

Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (Text with EEA relevance)

## CHAPTER VIII

### UNION AUTHORISATIONS OF BIOCIDAL PRODUCTS

#### SECTION 2

##### *Renewal of Union authorisations*

###### *Article 45*

###### **Submission and acceptance of applications**

1 An application by or on behalf of an authorisation holder wishing to seek the renewal of a Union authorisation shall be submitted to the Agency at least 550 days before the expiry date of the authorisation.

[<sup>F1</sup> . . . .]

2 When applying for renewal, the applicant shall submit:

- a without prejudice to Article 21(1), all relevant data required under Article 20 that it has generated since the initial authorisation or, as appropriate, previous renewal; and
- b its assessment of whether the conclusions of the initial or previous assessment of the biocidal product remain valid and any supporting information.

3 The applicant shall also submit the name of the competent authority of the Member State that it proposes should evaluate the application for renewal and provide written confirmation that that competent authority agrees to do so. That competent authority shall be the evaluating competent authority.

The Agency shall inform the applicant of the fees payable to it under Article 80(1) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant and the evaluating competent authority accordingly.

Upon receipt of the fees payable to it under Article 80(1), the Agency shall accept the application and inform the applicant and the evaluating competent authority accordingly, indicating the date of acceptance.

4 An appeal may be brought, in accordance with Article 77, against decisions of the Agency under paragraph 3 of this Article.

#### **Textual Amendments**

- F1** Deleted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

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**Changes to legislation:** There are outstanding changes not yet made to Regulation (EU) No 528/2012 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](#)

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## Article 46

### **Evaluation of applications for renewal**

1 On the basis of an assessment of the available information and the need to review the conclusions of the initial evaluation of the application for Union authorisation or, as appropriate, the previous renewal, the evaluating competent authority shall, within 30 days of the Agency accepting the application in accordance with Article 45(3), decide whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary.

2 Where the evaluating competent authority decides that a full evaluation of the application is necessary, the evaluation shall be carried out in accordance with paragraphs 1 and 2 of Article 44.

Where the evaluating competent authority decides that a full evaluation of the application is not necessary, it shall, within 180 days of the Agency accepting the application, prepare and submit to the Agency a recommendation on the renewal of the authorisation. It shall provide the applicant with a copy of its recommendation.

The evaluating competent authority shall, as soon as possible after the Agency has accepted the application, inform the applicant of the fees payable under Article 80(2) and shall reject the application if the applicant fails to pay the fees within 30 days. It shall inform the applicant accordingly.

3 Within 180 days of receipt of a recommendation from the evaluating competent authority, the Agency shall prepare and submit to the Commission an opinion on the renewal of the Union authorisation.

4 On receipt of the opinion of the Agency, the Commission shall adopt either an implementing Regulation to renew the Union authorisation or an implementing decision to refuse to renew the Union authorisation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

The Commission shall renew a Union authorisation, provided that the conditions set out in Article 19 are still satisfied.

5 Where, for reasons beyond the control of the holder of the Union authorisation, no decision is taken on the renewal of the authorisation before its expiry, the Commission shall grant the renewal of the Union authorisation for the period necessary to complete the evaluation by means of implementing acts. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2).

### Changes to legislation:

There are outstanding changes not yet made to Regulation (EU) No 528/2012 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](#)

