

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 XI

TECHNICAL EQUIVALENCE

Article 54

**Assessment of technical equivalence**

[<sup>F1</sup> Where it is necessary to establish the technical equivalence of active substances, the person seeking to establish that equivalence ('the applicant') shall submit an application to the Agency.]

2 The applicant shall submit all data that the Agency requires to assess technical equivalence.

[<sup>F13</sup> The Agency shall inform the applicant of the fees payable 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 accordingly.]

4 After giving the applicant the opportunity to submit comments, the Agency shall take a decision within 90 days of receipt of the application referred to in paragraph 1 and shall communicate it to Member States and to the applicant.

5 Where, in the opinion of the Agency, additional information is necessary to carry out the assessment of technical equivalence, the Agency shall ask the applicant to submit such information within a time limit specified by the Agency. The Agency shall reject the application if the applicant fails to submit the additional information within the specified time limit. The 90-day period referred to in paragraph 4 shall be suspended from the date of issue of the request until the information is received. The suspension shall not exceed 180 days except where justified by the nature of the data requested or in exceptional circumstances.

6 Where appropriate, the Agency may consult the competent authority of the Member State which acted as the evaluating competent authority for the evaluation of the active substance.

7 An appeal may be brought, in accordance with Article 77, against decisions of the Agency under paragraphs 3, 4 and 5 of this Article.

8 The Agency shall draw up technical guidance notes to facilitate the implementation of this Article.

**Textual Amendments**

**F1** Substituted 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).

**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 point 2 para. 4 words inserted by S.I. 2024/352 Sch. 2 para. 1(2)(b)
- 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 3 point 2 para. 4 words substituted by S.I. 2024/352 Sch. 2 para. 1(2)(a)
- 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)
- Art. 8(2A) inserted by S.I. 2019/720 Sch. 2 para. 68(5)
- Art. 8A inserted by S.I. 2019/720 Sch. 2 para. 69
- Art. 8A word substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 69 by S.I. 2020/1567 Sch. 2 para. 24
- Art. 9(1)(a) words substituted by S.I. 2019/720 Sch. 2 para. 70(2)(c)
- Art. 9(1)(b) words substituted by S.I. 2019/720 Sch. 2 para. 70(2)(d)
- Art. 9(1A) inserted by S.I. 2019/720 Sch. 2 para. 70(3)
- Art. 12(4) inserted by S.I. 2019/720 Sch. 2 para. 73(d)
- Art. 14(4)(a) words substituted by S.I. 2019/720 Sch. 2 para. 75(5)(d)
- Art. 14(4)(b) word substituted by S.I. 2019/720 Sch. 2 para. 75(5)(e)
- Art. 14(4A) inserted by S.I. 2019/720 Sch. 2 para. 75(6)
- Art. 14(4A) word substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 75(6) by S.I. 2020/1567 Sch. 2 para. 26
- Art. 14(5A) inserted by S.I. 2019/720 Sch. 2 para. 75(8)
- Art. 17A inserted by S.I. 2019/720, Sch. 2 para. 78A (as inserted) by S.I. 2020/1567 Sch. 2 para. 27
- Art. 19(1)(a) words substituted by S.I. 2019/720 Sch. 2 para. 80(a)
- Art. 19(4)(a) omitted by S.I. 2019/720 Sch. 2 para. 80(b)
- Art. 24A inserted by S.I. 2019/720 Sch. 2 para. 85
- Art. 25(1)(a) words substituted by S.I. 2019/720 Sch. 2 para. 86(a)
- Art. 25(1)(a) words substituted by S.I. 2019/720 Sch. 2 para. 86(b)
- Art. 26(2A)-(2C) inserted by S.I. 2022/1291 reg. 2(2)(a)
- Art. 26(3A)(3B) inserted by S.I. 2022/1291 reg. 2(2)(c)
- Art. 28(3)-(7) substituted for Art. 28(3)-(5) by S.I. 2019/720 Sch. 2 para. 89(c)
- Art. 29(1A)(1B) inserted by S.I. 2022/1291 reg. 2(3)
- Art. 29(2)(a) omitted by S.I. 2019/720 Sch. 2 para. 90(4)(b)
- Art. 29(2)(b) omitted by S.I. 2019/720 Sch. 2 para. 90(4)(b)
- Art. 30(1A)-(1C) inserted by S.I. 2022/1291 reg. 2(4)(b)
- Art. 30(2A) inserted by S.I. 2022/1291 reg. 2(4)(d)
- Art. 30(4) inserted by S.I. 2022/1291 reg. 2(4)(f)
- Art. 55(4)(d) and semicolon omitted in earlier amending provision S.I. 2019/720, Sch. 2 para. 102 by S.I. 2020/1567 Sch. 2 para. 28(a)
- Art. 55(7) Art. 55(9) renumbered as Art. 55(7) in earlier amending provision S.I. 2019/720, Sch. 2 para. 102 by S.I. 2020/1567 Sch. 2 para. 28(c)
- Art. 55(7)(8) omitted in earlier amending provision S.I. 2019/720, Sch. 2 para. 102 by S.I. 2020/1567 Sch. 2 para. 28(b)
- Art. 55(7) words substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 102 by S.I. 2020/1567 Sch. 2 para. 28(d)
- Art. 58(9) inserted by S.I. 2019/720 Sch. 2 para. 105(6)
- Art. 60(4)(5) inserted by S.I. 2019/720 Sch. 2 para. 107(3)
- Art. 60(4)(5) words substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 107(3) by S.I. 2020/1567 Sch. 2 para. 29
- Art. 69(2)(c) words omitted by S.I. 2019/720 Sch. 2 para. 115(3)(a)
- Art. 69(2)(o) words substituted by S.I. 2019/720 Sch. 2 para. 115(3)(b) (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)
- Art. 69(2)(o) words substituted by S.I. 2019/720, Sch. 2 para. 115(3)(b) (as substituted) by S.I. 2020/1567 Sch. 2 para. 32
- Art. 83A83B inserted by S.I. 2019/720 Sch. 2 para. 125
- Art. 83B(1) words substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 125 by S.I. 2020/1567 Sch. 2 para. 35(a)
- Art. 83B(4)-(7) omitted in earlier amending provision S.I. 2019/720, Sch. 2 para. 129 by S.I. 2020/1567 Sch. 2 para. 35(b)
- Art. 88(2) words substituted in earlier amending provision S.I. 2019/720, Sch. 2 para. 129 by S.I. 2020/1567 Sch. 2 para. 36(a)

- Art. 88(3)(d) omitted in earlier amending provision S.I. 2019/720, Sch. 2 para. 129 by [S.I. 2020/1567 Sch. 2 para. 36\(b\)](#)
- 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\(8\)](#)