

## SCHEDULE 33

Regulation 36

### Amendment of Regulation (EC) No 765/2008

#### Introduction

1. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 is amended in accordance with paragraphs 2 to 38.

#### Amendments to Chapter 1

2. In Article 1—

(a) in paragraph 3, for “from third countries”, substitute “imported into the United Kingdom”; and

(b) for paragraph 4 substitute—

“4. This Regulation provides the requirements as to the form of the UK marking.”.

3. In Article 2—

(a) in the text before paragraph 1 omit “shall”;

(b) in paragraphs 1 to 3, 6, 7, 12 to 15 and 17 for “shall mean” substitute “means”;

(c) in paragraph 1—

(i) for “Community” substitute “United Kingdom”;

(ii) at the end, insert “and related expressions must be construed accordingly”;

(d) in paragraph 2—

(i) for “Community” substitute “United Kingdom”;

(ii) at the end, insert “and related expressions must be construed accordingly”;

(e) for paragraph 4 substitute—

“4. “authorised representative” means —

(a) a person who—

(i) immediately before exit day was established in the United Kingdom or any EEA state and has received a written mandate from a manufacturer to act on the manufacturer’s behalf in relation to specified tasks with regard to the manufacturer’s obligation under any relevant enactment or EU instrument harmonising the conditions for the marketing of products; and

(ii) on or after exit day continues to be so established and mandated by the manufacturer to act on the manufacturer’s behalf in relation to those tasks; or

(b) a person who, on or after exit day—

(i) is established in the United Kingdom; and

(ii) has received a written mandate from a manufacturer to act on the manufacturer’s behalf in relation to specified tasks under any relevant enactment;”;

(f) for paragraph 5 substitute—

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“5. “importer” means any person established in the United Kingdom who places a product from a country outside of the United Kingdom on the market;”;

- (g) omit paragraphs 8 and 9;
- (h) for paragraph 10 substitute—

“10. “accreditation” means an attestation by a national accreditation body conveying formal recognition that a conformity assessment body is competent to carry out a specific conformity assessment activity;”;

- (i) for paragraph 11 substitute—

“11. “UK national accreditation body” means the body appointed by the Secretary of State in accordance with Article 4;”;

- (j) omit paragraph 16;
- (k) in paragraph 17 for “the relevant Community harmonisation legislation” substitute “any relevant enactment;”;
- (l) for paragraph 18 substitute—

“18. “market surveillance authority” means an authority responsible for carrying out market surveillance in the United Kingdom;”;

- (m) for paragraph 19 substitute—

“19. “the free circulation procedure” means the procedure set out in Schedule 1 to the Taxation (Cross-border Trade) Act 2018(1);”;

- (n) for paragraph 20 substitute—

“20. “conformity marking” means a marking, such as the UK marking, by which the manufacturer indicates that a product is in conformity with the applicable requirements of any enactment providing for the affixing such a marking;”;

- (o) for paragraph 21 substitute—

“21. “relevant enactment” means any retained EU law derived from an EU instrument harmonising the conditions for the marketing of products in the EU;”;

- (p) after paragraph 21 insert—

“22. “UK marking” means the marking in the form set out in Annex 2.”.

## Amendments to Chapter 2

- 4. In Article 3 for “shall apply” substitute “applies”.
- 5. For Article 4 substitute—

### *“Article 4*

#### *UK national accreditation body*

1. The Secretary of State must by regulations appoint a single UK national accreditation body.

2. The appointment of the UK national accreditation body under regulation 3 of the Accreditation Regulations 2009(2) is to be treated on and after exit day as having been made

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(1) 2018 c.22.  
(2) S.I. 2009/3155.

in pursuance of the duty on the Secretary of State to appoint a UK national accreditation body set out in paragraph 1.

**3.** The UK national accreditation body must perform its functions in accordance with the provisions of this Chapter.

**4.** Regulations made under this Article may—

- (a) terminate the appointment of a UK national accreditation body; and
- (b) appoint a different body as the UK national accreditation body

where the Secretary of State considers that a UK national accreditation body is not performing its functions in accordance with this Chapter.

**5.** Regulations made under this Article must establish procedures for the resolution of appeals against accreditation decisions made by the appointed UK national accreditation body.

