

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 XII

DEROGATIONS

Article 55

Derogation from the requirements

1 By way of derogation from Articles 17 and 19, a competent authority may permit, for a period not exceeding 180 days, the making available on the market or use of a biocidal product which does not fulfil the conditions for authorisation laid down in this Regulation, for a limited and controlled use under the supervision of the competent authority, if such a measure is necessary because of a danger to public health, animal health or the environment which cannot be contained by other means.

The competent authority referred to in the first subparagraph shall, without delay, inform the other competent authorities and the Commission of its action and the justification for it. The competent authority shall, without delay, inform the other competent authorities and the Commission of the revocation of such action.

On receipt of a reasoned request from the competent authority, the Commission shall, without delay and by means of implementing acts, decide whether, and under what conditions, the action taken by that competent authority may be extended, for a period not exceeding 550 days. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 82(3).

2 By way of derogation from point (a) of Article 19(1) and until an active substance is approved, competent authorities and the Commission may authorise, for a period not exceeding three years, a biocidal product containing a new active substance.

Such a provisional authorisation may be issued only if, after dossiers have been evaluated in accordance with Article 8, the evaluating competent authority has submitted a recommendation for approval of the new active substance and the competent authorities which received the application for the provisional authorisation or, in the case of a provisional Union authorisation, the Agency, consider that the biocidal product is expected to comply with points (b), (c) and (d) of Article 19(1) taking into account the factors set out in Article 19(2).

If the Commission decides not to approve the new active substance, the competent authorities which granted the provisional authorisation or the Commission shall cancel that authorisation.

Where a decision on the approval of the new active substance has not yet been adopted by the Commission when the period of three years expires, the competent authorities which granted the provisional authorisation, or the Commission, may extend the provisional authorisation for a period not exceeding one year, provided that there are good reasons to believe that the active substance will satisfy the conditions laid down in Article 4(1) or, where applicable, the conditions set out in Article 5(2). Competent

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](#)

authorities which extend the provisional authorisation shall inform the other competent authorities and the Commission of such action.

3 By way of derogation from point (a) of Article 19(1), the Commission may, by means of implementing acts, allow a Member State to authorise a biocidal product containing a non-approved active substance if it is satisfied that that active substance is essential for the protection of cultural heritage and that no appropriate alternatives are available. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 82(2). A Member State wishing to obtain such a derogation shall apply to the Commission, providing due justification.

Article 56

Research and development

[^{F1}1 By way of derogation from Article 17, an experiment or a test for the purposes of scientific or product and process-orientated research and development involving an unauthorised biocidal product or a non-approved active substance intended exclusively for use in a biocidal product ('experiment' or 'test') may take place only under the conditions provided for in this Article.]

Persons carrying out an experiment or test shall draw up and maintain written records detailing the identity of the biocidal product or active substance, labelling data, quantities supplied and the names and addresses of those persons receiving the biocidal product or active substance, and shall compile a dossier containing all available data on possible effects on human or animal health or impact on the environment. They shall make this information available to the competent authority on request.

2 Any person intending to carry out an experiment or test that may involve, or result in, release of the biocidal product into the environment shall first notify the competent authority of the Member State where the experiment or test will occur. The notification shall include the identity of the biocidal product or active substance, labelling data and quantities supplied, and all available data on possible effects on human or animal health or impact on the environment. The person concerned shall make available any other information requested by the competent authorities.

In the absence of an opinion from the competent authority within 45 days of the notification referred to in the first subparagraph, the notified experiment or test may take place.

3 If the experiments or tests could have harmful effects, whether immediate or delayed, on the health of humans, particularly of vulnerable groups, or animals, or any unacceptable adverse effect on humans, animals or the environment, the relevant competent authority of the Member State concerned may prohibit them or allow them subject to such conditions as it considers necessary to prevent those consequences. The competent authority shall, without delay, inform the Commission and other competent authorities of its decision.

4 The Commission shall be empowered to adopt delegated acts in accordance with Article 83 specifying detailed rules supplementing this Article.

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

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and use of biocidal products, with regard to certain conditions for access to the market (Text with EEA relevance).

Article 57

Exemption from registration under Regulation (EC) No 1907/2006

In addition to the active substances referred to in Article 15(2) of Regulation (EC) No 1907/2006, active substances manufactured or imported for use in biocidal products authorised for placing on the market in accordance with Article 27, 55 or 56 shall be regarded as being registered and the registration as completed for manufacture or import for use in a biocidal product and therefore as fulfilling the requirements of Chapters 1 and 5, Title II of Regulation (EC) No 1907/2006.

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\(8\)](#)