

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 II

**APPROVAL OF ACTIVE SUBSTANCES**

*Article 6*

**Data requirements for an application**

1 An application for approval of an active substance shall contain at least the following elements:

- a a dossier for the active substance satisfying the requirements set out in Annex II;
- b a dossier satisfying the requirements set out in Annex III for at least one representative biocidal product that contains the active substance; and
- c if the active substance meets at least one of the exclusion criteria listed in Article 5(1), evidence that Article 5(2) is applicable.

2 Notwithstanding paragraph 1, the applicant need not provide data as part of the dossiers required under points (a) and (b) of paragraph 1 where any of the following applies:

- a the data are not necessary owing to the exposure associated with the proposed uses;
- b it is not scientifically necessary to supply the data; or
- c it is not technically possible to generate the data.

However, sufficient data shall be provided in order to make it possible to determine whether an active substance meets the criteria referred to in Article 5(1) or Article 10(1), if required by the evaluating competent authority under Article 8(2).

3 An applicant may propose to adapt the data as part of the dossiers required under points (a) and (b) of paragraph 1 in accordance with Annex IV. The justification for the proposed adaptations to the data requirements shall be clearly stated in the application with a reference to the specific rules in Annex IV.

4 The Commission shall be empowered to adopt delegated acts in accordance with Article 83 specifying criteria for determining what constitutes adequate justification to adapt the data requirements under paragraph 1 of this Article on the grounds referred to in point (a) of paragraph 2 of this Article.

**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. 6(2) word omitted by S.I. 2019/720 Sch. 2 para. 66(2)
- Art. 6(4) words substituted by S.I. 2019/720 Sch. 2 para. 66(3)

**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\(8\)](#)