**6.** Regulation 5 of the Accreditation Regulations 2009 is to be treated as meeting the requirements of paragraph 5.

**7.** The UK national accreditation body must operate on a not-for-profit basis.

**8.** The UK national accreditation body must not—

- (a) offer or provide any activities or services that are provided by conformity assessment bodies,
- (b) provide consultancy services; and
- (c) own shares in, or otherwise have any financial or managerial interest in, a conformity assessment body.

**9.** The UK national accreditation body must establish and maintain appropriate structures to ensure—

- (a) consultation on its activities with interested parties; and
- (b) responses of interested parties to consultation are adequately taken into account.

**10.** The Secretary of State must ensure that the UK national accreditation body has the appropriate financial and personnel resources for the proper fulfilment of its tasks, including—

- (a) the fulfilment of special tasks such as activities related to international accreditation cooperation; and
- (b) activities that are required to support public policy and which are not self-financing.

**11.** Regulations made under this Article must be made by statutory instrument.

**12.** Regulations made under this Article may make such transitional, transitory or saving provision as the Secretary of State considers appropriate.

**13.** A statutory instrument containing regulations made under this Article is subject to annulment in pursuance of a resolution of either House of Parliament.”.

**6.** In Article 5—

(a) in paragraph 1—

- (i) for “A national accreditation body shall” substitute “The UK national accreditation body must”;

**Status:** This is the original version (as it was originally made).

- (ii) for “the national accreditation body shall” substitute “the UK national accreditation body must”;
  - (b) omit paragraph 2;
  - (c) in paragraph 3—
    - (i) for “National accreditation bodies shall” substitute “The UK national accreditation body must”;
    - (ii) for “they have” substitute “it has”;
  - (d) in paragraph 4—
    - (i) for “a national accreditation body” substitute “the UK national accreditation body”;
    - (ii) for “that national accreditation body shall” substitute “the UK national accreditation body must”;
  - (e) omit paragraph 5.
- 7.** In Article 6—
- (a) in paragraph 1 for “National accreditation bodies shall” substitute “The UK national accreditation body must”;
  - (b) omit paragraphs 2 and 3.
- 8.** Omit Article 7.
- 9.** In Article 8—
- (a) in the heading, for “national accreditation bodies” substitute “the UK national accreditation body”;
  - (b) in the words before paragraph 1, for “A national accreditation body shall” substitute “The UK national accreditation body must”;
  - (c) in each paragraph for “shall” substitute “must”;
  - (d) in paragraph 5 for “relevant Community or national legislation” substitute “any enactment”.
- 10.** In Article 9—
- (a) in paragraph 1—
    - (i) for “a national accreditation body” substitute “the UK national accreditation body”;
    - (ii) for “Member State concerned shall” substitute “Secretary of State must”;
    - (iii) for “shall ensure” substitute “must ensure”;
    - (iv) omit “, and shall inform the Commission thereof”;
  - (b) in paragraph 2—
    - (i) for “Member States shall” substitute “The Secretary of State must”;
    - (ii) for “their national accreditation bodies” substitute “the UK national accreditation body”;
    - (iii) for “they fulfil” substitute “it fulfils”;
  - (c) omit paragraph 3;
  - (d) in paragraph 4—
    - (i) for “National accreditation bodies shall” substitute “The UK national accreditation body must”;
    - (ii) for “they have” substitute “it has”.

**11. For Article 10 substitute—**

*“Article 10*

*Peer evaluation*

- 1.** The UK national accreditation body must—
  - (a) ensure that it is evaluated in accordance with the requirements of this Article, by a body—
    - (i) responsible for accreditation in a country other than the United Kingdom; and
    - (ii) approved by the Secretary of State;
  - (b) set out the results of the evaluation in a report;
  - (c) make that report publicly available; and
  - (d) provide a copy of that report to the Secretary of State.
- 2.** The evaluation referred to in paragraph 1(a) must—
  - (a) be based on evaluation criteria and procedures—
    - (i) agreed between the national accreditation body and the body undertaking the evaluation; and
    - (ii) approved by the Secretary of State; and
  - (b) evaluate whether the UK national accreditation body meets the requirements of Article 8.
- 3.** The procedures referred to in paragraph 2(a) must include provision for appeal by the UK national accreditation body against the results of the evaluation.
- 4.** The report paragraph (1)(c) must include the evaluation criteria and procedures referred to in paragraph (2)(a).
- 5.** The first report under paragraph (1) must be made publicly available before the end of the period of five years beginning on exit day.
- 6.** After the first report, reports made under this Article are to be made publicly available at intervals not exceeding five years”