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

- Annex 3 para. 4 substituted by [S.I. 2019/720 Sch. 2 para. 141\(3\)](#)
- Annex 3 para. 2 words omitted by [S.I. 2019/720 Sch. 2 para. 141\(2\)\(c\)](#)
- Annex 3 para. 2 words omitted by [S.I. 2019/720 Sch. 2 para. 141\(2\)\(d\)](#)
- Annex 3 para. 8 words omitted by [S.I. 2019/720 Sch. 2 para. 141\(5\)](#)
- Annex 3 para. 2 words substituted by [S.I. 2019/720 Sch. 2 para. 141\(2\)\(a\)](#)
- Annex 3 para. 2 words substituted by [S.I. 2019/720 Sch. 2 para. 141\(2\)\(b\)](#)
- Annex 3 para. 6 words substituted by [S.I. 2019/720 Sch. 2 para. 141\(4\)](#)
- Annex 2 para. 4 substituted by [S.I. 2019/720 Sch. 2 para. 140\(3\)](#)
- Annex 2 para. 2 words omitted by [S.I. 2019/720 Sch. 2 para. 140\(2\)\(b\)](#)
- Annex 2 para. 8 words omitted by [S.I. 2019/720 Sch. 2 para. 140\(5\)](#)
- Annex 2 para. 2 words substituted by [S.I. 2019/720 Sch. 2 para. 140\(2\)\(a\)](#)
- Annex 2 para. 6 words substituted by [S.I. 2019/720 Sch. 2 para. 140\(4\)](#)
- Annex 4 para. 1.3 words omitted by [S.I. 2019/720 Sch. 2 para. 142\(b\)](#)
- Annex 4 para. 1.5 words omitted by [S.I. 2019/720 Sch. 2 para. 142\(c\)](#)
- Annex 4 para. 3.1 words omitted by [S.I. 2019/720 Sch. 2 para. 142\(d\)](#)
- Annex 4 para. 1.2 words substituted by [S.I. 2019/720 Sch. 2 para. 142\(a\)](#)
- Annex 6 para. 10 word substituted by [S.I. 2019/720 Sch. 2 para. 143\(6\)](#)
- Annex 6 para. 13 words omitted by [S.I. 2019/720 Sch. 2 para. 143\(9\)\(a\)](#)
- Annex 6 para. 15 words omitted by [S.I. 2019/720 Sch. 2 para. 143\(10\)](#)
- Annex 6 para. 1 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(2\)\(a\)](#)
- Annex 6 para. 1 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(2\)\(b\)](#)
- Annex 6 para. 6 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(3\)](#)
- Annex 6 para. 8 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(4\)](#)
- Annex 6 para. 9 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(5\)\(a\)](#)
- Annex 6 para. 9 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(5\)\(b\)](#)
- Annex 6 para. 11 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(7\)](#)
- Annex 6 para. 12 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(8\)](#)
- Annex 6 para. 13 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(9\)\(b\)](#)
- Annex 6 para. 20 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(11\)](#)
- Annex 6 para. 26 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(11\)](#)
- Annex 6 para. 36 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(11\)](#)
- Annex 6 para. 48 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(11\)](#)
- Annex 6 para. 50 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(11\)](#)
- Annex 6 para. 51 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(11\)](#)
- Annex 6 para. 52 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(11\)](#)
- Annex 6 para. 53 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(11\)](#)
- Annex 6 para. 55 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(11\)](#)
- Annex 6 para. 56 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(11\)](#)
- Annex 6 para. 57 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(11\)](#)
- Annex 6 para. 58 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(11\)](#)
- Annex 6 para. 59 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(11\)](#)
- Annex 6 para. 60 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(11\)](#)
- Annex 6 para. 62 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(11\)](#)
- Annex 6 para. 64 words substituted by [S.I. 2019/720 Sch. 2 para. 143\(11\)](#)

