

ANNEX VI

COMMON PRINCIPLES FOR THE EVALUATION OF DOSSIERS FOR BIOCIDAL PRODUCTS

INTRODUCTION

1. This Annex sets out the common principles for the evaluation of dossiers for biocidal products referred to in Article 19(1)(b). A decision by a Member State or the Commission to authorise a biocidal product shall be taken on the basis of the conditions set down in Article 19, taking account of the evaluation carried out according to this Annex. Detailed technical guidance regarding the application of this Annex is available on the website of the Agency.
2. The principles set out in this Annex can be applied in their entirety to the evaluation of biocidal products comprised of chemical substances. For biocidal products containing micro-organisms, these principles should be further developed in technical guidance taking into account practical experience gained, and be applied taking into account the nature of the product and the latest scientific information. In the case of biocidal products containing nanomaterials, the principles set out in this Annex will also need to be adapted and elaborated in technical guidance to take account of the latest scientific information.
3. In order to ensure a high and harmonised level of protection of human health, animal health and the environment, any risks arising from the use of a biocidal product shall be identified. To achieve this, a risk assessment shall be carried out to determine the acceptability or otherwise of any risks that are identified. This is done by carrying out an assessment of the risks associated with the relevant individual components of the biocidal product, taking into account any cumulative and synergistic effects.
4. A risk assessment on the active substance(s) present in the biocidal product is always required. This risk assessment shall entail hazard identification, and, as appropriate, dose (concentration) - response (effect) assessment, exposure assessment and risk characterisation. Where a quantitative risk assessment cannot be made a qualitative assessment shall be produced.
5. Additional risk assessments shall be carried out, in the same manner as described above, on any substance of concern present in the biocidal product. Information submitted in the framework of Regulation (EC) No 1907/2006 shall be taken into account where appropriate.
6. In order to carry out a risk assessment, data are required. These data are detailed in Annexes II and III and take account of the fact that there are a wide variety of applications as well as different product-types and that this has an impact on the associated risks. The data required shall be the minimum necessary to carry out an appropriate risk assessment. The evaluating body shall take due consideration of the requirements of Articles 6, 21 and 62 in order to avoid duplication of data submissions. Data may also be required on a substance of concern present in a biocidal product. For in-situ generated active substances, the risk assessment includes also the possible risks from the precursor(s).
7. The results of the risk assessments carried out on the active substance and on the substances of concern present in the biocidal product shall be integrated to produce an overall assessment for the biocidal product itself.
8. When making evaluations of a biocidal product the evaluating body shall:

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](#)

- (a) take into consideration other relevant technical or scientific information which is reasonably available to them with regard to the properties of the biocidal product, its components, metabolites, or residues;
 - (b) evaluate, where relevant, justifications submitted by the applicant for not supplying certain data.
9. The application of these common principles shall, when taken together with the other conditions set out in Article 19, lead to the competent authorities or the Commission deciding whether or not a biocidal product can be authorised. Such authorisation may include restrictions on use or other conditions. In certain cases the competent authorities may conclude that more data are required before an authorisation decision can be made.
10. In the case of biocidal products containing active substances covered by the exclusion criteria in Article 5(1), the competent authorities or the Commission shall also evaluate whether the conditions of Article 5(2) can be satisfied.
11. During the process of evaluation, applicants and the evaluating bodies shall cooperate in order to resolve quickly any questions on the data requirements, to identify at an early stage any additional studies required, to amend any proposed conditions for the use of the biocidal product, or to modify its nature or its composition in order to ensure full compliance with the requirements of Article 19 and of this Annex. The administrative burden, especially for SMEs, shall be kept to the minimum necessary without prejudicing the level of protection afforded to humans, animals and the environment.
12. The judgments made by the evaluating body during the evaluation must be based on scientific principles, preferably recognised at international level, and must be made with the benefit of expert advice.

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.

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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)

	<ul style="list-style-type: none">- 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)
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- 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\(8\)](#)