
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

ANNEX VI

COMMON PRINCIPLES FOR THE EVALUATION OF DOSSIERS FOR BIOCIDAL PRODUCTS

ASSESSMENT

General principles

13. The data submitted in support of an application for authorisation of a biocidal product shall be validated by the evaluating or receiving competent authority in accordance with the relevant articles of the Regulation. After validation of these data the competent authorities shall utilise them by carrying out a risk assessment based on the proposed use. Information submitted in the framework of Regulation (EC) No 1907/2006 shall be taken into account where appropriate.
14. A risk assessment on the active substance present in the biocidal product shall always be carried out. If there are, in addition, any substances of concern present in the biocidal product then a risk assessment shall be carried out for each of these. The risk assessment shall cover the proposed normal use of the biocidal product, together with a realistic worst-case scenario including any relevant production and disposal issue. The assessment shall also take account of how any 'treated articles' treated with or containing the product may be used and disposed of. Active substances that are generated in-situ and the associated precursors shall also be considered.
15. In carrying out the assessment, the possibility of cumulative or synergistic effects shall also be taken into account. The Agency shall, in collaboration with the Commission, Member States and interested parties, develop and provide further guidance on the scientific definitions and methodologies for the assessment of cumulative and synergistic effects.
16. For each active substance and each substance of concern present in the biocidal product, the risk assessment shall entail hazard identification and the establishment of appropriate reference values for dose or effect concentrations such as NOAEL or Predicted No Effect Concentrations (PNEC), where possible. It shall also include, as appropriate, a dose (concentration) — response (effect) assessment, together with an exposure assessment and a risk characterisation.
17. The results arrived at from a comparison of the exposure to the appropriate reference values for each of the active substances and for any substances of concern shall be integrated to produce an overall risk assessment for the biocidal product. Where quantitative results are not available the results of the qualitative assessments shall be integrated in a similar manner.
18. The risk assessment shall determine:
 - (a) the hazards due to the physico-chemical properties,
 - (b) the risk to humans and animals,
 - (c) the risk to the environment,
 - (d) the measures necessary to protect humans, animals and the environment, both during the proposed normal use of the biocidal product and in a realistic worst-case situation.
19. In certain cases it may be concluded that further data are required before a risk assessment can be finalised. Any such additional data requested shall be the minimum necessary to complete such a risk assessment.

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20. The information provided on the biocidal product family shall permit the evaluating body to reach a decision on whether all the products within the biocidal product family comply with the criteria under Article 19(1)(b).
21. Where relevant the technical equivalence for every active substance contained in the biocidal product shall be established with reference to active substances already included in the list of approved active substances.

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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

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\(8\)](#)