

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 1

Granting of Union authorisations

Article 44

Evaluation of applications

1 The evaluating competent authority shall, within 365 days of the validation of an application, evaluate it in accordance with Article 19, including, where relevant, any proposal to adapt data requirements submitted in accordance with Article 21(2), and send an assessment report and the conclusions of its evaluation to the Agency.

Prior to submitting its conclusions to the Agency, the evaluating competent authority shall provide the applicant with the opportunity to provide written comments on the conclusions of the evaluation within 30 days. The evaluating competent authority shall take due account of those comments when finalising its evaluation.

2 Where it appears that additional information is necessary to carry out the evaluation, the evaluating competent authority shall ask the applicant to submit such information within a specified time limit, and shall inform the Agency accordingly. The 365-day period referred to in paragraph 1 shall be suspended from the date of issue of the request until the date the information is received. However, the suspension shall not exceed 180 days in total other than in exceptional cases and where justified by the nature of the information requested.

3 Within 180 days of receipt of the conclusions of the evaluation, the Agency shall prepare and submit to the Commission an opinion on the authorisation of the biocidal product.

If the Agency recommends the authorisation of the biocidal product, the opinion shall contain at least the following elements:

- a a statement on whether the conditions laid down in Article 19(1) are fulfilled, and a draft summary of biocidal product characteristics, as referred to in Article 22(2);
- b where relevant, details of any terms or conditions which should be imposed on the making available on the market or use of the biocidal product;
- c the final assessment report on the biocidal product.

4 Within 30 days of submitting its opinion to the Commission, the Agency shall transmit to the Commission, in all the official languages of the Union, the draft summary of the biocidal product characteristics, as referred to in Article 22(2), where applicable.

5 On receipt of the opinion of the Agency, the Commission shall adopt either an implementing regulation granting the Union authorisation to the biocidal product or an

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](#)*

implementing decision stating that the Union authorisation of the biocidal product has not been granted. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

The Commission shall, at the request of a Member State, decide to adjust certain conditions of a Union authorisation specifically for the territory of that Member State or decide that a Union authorisation shall not apply in the territory of that Member State, provided that such a request can be justified on one or more of the grounds referred to in Article 37(1).

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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.

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Changes and effects yet to be applied to :

- Regulation applied (with modifications) by [S.I. 2023/959 reg. 4\(a\)](#)Sch. 1
- Art. 32-46 omitted by [S.I. 2019/720 Sch. 2 para. 93](#)

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\(4\)](#)
- 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\(8\)](#)