

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 XV

INFORMATION AND COMMUNICATION

SECTION I

Monitoring and reporting

Article 66

Confidentiality

1 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents⁽¹⁾ and the rules of the Management Board of the Agency, adopted in accordance with Article 118(3) of Regulation (EC) No 1907/2006, shall apply to documents held by the Agency for the purposes of this Regulation.

2 The Agency and the competent authorities shall refuse access to information where disclosure would undermine the protection of the commercial interests or the privacy or safety of the persons concerned.

Disclosure of the following information shall normally be deemed to undermine the protection of the commercial interests or the privacy or safety of the persons concerned:

- a details of the full composition of a biocidal product;
- b the precise tonnage of the active substance or biocidal product manufactured or made available on the market;
- c links between a manufacturer of an active substance and the person responsible for the placing of a biocidal product on the market or between the person responsible for the placing of a biocidal product on the market and the distributors of the product;
- d names and addresses of persons involved in testing on vertebrates.

However, where urgent action is essential to protect human health, animal health, safety or the environment or for other reasons of overriding public interest, the Agency or the competent authorities shall disclose the information referred to in this paragraph.

3 Notwithstanding paragraph 2, after the authorisation has been granted, access to the following information shall not in any case be refused:

- a the name and address of the authorisation holder;
- b the name and address of the biocidal product manufacturer;
- c the name and address of the active substance manufacturer;
- d the content of the active substance or substances in the biocidal product and the name of the biocidal product;
- e physical and chemical data concerning the biocidal product;

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](#)

- f any methods for rendering the active substance or biocidal product harmless;
- g a summary of the results of the tests required pursuant to Article 20 to establish the product's efficacy and effects on humans, animals and the environment and, where applicable, its ability to promote resistance;
- h recommended methods and precautions to reduce dangers from handling, transport and use as well as from fire or other hazards;
- i safety data sheets;
- j methods of analysis referred to in Article 19(1)(c);
- k methods of disposal of the product and of its packaging;
- l procedures to be followed and measures to be taken in the case of spillage or leakage;
- m first aid and medical advice to be given in the case of injury to persons.

[^{F14} Any person submitting information related to an active substance or a biocidal product to the Agency or a competent authority for the purposes of this Regulation may request that the information in Article 67(3) and (4) not be made available, including a justification as to why the disclosure of the information could be harmful for that person's commercial interests or those of any other party concerned.]

Textual Amendments

- F1** Substituted by Regulation (EU) No 334/2014 of the European Parliament and of the Council of 11 March 2014 amending Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

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](#)

- (1) [OJ L 145, 31.5.2001, p. 43.](#)

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](#)
- Art. 66(1) omitted by [S.I. 2019/720 Sch. 2 para. 112\(2\)](#)
- Art. 66(2) words substituted by [S.I. 2019/720 Sch. 2 para. 112\(3\)\(a\)](#)
- Art. 66(2) words substituted by [S.I. 2019/720 Sch. 2 para. 112\(3\)\(b\)](#)
- Art. 66(4) words omitted by [S.I. 2019/720 Sch. 2 para. 112\(4\)](#)

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)

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