
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 III

INFORMATION REQUIREMENTS FOR BIOCIDAL PRODUCTS

2. The data elements set down in this Annex comprise a Core Data Set (CDS) and an Additional Data Set (ADS). The data elements belonging to the CDS are considered as the basic data which should, in principle, be provided for all biocidal products.

With regard to the ADS, the data elements to be provided for a specific biocidal product shall be determined by considering each of the ADS data elements indicated in this Annex taking into account, inter alia, the physical and chemical properties of the product, existing data, information which is part of the CDS and the types of products and the exposure patterns related to these uses.

Specific indications for the inclusion of some data elements are provided in column 1 of the Annex III table. The general considerations regarding adaptation of information requirements as set out in Annex IV to this Regulation shall also apply. In light of the importance of reducing testing on vertebrates, column 3 of the table gives specific indications for the adaptation of some of the data elements which might require the use of such tests on vertebrates.

For some of the information requirements set out in this Annex, it may be possible to satisfy these requirements based on available information of the properties of the active substance(s) contained in the product and the properties of non-active substance(s) included in the product. For non-active substances, applicants shall use the information provided to them in the context of Title IV of Regulation (EC) No 1907/2006, where relevant, and the information made available by the Agency in accordance with point (e) of Article 77(2) of that Regulation.

The relevant calculation methods used for the classification of mixtures as laid down in Regulation (EC) No 1272/2008 shall, where appropriate, be applied in the hazard assessment of the biocidal product. Such calculation methods shall not be used if, in relation to a particular hazard, synergistic and antagonistic effects between the different substances contained in the product are considered likely.

Detailed technical guidance regarding the application of this Annex and the preparation of the dossier is available on the website of the Agency.

The applicant has the obligation to initiate a pre-submission consultation. In addition to the obligation set out in Article 62(2), applicants may also consult with the competent authority that will evaluate the dossier with regard to the proposed information requirements and in particular the testing on vertebrates that the applicant proposes to carry out.

Additional information may need to be submitted if necessary to carry out the evaluation as indicated in Article 29(3) or Article 44(2).

The information submitted shall, in any case, be sufficient to support a risk assessment demonstrating that the criteria in Article 19(1)(b) are met.

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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\(8\)](#)