

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 VI

NATIONAL AUTHORISATIONS OF BIOCIDAL PRODUCTS

Article 30

Evaluation of applications

1 The receiving competent authority shall, within 365 days of the validation of an application in accordance with Article 29, decide whether to grant an authorisation in accordance with Article 19. It shall take into account the results of the comparative assessment carried out in accordance with Article 23, if applicable.

2 Where it appears that additional information is necessary to carry out the evaluation, the receiving competent authority shall ask the applicant to submit such information within a specified time limit. 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. The suspension shall not exceed 180 days in total unless it is justified by the nature of the data requested or by exceptional circumstances.

The receiving competent authority shall reject the application if the applicant fails to submit the requested information within the deadline and shall inform the applicant accordingly.

3 Within the 365-day period referred to in paragraph 1, the receiving competent authority shall:

- a draft a report summarising the conclusions of its assessment and the reasons for authorising the biocidal product or for refusing to grant an authorisation (the 'assessment report');
- b send an electronic copy of the draft assessment report to the applicant and provide it with the opportunity to submit comments within 30 days; and
- c take due account of those comments when finalising its assessment.

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
- Art. 30 word omitted by S.I. 2019/720 Sch. 2 para. 91
- Art. 30(1) words inserted by S.I. 2022/1291 reg. 2(4)(a)
- Art. 30(2) words inserted by S.I. 2022/1291 reg. 2(4)(c)
- Art. 30(3) words inserted by S.I. 2022/1291 reg. 2(4)(e)

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\(8\)](#)