**12. Omit Articles 11 to 14.**

**Amendment to Chapter 3**

- 13.** After “CHAPTER III”, in the heading—
  - (a) omit “COMMUNITY” in the first place it occurs;
  - (b) for “COMMUNITY” in the second place it occurs substitute “UNITED KINGDOM”.
- 14.** In Article 15—
  - (a) in paragraphs 1, 2 and 4 before “26”, insert “22 and”;
  - (b) in paragraphs 1 and 2, for “Community harmonisation legislation”, substitute “any relevant enactment”;
  - (c) in paragraphs 1 and 5 omit “shall”;
  - (d) in paragraph 2 for “shall apply” substitute “applies”;
  - (e) in paragraph 3—

*Status: This is the original version (as it was originally made).*

- (i) for “[Directive 2001/95/EC](#)” substitute “the General Product Safety Regulations 2005(3)”;
  - (ii) for “shall” substitute “does”;
  - (f) in paragraph 4 for “shall mean” substitute “means”;
  - (g) in paragraph 5—
    - (i) for “Community legislation” in the first place it occurs, substitute “any relevant enactment”;
    - (ii) for “Community legislation does” substitute “enactments do”.
- 15.** In Article 16—
- (a) omit paragraph 1;
  - (b) in paragraph 2—
    - (i) after “Market surveillance”, insert “authorities”;
    - (ii) for “shall” substitute “must”;
    - (iii) for “Community harmonisation legislation” substitute “any relevant enactment” in both places in which it occurs;
    - (iv) for “, the Commission and the other Member States”, substitute “and the Secretary of State”;
  - (c) for paragraph 3 substitute—

“3. The Secretary of State must ensure that there is a national market surveillance infrastructure and programme so that effective measures may be taken in relation to any product subject to any relevant enactment.”;
  - (d) in paragraph 4—
    - (i) for “shall” in the first place it occurs substitute “must”;
    - (ii) for “Community harmonisation legislation”, substitute “any relevant enactment”;
    - (iii) omit “shall” in the second place it occurs.
- 16.** After Article 16, in the heading, after “SECTION 2” for “Community market” substitute “Market”.
- 17.** In Article 17—
- (a) omit paragraph 1;
  - (b) in paragraph 2, for “Member States shall” substitute “The Secretary of State must take appropriate measures to”.
- 18.** In Article 18—
- (a) in the heading, omit “of the Member States”;
  - (b) omit paragraph 1;
  - (c) in paragraph 2—
    - (i) for “Member States shall” substitute “The Secretary of State must”;
    - (ii) in sub-paragraph (a) for “Community harmonisation legislation” substitute “any relevant enactment”;
  - (d) for paragraph 3, substitute—

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(3) [S.I. 2005/1803](#).

“3. The Secretary of State may by regulations make such provision as the Secretary of State considers appropriate to ensure that market surveillance authorities have the powers necessary for the proper performance of their duties.

The Secretary of State must entrust market surveillance authorities with the resources and knowledge necessary for the proper performance of their duties.

Regulations made under this paragraph must be made by statutory instrument.

A statutory instrument containing regulations under this paragraph may not be made unless a draft of the instrument has been laid before, and approved by a resolution of, each House of Parliament.”;

(e) for paragraph 4, substitute—

“4. Market surveillance authorities must exercise their powers proportionately.”;

(f) for paragraph 5, substitute—

“5. The Secretary of State must establish, implement and periodically update the United Kingdom’s market surveillance programme setting out the principles as to how market surveillance is to be organised and covering the sectors in which market surveillance is conducted in the United Kingdom. The Secretary of State must make this programme available to the public by way of electronic communication and, where appropriate, by other means.”;

(g) in paragraph 6—

(i) for “Member States” substitute “The Secretary of State”;

(ii) for “shall” substitute “must” in each place it occurs;

(iii) omit “their”;

(iv) after “activities” insert “by market surveillance authorities”; and

(v) omit “be communicated to the other Member States and the Commission and”.