- Annex 6 para. 66 words substituted by S.I. 2019/720 Sch. 2 para. 143(11)
- Annex 6 para. 67 words substituted by S.I. 2019/720 Sch. 2 para. 143(11)
- Annex 6 para. 68 words substituted by S.I. 2019/720 Sch. 2 para. 143(11)
- Annex 6 para. 69 words substituted by S.I. 2019/720 Sch. 2 para. 143(11)
- Annex 6 para. 71 words substituted by S.I. 2019/720 Sch. 2 para. 143(11)
- Annex 6 para. 72 words substituted by S.I. 2019/720 Sch. 2 para. 143(11)
- Annex 6 para. 73 words substituted by S.I. 2019/720 Sch. 2 para. 143(11)
- Annex 6 para. 74 words substituted by S.I. 2019/720 Sch. 2 para. 143(11)
- Annex 6 para. 75 words substituted by S.I. 2019/720 Sch. 2 para. 143(11)
- Annex 6 para. 77 words substituted by S.I. 2019/720 Sch. 2 para. 143(11)
- Annex 6 para. 78 words substituted by S.I. 2019/720 Sch. 2 para. 143(11)
- Annex 6 para. 52 words substituted by S.I. 2019/720 Sch. 2 para. 143(12)
- Annex 6 para. 75 words substituted by S.I. 2019/720 Sch. 2 para. 143(13)
- Annex 6 para. 77 words substituted by S.I. 2019/720 Sch. 2 para. 143(14) (This amendment not applied to legislation.gov.uk. Sch. 2 para. 143(14) substituted immediately before IP completion day by S.I. 2020/1567, reg. 1(2), Sch. 2 para. 39(b))
- Annex 6 para. 77 words substituted by S.I. 2019/720, Sch. 2 para. 143(14) (as substituted) by S.I. 2020/1567 Sch. 2 para. 39(b)
- Annex 6 para. 52 words substituted in earlier amending S.I. 2019/720, Sch. 2 para. 143(12) by S.I. 2020/1567 Sch. 2 para. 39(a)
- Art. 1(2)(c) omitted by S.I. 2019/720 Sch. 2 para. 62(3)(b)
- Art. 2(b) words substituted by S.I. 2019/720, Sch. 2 para. 63(2)(b) (as substituted) by S.I. 2020/1567 Sch. 2 para. 22
- Art. 2(c) words substituted by S.I. 2019/720, Sch. 2 para. 63(2)(c) (as substituted) by S.I. 2020/1567 Sch. 2 para. 22
- Art. 2(k) substituted by S.I. 2019/720, Sch. 2 para. 63(2)(d) (as substituted) by S.I. 2020/1567 Sch. 2 para. 22
- Art. 3(1)(d) words inserted by S.I. 2019/720 Sch. 2 para. 64(2)(a)
- Art. 3(1)(e) words inserted by S.I. 2019/720 Sch. 2 para. 64(2)(b)
- Art. 3(1)(f) words omitted by S.I. 2019/720 Sch. 2 para. 64(2)(c)
- Art. 3(1)(k) words substituted by S.I. 2019/720 Sch. 2 para. 64(2)(d) (This amendment not applied to legislation.gov.uk. Sch. 2 para. 64(2)(d) substituted immediately before IP completion day by S.I. 2020/1567, reg. 1(2), Sch. 2 para. 23(a))
- Art. 3(1)(k) words substituted by S.I. 2019/720, Sch. 2 para. 64(2)(d) (as substituted) by S.I. 2020/1567 Sch. 2 para. 23(a)
- Art. 3(1)(m) words omitted by S.I. 2019/720 Sch. 2 para. 64(2)(e)(i)
- Art. 3(1)(m) words omitted by S.I. 2019/720 Sch. 2 para. 64(2)(e)(ii)
- Art. 3(1)(n) substituted by S.I. 2019/720 Sch. 2 para. 64(2)(f)
- Art. 3(1)(n) words substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 64(2)(f) by S.I. 2020/1567 Sch. 2 para. 23(b)
- Art. 3(1)(o) words omitted by S.I. 2019/720 Sch. 2 para. 64(2)(g)
- Art. 3(1)(p) words substituted by S.I. 2019/720 Sch. 2 para. 64(2)(h)(i)
- Art. 3(1)(p) words substituted by S.I. 2019/720 Sch. 2 para. 64(2)(h)(ii)
- Art. 3(1)(p) words substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 64(2)(h)(ii) by S.I. 2020/1567 Sch. 2 para. 23(c)
- Art. 3(1)(t) words inserted by S.I. 2019/720 Sch. 2 para. 64(2)(i)
- Art. 3(1)(x) omitted by S.I. 2019/720 Sch. 2 para. 64(2)(j)
- Art. 3(1)(af)-(ah) inserted by S.I. 2019/720 Sch. 2 para. 64(2)(k)
- Art. 3(1)(ai) substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 64(2)(k) by S.I. 2020/1567 Sch. 2 para. 23(d)(i)
- Art. 3(1)(aj) substituted for point (ah) the second time it occurs in earlier amending provision S.I. 2019/720, Sch. 2 para. 64(2)(k) by S.I. 2020/1567 Sch. 2 para. 23(d)(ii)
- Art. 3(3)-(7) substituted for Art. 3(3)(4) by S.I. 2019/720 Sch. 2 para. 64(3)
- Art. 5(1)(d) words substituted by S.I. 2019/720 Sch. 2 para. 65(a)
- Art. 6(5)(6) inserted by S.I. 2019/720 Sch. 2 para. 66(4)

