, sub-assemblies and circuits;

(c) descriptions and explanations necessary for the understanding of the drawings and schemes and the operation of the explosive;

(d) a list of the designated standards applied in full or in part and, where those designated standards have not been applied, descriptions of the solutions adopted to meet the essential safety requirements of these Regulations, including a list of other relevant technical specifications applied; and in the case of partly applied designated standards, the technical documentation must specify the parts which have been applied;

(e) results of design calculations made and examinations carried out; and

(f) test reports.

(3) A manufacturer must keep the technical documentation at the disposal of the relevant authority for 10 years beginning on the day on which the explosive has been placed on the market.

Manufacturing

47. A manufacturer must take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured explosive with the applicable requirements of these Regulations.

Verification

48.—(1) An approved body chosen by the manufacturer must carry out, or have carried out, appropriate examinations and tests set out in the relevant designated standards, or equivalent tests set out in other relevant technical specifications, to check the conformity of the explosive with the applicable requirements of these Regulations; in the absence of such a designated standard, the approved body concerned must decide on the appropriate tests to be carried out.

(2) The approved body must issue a certificate of conformity in respect of the examinations and tests carried out and must affix its identification number to the approved explosive, or have it affixed under its responsibility.

(3) A manufacturer must keep the certificates of conformity at the disposal of the relevant authority for 10 years beginning on the day on which the explosive has been placed on the market.

UK marking and declaration of conformity

49.—(1) A manufacturer must affix the UK marking and, under the responsibility of the approved body referred to in paragraph 48, the latter's identification number to each explosive that satisfies the applicable requirements of these Regulations.

(2) A manufacturer must draw up a written declaration of conformity and keep it at the disposal of the relevant authority for 10 years beginning on the day on which the explosive has been placed on the market and, the declaration of conformity must identify the explosive for which it has been drawn up.

(3) A copy of the declaration of conformity must be made available to the relevant authority upon request.

Authorised representative

50. A manufacturer's obligations set out in paragraphs 46(3) and 49 may be fulfilled by the manufacturer's authorised representative (if any), on the manufacturer's behalf and under the manufacturer's responsibility, provided that they are specified in the mandate by which they were appointed under regulation 12.

SCHEDULE 6

Regulation 33(c)

DECLARATION OF CONFORMITY

Declaration of conformity (No XXXX) [M3]

1. No … (product, type, batch or serial number):

2. Name and address of the manufacturer and, where applicable, the manufacturer's authorised representative:

3. This declaration of conformity is issued under the sole responsibility of the manufacturer.

4. Object of the declaration (identification of product allowing traceability):

5. The object of the declaration described above is in conformity with the relevant statutory requirements:

6. References to the relevant designated standards used or references to the other technical specifications in relation to which conformity is declared:

7. The approved body … (name, number) performed … (description of intervention) and issued the certificate:

8. Additional information:

Signed for and on behalf of: (place and date of issue): (name, function) (signature):".

Commencement Information

I34 Sch. 31 para. 34 in force at 31.12.2020 on IP completion day (in accordance with 2020 c. 1, **Sch. 5 para. 1(1)**), see reg. 1

Marginal Citations

M3 It is optional for the manufacturer to assign a number to the declaration of conformity.

Changes to legislation:
There are currently no known outstanding effects for the The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019, SCHEDULE 31.