**19.** In Article 19—

(a) in paragraphs 1, 2, 4 and 5 for “shall” substitute “must” in each place it occurs;

(b) in paragraph 2 omit “within their territories”;

(c) for paragraph 3 substitute—

“3. Where a market surveillance authority decides to withdraw a product manufactured in the United Kingdom, it must inform the economic operator concerned at the address indicated on the product in question or in the documentation accompanying the product.”

(d) for paragraph 5, substitute—

“5. Market surveillance authorities must observe confidentiality where necessary in order to protect commercial secrets or to preserve personal data pursuant to national legislation, subject to the requirements that:

(a) information be made public under this Regulation to the fullest extent necessary in order to protect the users in the United Kingdom;

(b) the protection of confidentiality shall not prevent the dissemination to market surveillance authorities of information relevant to ensuring the effectiveness of market surveillance activities.”

**20.** In Article 20—

(a) in paragraph 1—

*Status: This is the original version (as it was originally made).*

- (i) for “Member States shall”, substitute, “Market surveillance authorities must”;
  - (ii) for “their”, in the second place it occurs, substitute “the”; and
  - (iii) for “Commission” substitute “Secretary of State”;
- (b) in paragraph 2 for “shall”—
- (i) in the first place it occurs substitute “must”;
  - (ii) in the second place it occurs substitute “does”.
- 21.** In Article 21—
- (a) in paragraph 1—
- (i) for “Member States shall”, substitute “Market surveillance authorities must”; and
  - (ii) for “the relevant Community harmonisation legislation”, substitute “any relevant enactment”;
- (b) in paragraph 2—
- (i) for “shall” substitute “must” in both places it occurs;
  - (ii) after “informed of the”, insert “legal”; and
  - (iii) omit “under the law of the Member State concerned”; and
- (c) in paragraph 3—
- (i) for “shall” substitute “must” in each place it occurs;
  - (ii) for “the relevant Community harmonisation legislation”, substitute “any of the relevant enactments”.
- (d) in paragraph 4 for “shall” substitute “must”.
- 22.** In Article 22—
- (a) for the heading and paragraph 1, substitute—
- “Notification of serious risk”**
1. Where a market surveillance authority takes or intends to take a measure in accordance with Article 20 it must immediately notify the Secretary of State of that measure.”
- (b) in paragraphs 2 and 3 for “shall” substitute “must” in each place it occurs;
- (c) in paragraph 2—
- (i) for “Member States” substitute “the market surveillance authority”;
  - (ii) for “Commission” substitute “the Secretary of State”;
- (d) in paragraph 3 omit “national”;
- (e) in paragraph 4 from “and information” to the end of that paragraph, substitute “authority must notify the Secretary of State through the database containing information relating to market surveillance and product safety established by regulation 33(A1) of the General Product Safety Regulations 2005(4)”.
- 23.** Omit Articles 23 to 25.
- 24.** In Article 26—
- (a) in paragraph 1—

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(4) [S.I. 2005/1803](#), paragraph (A1) is inserted by Schedule 9 of these regulations.



- (i) omit “, promoting and facilitating access to European systems”;
    - (ii) omit “The Commission shall, in cooperation with Member States, develop appropriate programmes for that purpose.”
  - (b) omit paragraph 2.
- 25.** After “SECTION 3”, in the heading—
- (a) after “of” insert “imported”;
  - (b) omit “entering the Community market”.
- 26.** In Article 27—
- (a) for the heading and paragraph 1, substitute—

