

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 1

#### **Monitoring and reporting**

##### *Article 65*

#### **Compliance with requirements**

1 Member States shall make the necessary arrangements for the monitoring of biocidal products and treated articles which have been placed on the market to establish whether they comply with the requirements of this Regulation. Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products<sup>(1)</sup> shall apply accordingly.

2 Member States shall make the necessary arrangements for official controls to be carried out in order to enforce compliance with this Regulation.

In order to facilitate such enforcement, manufacturers of biocidal products placed on the Union market shall maintain, in relation to the manufacturing process, appropriate documentation in paper or electronic format relevant for the quality and safety of the biocidal product to be placed on the market and shall store production batch samples. The documentation shall include as a minimum:

- a safety data sheets and specifications of active substances and other ingredients used for manufacturing the biocidal product;
- b records of the various manufacturing operations performed;
- c results of internal quality controls;
- d identification of production batches.

Where necessary in order to ensure uniform application of this paragraph, the Commission may adopt implementing acts in accordance with the examination procedure referred to in Article 82(3).

Measures taken pursuant to this paragraph shall avoid causing disproportionate administrative burden to economic operators and Member States.

3 Every five years, from 1 September 2015, Member States shall submit to the Commission a report on the implementation of this Regulation in their respective territories. The report shall include in particular:

- a information on the results of official controls carried out in accordance with paragraph 2;

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**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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- b information on any poisonings and, where available, occupational diseases involving biocidal products, especially regarding vulnerable groups, and any specific measures taken to mitigate the risk of future cases;
- c any available information on adverse environmental effects experienced through using biocidal products;
- d information on the use of nanomaterials in biocidal products and the potential risks thereof.

Reports shall be submitted by 30 June of the relevant year and shall cover the period until 31 December of the year preceding their submission.

The reports shall be published on the relevant website of the Commission.

4 On the basis of the reports received in accordance with paragraph 3, and within 12 months from the date referred to in the second subparagraph of that paragraph, the Commission shall draw up a composite report on the implementation of this Regulation, in particular Article 58. The Commission shall submit the report to the European Parliament and to the Council.

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(1) [OJ L 218, 13.8.2008, p. 30.](#)

**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. 65(1) words substituted by [S.I. 2019/720 Sch. 2 para. 111\(2\)](#)
- Art. 65(2) words omitted by [S.I. 2019/720 Sch. 2 para. 111\(3\)\(c\)](#)
- Art. 65(2) words substituted by [S.I. 2019/720 Sch. 2 para. 111\(3\)\(a\)](#)
- Art. 65(2) words substituted by [S.I. 2019/720 Sch. 2 para. 111\(3\)\(b\)](#) (This amendment not applied to legislation.gov.uk. Sch. 2 para. 111(3)(b) substituted immediately before IP completion day by [S.I. 2020/1567, reg. 1\(2\), Sch. 2 para. 31](#))
- Art. 65(2) words substituted by [S.I. 2019/720 Sch. 2 para. 111\(3\)\(d\)](#)
- Art. 65(2) words substituted by [S.I. 2019/720, Sch. 2 para. 111\(3\)\(b\)](#) (as substituted by [S.I. 2020/1567 Sch. 2 para. 31](#))
- Art. 65(3) omitted by [S.I. 2019/720 Sch. 2 para. 111\(4\)](#)
- Art. 65(4) omitted by [S.I. 2019/720 Sch. 2 para. 111\(5\)](#)

**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\(8\)](#)