

**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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## ANNEX VI

### COMMON PRINCIPLES FOR THE EVALUATION OF DOSSIERS FOR BIOCIDAL PRODUCTS

#### ASSESSMENT

Effects on human and animal health

Effects on human health

27. For repeated dose toxicity and reproductive toxicity the dose-response relationship shall be assessed for each active substance or substance of concern and, where possible, a NOAEL identified. If it is not possible to identify a NOAEL, the lowest-observed-adverse-effect level (LOAEL) shall be identified. Where appropriate, other dose-effect descriptors may be used as reference values.

**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\(4\)](#)

- 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\(8\)](#)