

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 (Text with EEA relevance)

CHAPTER II **U.K.**

ACCREDITATION

Article 3 **U.K.**

**Scope**

This Chapter [<sup>F1</sup>applies] to accreditation, used on a compulsory or voluntary basis, relating to conformity assessment, whether that assessment is compulsory or not, and irrespective of the legal status of the body performing the accreditation.

**Textual Amendments**

- F1** Word in Art. 3 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, Sch. 33 para. 4; 2020 c. 1, Sch. 5 para. 1(1)

[<sup>F2</sup>Article 4 **U.K.**

**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 is to be treated on and after IP completion day as having been made 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.

Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 765/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

- 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, consequential 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.]

**Textual Amendments**

**F2** Art. 4 substituted (31.12.2020) by [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 33 para. 5** (as amended by [S.I. 2020/852](#), regs. 2(2), 4(2), **Sch. 1 para. 1(s)(ii)**; [S.I. 2020/1460](#), reg. 1(4), **Sch. 3 para. 22(4)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Article 5 **U.K.**

**Operation of accreditation**

1 <sup>[F3]</sup>The UK national accreditation body must], when requested by a conformity assessment body, evaluate whether that conformity assessment body is competent to carry out a specific conformity assessment activity. Where it is found to be competent, <sup>[F4]</sup>the UK national accreditation body must] issue an accreditation certificate to that effect.

<sup>F5</sup>2 .....

3 <sup>[F6]</sup>The UK national accreditation body must] monitor the conformity assessment bodies to which <sup>[F7]</sup>it has] issued an accreditation certificate.

4 Where <sup>[F8]</sup>the UK national accreditation body] ascertains that a conformity assessment body which has received an accreditation certificate is no longer competent to carry out a specific conformity assessment activity or has committed a serious breach of its obligations, <sup>[F9]</sup>the UK national accreditation body must] take all appropriate measures within a reasonable timeframe to restrict, suspend or withdraw the accreditation certificate.

<sup>F10</sup>5 .....

**Changes to legislation:** There are outstanding changes not yet made to Regulation (EC) No 765/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

### Textual Amendments

- F3** Words in Art. 5(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 6(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F4** Words in Art. 5(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 6(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F5** Art. 5(2) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 6(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F6** Words in Art. 5(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 6(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F7** Words in Art. 5(3) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 6(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F8** Words in Art. 5(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 6(d)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F9** Words in Art. 5(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 6(d)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F10** Art. 5(5) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 6(e)**; 2020 c. 1, Sch. 5 para. 1(1)

## Article 6 **U.K.**

### Principle of non-competition

1 <sup>F11</sup>[The UK national accreditation body must] not compete with conformity assessment bodies.

<sup>F12</sup> .....

<sup>F12</sup>3 .....

### Textual Amendments

- F11** Words in Art. 6(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 7(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F12** Art. 6(2)(3) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 7(b)**; 2020 c. 1, Sch. 5 para. 1(1)

## <sup>F13</sup>Article 7 **U.K.**

### Cross-border accreditation

.....

**Changes to legislation:** There are outstanding changes not yet made to Regulation (EC) No 765/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

### Textual Amendments

**F13** Art. 7 omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 8**; 2020 c. 1, **Sch. 5 para. 1(1)**

## Article 8 **U.K.**

### Requirements for <sup>F14</sup>the UK national accreditation body]

<sup>F15</sup>The UK national accreditation body must] fulfil the following requirements:

1. it <sup>F16</sup>must] be organised in such a manner as to make it independent of the conformity assessment bodies it assesses and of commercial pressures, and to ensure that no conflicts of interest with conformity assessment bodies occur;
2. it <sup>F16</sup>must] be organised and operated so as to safeguard the objectivity and impartiality of its activities;
3. it <sup>F16</sup>must] ensure that each decision relating to the attestation of competence is taken by competent persons different from those who carried out the assessment;
4. it <sup>F16</sup>must] have adequate arrangements to safeguard the confidentiality of the information obtained;
5. it <sup>F16</sup>must] identify the conformity assessment activities for which it is competent to perform accreditation, referring, where appropriate, to <sup>F17</sup>any enactment] and standards;
6. it <sup>F16</sup>must] set up the procedures necessary to ensure efficient management and appropriate internal controls;
7. it <sup>F16</sup>must] have a number of competent personnel at its disposal sufficient for the proper performance of its tasks;
8. it <sup>F16</sup>must] document the duties, responsibilities and authorities of personnel who could affect the quality of the assessment and of the attestation of competence;
9. it <sup>F16</sup>must] establish, implement and maintain procedures for monitoring the performance and competence of the personnel involved;
10. it <sup>F16</sup>must] verify that conformity assessments are carried out in an appropriate manner, meaning that unnecessary burdens are not imposed on undertakings and that due account is taken of the size of an undertaking, the sector in which it operates, its structure, the degree of complexity of the product technology in question and the mass or serial nature of the production process;
11. it <sup>F16</sup>must] publish audited annual accounts prepared in accordance with generally accepted accounting principles.

### Textual Amendments

**F14** Words in Art. 8 heading substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 9(a)**; 2020 c. 1, **Sch. 5 para. 1(1)**

**Changes to legislation:** There are outstanding changes not yet made to Regulation (EC) No 765/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

- F15** Words in Art. 8 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 9(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F16** Word in Art. 8 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 9(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F17** Words in Art. 8(5) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 9(d)**; 2020 c. 1, Sch. 5 para. 1(1)

## Article 9 **U.K.**

### Compliance with requirements

1 Where [<sup>F18</sup>the UK national accreditation body] does not meet the requirements of this Regulation or fails to fulfil its obligations hereunder, the [<sup>F19</sup>Secretary of State must] take appropriate corrective action or [<sup>F20</sup>must ensure] that such corrective action is taken <sup>F21</sup>...