**“Controls of imported products**

**1.** The authorities in charge of the control of products entering the United Kingdom must carry out appropriate checks on the characteristics of products on an adequate scale, in accordance with the principles set out in Article 19(1), before those products are discharged from the free-circulation procedure.”
  - (b) in paragraph 2—
    - (i) omit “in a Member State”;
    - (ii) for “shall” substitute “must”;
  - (c) in paragraph 3—
    - (i) for “shall” substitute “must” in both places it occurs;
    - (ii) for “release of a product for free circulation on the Community market”, substitute “the discharge of a product from the free-circulation procedure”; and
    - (iii) in point (b), for “the relevant Community harmonisation legislation”, substitute “any relevant enactment”;
    - (iv) in point (c), for “the CE”, substitute “a conformity”;
  - (d) in paragraph 4 for “shall” substitute “must”;
  - (e) omit paragraph 5.
- 27.** In Article 28—
- (a) in the heading for “Release” substitute “Discharge”;
  - (b) in paragraph 1—
    - (i) for “release” in each place it occurs substitute “discharge”;
    - (ii) for “shall” substitute “must”;
    - (iii) for “released” substitute “discharged from the free-circulation procedure”; and
  - (c) in paragraph 2—
    - (i) for “Community harmonisation legislation”, substitute “any relevant enactment”; and
    - (ii) for “shall be released”, substitute “must be discharged from the free-circulation procedure”
    - (iii) for “release” substitute “discharge”.
- 28.** In Article 29—
- (a) in paragraphs 1 and 2—

*Status: This is the original version (as it was originally made).*

- (i) for “the market surveillance authorities find” substitute “a market surveillance authority finds” in both places it occurs;
- (ii) for “they”, substitute “it” in both places it occurs;
- (b) in paragraph 1—
  - (i) for “shall” substitute “must” in each place it occurs;
  - (ii) for “release for free circulation”, substitute “discharge from the free-circulation procedure”.
- (c) in paragraph 2—
  - (i) for “Community harmonisation legislation”, substitute “any relevant enactment”;
  - (ii) for “shall” substitute “must” in both places it occurs;
  - (iii) for “authorities” substitute “authority”;
  - (iv) for “release the product for free circulation”, substitute “discharge the product from the free-circulation procedure”; and
  - (v) for “release for free circulation”, substitute “discharge from the free-circulation procedure”;
- (d) in paragraph 3—
  - (i) for “release for free circulation”, substitute “the free-circulation procedure”;
  - (ii) for “shall” substitute “must”;
- (e) in paragraph 4 for “Member States” substitute “Market surveillance”;
- (f) in paragraph 5 for “shall” substitute “must”.

#### **Amendment to Chapter 4**

**29.** For Chapter 4, substitute—

### “CHAPTER 4

#### UK MARKING

##### Article 30

- 1.** The Secretary of State must publish the form of the UK marking as set out in Annex 2 on the Gov.uk website (<https://www.gov.uk>)(**5**).
- 2.** Annex 2 has effect.
- 3.** Any reference to the UK marking in any enactment is a reference to the UK marking in the form set out in Annex 2 and published in accordance with paragraph 1.
- 4.** A requirement in any enactment to affix the UK marking is a requirement to affix the UK marking in accordance with the requirements in Annex 2.
- 5.** The UK marking must not be affixed to a product unless an enactment provides for its affixing.
- 6.** An economic operator must not affix any other marking, sign or inscription which is likely to mislead any person as to the meaning or form of the UK marking.

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(5) Copies are available from the Department for Business, Energy and Industrial Strategy (Goods, Borders and Customs team), 1 Victoria Street, London SW1H 0ET.

7. An economic operator must not affix any other marking if the visibility, legibility and meaning of the UK marking would be impaired as a result.

8. Where the UK marking is affixed to a product in breach of paragraph 4, the UK marking is affixed in a false or misleading manner and Article 27(3)(c) applies.”.

**Omission of Chapter 5**

30. Omit Chapter 5.

**Amendments to Chapter 6**

31. Omit Article 38.

32. Omit Article 40.

33. Omit Article 41.

34. Omit Article 42.

35. In Article 43 omit the words from “references to the repealed Regulation” to the end.

36. Omit Article 44.

37. After Article 44, omit—

- (a) the words “This Regulation shall be binding” to the end;
- (b) “Done at Strasbourg, 9 July 2008”; and
- (c) the signature text.

**Omission of Annex 1**

38. Omit Annex 1.

**Substitution of Annex 2**

39. For Annex 2 substitute—

“ANNEX 2

Article 30

UK marking

1. The UK marking consists of the initials “UKCA” taking the following form—



**Status:** This is the original version (as it was originally made).

2. Where the UK marking is reduced or enlarged, the proportions given in the graduated drawing in paragraph 1 must be respected.
3. Where an enactment does not require specific dimensions, the UK marking must be at least 5 millimetres high.”.