	<ul style="list-style-type: none"><li>- Art. 8(2A) inserted by <a href="#">S.I. 2019/720 Sch. 2 para. 68(5)</a></li><li>- Art. 8A inserted by <a href="#">S.I. 2019/720 Sch. 2 para. 69</a></li><li>- Art. 8A word substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 69 by <a href="#">S.I. 2020/1567 Sch. 2 para. 24</a></li><li>- Art. 9(1)(a) words substituted by <a href="#">S.I. 2019/720 Sch. 2 para. 70(2)(c)</a></li><li>- Art. 9(1)(b) words substituted by <a href="#">S.I. 2019/720 Sch. 2 para. 70(2)(d)</a></li><li>- Art. 9(1A) inserted by <a href="#">S.I. 2019/720 Sch. 2 para. 70(3)</a></li><li>- Art. 12(4) inserted by <a href="#">S.I. 2019/720 Sch. 2 para. 73(d)</a></li><li>- Art. 14(4)(a) words substituted by <a href="#">S.I. 2019/720 Sch. 2 para. 75(5)(d)</a></li><li>- Art. 14(4)(b) word substituted by <a href="#">S.I. 2019/720 Sch. 2 para. 75(5)(e)</a></li><li>- Art. 14(4A) inserted by <a href="#">S.I. 2019/720 Sch. 2 para. 75(6)</a></li><li>- Art. 14(4A) word substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 75(6) by <a href="#">S.I. 2020/1567 Sch. 2 para. 26</a></li><li>- Art. 14(5A) inserted by <a href="#">S.I. 2019/720 Sch. 2 para. 75(8)</a></li><li>- Art. 17A inserted by S.I. 2019/720, Sch. 2 para. 78A (as inserted) by <a href="#">S.I. 2020/1567 Sch. 2 para. 27</a></li><li>- Art. 19(1)(a) words substituted by <a href="#">S.I. 2019/720 Sch. 2 para. 80(a)</a></li><li>- Art. 19(4)(a) omitted by <a href="#">S.I. 2019/720 Sch. 2 para. 80(b)</a></li><li>- Art. 24A inserted by <a href="#">S.I. 2019/720 Sch. 2 para. 85</a></li><li>- Art. 25(1)(a) words substituted by <a href="#">S.I. 2019/720 Sch. 2 para. 86(a)</a></li><li>- Art. 25(1)(a) words substituted by <a href="#">S.I. 2019/720 Sch. 2 para. 86(b)</a></li><li>- Art. 26(2A)-(2C) inserted by <a href="#">S.I. 2022/1291 reg. 2(2)(a)</a></li><li>- Art. 26(3A)-(3B) inserted by <a href="#">S.I. 2022/1291 reg. 2(2)(c)</a></li><li>- Art. 28(3)-(7) substituted for Art. 28(3)-(5) by <a href="#">S.I. 2019/720 Sch. 2 para. 89(c)</a></li><li>- Art. 29(1A)(1B) inserted by <a href="#">S.I. 2022/1291 reg. 2(3)</a></li><li>- Art. 29(2)(a) omitted by <a href="#">S.I. 2019/720 Sch. 2 para. 90(4)(b)</a></li><li>- Art. 29(2)(b) omitted by <a href="#">S.I. 2019/720 Sch. 2 para. 90(4)(b)</a></li><li>- Art. 30(1A)-(1C) inserted by <a href="#">S.I. 2022/1291 reg. 2(4)(b)</a></li><li>- Art. 30(2A) inserted by <a href="#">S.I. 2022/1291 reg. 2(4)(d)</a></li><li>- Art. 30(4) inserted by <a href="#">S.I. 2022/1291 reg. 2(4)(f)</a></li><li>- Art. 55(4)(d) and semicolon omitted in earlier amending provision S.I. 2019/720, Sch. 2 para. 102 by <a href="#">S.I. 2020/1567 Sch. 2 para. 28(a)</a></li><li>- Art. 55(7) Art. 55(9) renumbered as Art. 55(7) in earlier amending provision S.I. 2019/720, Sch. 2 para. 102 by <a href="#">S.I. 2020/1567 Sch. 2 para. 28(c)</a></li><li>- Art. 55(7)(8) omitted in earlier amending provision S.I. 2019/720, Sch. 2 para. 102 by <a href="#">S.I. 2020/1567 Sch. 2 para. 28(b)</a></li><li>- Art. 55(7) words substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 102 by <a href="#">S.I. 2020/1567 Sch. 2 para. 28(d)</a></li><li>- Art. 58(9) inserted by <a href="#">S.I. 2019/720 Sch. 2 para. 105(6)</a></li><li>- Art. 60(4)(5) inserted by <a href="#">S.I. 2019/720 Sch. 2 para. 107(3)</a></li><li>- Art. 60(4)(5) words substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 107(3) by <a href="#">S.I. 2020/1567 Sch. 2 para. 29</a></li><li>- Art. 69(2)(c) words omitted by <a href="#">S.I. 2019/720 Sch. 2 para. 115(3)(a)</a></li><li>- Art. 69(2)(o) words substituted by <a href="#">S.I. 2019/720 Sch. 2 para. 115(3)(b)</a> (This amendment not applied to legislation.gov.uk. Sch. 2 para. 115(3)(b) substituted immediately before IP completion day by S.I. 2020/1567, reg. 1(2), Sch. 2 para. 32)</li><li>- Art. 69(2)(o) words substituted by S.I. 2019/720, Sch. 2 para. 115(3)(b) (as substituted) by <a href="#">S.I. 2020/1567 Sch. 2 para. 32</a></li><li>- Art. 83A83B inserted by <a href="#">S.I. 2019/720 Sch. 2 para. 125</a></li><li>- Art. 83B(1) words substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 125 by <a href="#">S.I. 2020/1567 Sch. 2 para. 35(a)</a></li><li>- Art. 83B(4)-(7) omitted in earlier amending provision S.I. 2019/720, Sch. 2 para. 129 by <a href="#">S.I. 2020/1567 Sch. 2 para. 35(b)</a></li><li>- Art. 88(2) words substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 129 by <a href="#">S.I. 2020/1567 Sch. 2 para. 36(a)</a></li><li>- Art. 88(3)(d) omitted in earlier amending provision S.I. 2019/720, Sch. 2 para. 129 by <a href="#">S.I. 2020/1567 Sch. 2 para. 36(b)</a></li></ul>
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- Art. 88(6) Art. 88(8) renumbered as Art. 88(6) in earlier amending provision S.I. 2019/720, Sch. 2 para. 129 by [S.I. 2020/1567 Sch. 2 para. 36\(d\)](#)
- Art. 88(6) words substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 129 by [S.I. 2020/1567 Sch. 2 para. 36\(e\)](#)
- Art. 88(7)(8) omitted in earlier amending provision S.I. 2019/720, Sch. 2 para. 129 by [S.I. 2020/1567 Sch. 2 para. 36\(c\)](#)
- Art. 89(7) words inserted by [S.I. 2022/1291 reg. 2\(5\)\(a\)](#)
- Art. 89(7A)-(7C) inserted by [S.I. 2022/1291 reg. 2\(5\)\(b\)](#)
- Art. 89(8) words substituted by [S.I. 2022/1291 reg. 2\(5\)\(c\)](#)
- Art. 89(9) words inserted by [S.I. 2022/1291 reg. 2\(5\)\(d\)](#)
- Art. 89(9A) inserted by [S.I. 2022/1291 reg. 2\(5\)\(e\)](#)
- Art. 89(12) inserted by [S.I. 2022/1291 reg. 2\(5\)\(f\)](#)
- Art. 92(1A)-(1C) inserted by [S.I. 2019/720 Sch. 2 para. 133](#)
- Art. 93(a) word substituted by [S.I. 2019/720 Sch. 2 para. 134\(3\)\(a\)](#)
- Art. 93(a) words substituted by [S.I. 2019/720 Sch. 2 para. 134\(3\)\(b\)](#)
- Art. 93(b) word substituted by [S.I. 2019/720 Sch. 2 para. 134\(4\)](#)
- Art. 94(1)(a) words substituted by [S.I. 2019/720 Sch. 2 para. 135\(2\)\(b\)](#)
- Art. 94(1)(a) words substituted in earlier amending S.I. 2019/720, Sch. 2 para. 135(2)(b) by [S.I. 2020/1567 Sch. 2 para. 37](#)
- Art. 95(8) inserted by [S.I. 2019/720 Sch. 2 para. 136\(6\)](#)
- Art. 95A-95L inserted by [S.I. 2019/720 Sch. 2 para. 137](#) (This amendment not applied to legislation.gov.uk. Sch. 2 para. 137 omitted immediately before IP completion day by virtue of S.I. 2020/1567, reg. 1(2), Sch. 2 para. 38)
- Art. 95A-95N inserted by S.I. 2019/720, Sch. 4 para. 2 (as inserted) by [S.I. 2020/1567 Sch. 4](#)
- Art. 95B(4A) inserted by [S.I. 2022/1291 reg. 2\(6\)](#)
- Art. 95C(4A) inserted by [S.I. 2022/1291 reg. 2\(7\)](#)
- Art. 95H(4A) inserted by [S.I. 2022/1291 reg. 2\(9\)](#)
- Art. 95FA and cross-heading inserted by [S.I. 2022/1291 reg. 2\(8\)](#)