2 [<sup>F22</sup>The Secretary of State must] monitor [<sup>F23</sup>the UK national accreditation body] at regular intervals in order to ensure that [<sup>F24</sup>it fulfils] the requirements laid down in Article 8 on a continuing basis.

<sup>F25</sup>3 .....

4 [<sup>F26</sup>The UK national accreditation body must] have in place the necessary procedures to deal with complaints against the conformity assessment bodies [<sup>F27</sup>it has] accredited.

#### Textual Amendments

- F18** Words in Art. 9(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 10(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F19** Words in Art. 9(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 10(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F20** Words in Art. 9(1) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 10(a)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F21** Words in Art. 9(1) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 10(a)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)
- F22** Words in Art. 9(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 10(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F23** Words in Art. 9(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 10(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F24** Words in Art. 9(2) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 10(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F25** Art. 9(3) omitted (31.12.2020) by virtue of The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 10(c)**; 2020 c. 1, Sch. 5 para. 1(1)

**Changes to legislation:** There are outstanding changes not yet made to Regulation (EC) No 765/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

- F26** Words in Art. 9(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 10(d)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F27** Words in Art. 9(4) substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 10(d)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

## <sup>F28</sup> Article 10 **U.K.**

### 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 which is 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 IP completion day.
- 6 After the first report, reports made under this Article are to be made publicly available at intervals not exceeding five years]

#### Textual Amendments

- F28** Art. 10 substituted (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 33 para. 11** (as amended by S.I. 2019/1246, regs. 1(3), 17; S.I. 2020/852, regs. 2(2), 4(2), **Sch. 1 para. 1(s)(iii)**); 2020 c. 1, **Sch. 5 para. 1(1)**

## <sup>F29</sup> Article 11 **U.K.**

### Presumption of conformity for national accreditation bodies

.....

**Changes to legislation:** There are outstanding changes not yet made to Regulation (EC) No 765/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

**Textual Amendments**

**F29** Arts. 11-14 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 33 para. 12**; 2020 c. 1, Sch. 5 para. 1(1)

<sup>F29</sup> *Article 12* **U.K.**

**Information obligation**

**Textual Amendments**

**F29** Arts. 11-14 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 33 para. 12**; 2020 c. 1, Sch. 5 para. 1(1)

<sup>F29</sup> *Article 13* **U.K.**

**Requests to the body recognised under Article 14**

**Textual Amendments**

**F29** Arts. 11-14 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 33 para. 12**; 2020 c. 1, Sch. 5 para. 1(1)

<sup>F29</sup> *Article 14* **U.K.**

**European accreditation infrastructure**

**Textual Amendments**

**F29** Arts. 11-14 omitted (31.12.2020) by virtue of [The Product Safety and Metrology etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/696\)](#), reg. 1, **Sch. 33 para. 12**; 2020 c. 1, Sch. 5 para. 1(1)

**Changes to legislation:**

There are outstanding changes not yet made to Regulation (EC) No 765/2008 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

[View outstanding changes](#)

**Changes and effects yet to be applied to :**

- Regulation applied (with modifications) by [S.I. 2023/959 reg. 4\(a\)Sch. 1](#)
- Title replacement by [EUR 2019/1020 Regulation](#)

**Changes and effects yet to be applied to the whole legislation item and associated provisions**

- Ch. 3Art. 27 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 23 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 16 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 29 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 19 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 17 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 22 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 21 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 15 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 24 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 28 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 26 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 20 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 18 repeal by [EUR 2019/1020 Regulation](#)
- Ch. 3Art. 25 repeal by [EUR 2019/1020 Regulation](#)
- Art. 2(1) words substituted by [S.I. 2019/696 Sch. 33 para. 3\(c\)\(i\)](#) (This amendment not applied to legislation.gov.uk. Sch. 33 para. 3(c)(i) substituted immediately before IP completion day by virtue of S.I. 2020/1460, reg. 1(4), Sch. 3 para. 22(3)(a))
- Art. 2(2) words substituted by [S.I. 2019/696 Sch. 33 para. 3\(d\)\(i\)](#) (This amendment not applied to legislation.gov.uk. Sch. 33 para. 3(d)(i) substituted immediately before IP completion day by virtue of S.I. 2020/1460, reg. 1(4), Sch. 3 para. 22(3)(b))
- Art. 2(4) substituted by [S.I. 2019/696 Sch. 33 para. 3\(e\)](#) (This amendment not applied to legislation.gov.uk. Sch. 33 para. 3(e) omitted immediately before IP completion day by virtue of S.I. 2020/1460, reg. 1(4), Sch. 3 para. 3)
- Art. 2(4) words substituted in earlier amending provision S.I. 2019/696, Sch. 33 para. 3(e) by [S.I. 2020/852 reg. 4\(2\)Sch. 1 para. 1\(s\)\(i\)](#) (This amendment not applied to legislation.gov.uk. Sch. 1 para. 1(s)(i) omitted immediately before it comes into force by virtue of S.I. 2020/1460, regs. 1(3), Sch. 4 para. 1(3))