
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 VI

COMMON PRINCIPLES FOR THE EVALUATION OF DOSSIERS FOR BIOCIDAL PRODUCTS

ASSESSMENT

Effects on the environment

37. The risk assessment shall take account of any adverse effects arising in any of the three environmental compartments — air, soil and water (including sediment) — and of the biota, following the use of the biocidal product.
38. The hazard identification shall address the properties and potential adverse effects of the active substance and any substances of concern present in the biocidal product.
39. A dose (concentration) — response (effect) assessment shall be carried out in order to predict the concentration below which adverse effects in the environmental compartment of concern are not expected to occur. This shall be carried out for the active substance and for any substance of concern present in the biocidal product. This concentration is known as PNEC. However, in some cases, it may not be possible to establish a PNEC and a qualitative estimation of the dose (concentration) — response (effect) then has to be made.
40. The PNEC shall be determined from the data on effects on organisms and ecotoxicity studies submitted in accordance with requirements of Articles 6 and 20. It shall be calculated by applying an assessment factor to the reference values resulting from tests on organisms, e.g. LD₅₀ (median lethal dose), LC₅₀ (median lethal concentration), EC₅₀ (median effective concentration), IC₅₀ (concentration causing 50 % inhibition of a given parameter, e.g. growth), NOEL(C) (no-observed-effect level (concentration)), or LOEL(C) (lowest-observed-effect level (concentration)). Where appropriate, other dose-effect descriptors may be used as reference values.
41. An assessment factor is an expression of the degree of uncertainty in extrapolation from test data on a limited number of species to the real environment. Therefore, in general, the more extensive the data and the longer the duration of the tests, the smaller the degree of uncertainty and the size of the assessment factor.
42. For each environmental compartment, an exposure assessment shall be carried out in order to predict the likely concentration of each active substance or substance of concern present in the biocidal product. This concentration is known as the predicted environmental concentration (PEC). However, in some cases it may not be possible to establish a PEC and a qualitative estimate of exposure then has to be made.
43. A PEC, or where necessary a qualitative estimate of exposure, need only be determined for the environmental compartments to which emissions, discharges, disposal or distributions (including any relevant contribution from articles treated with biocidal products) are known or are reasonably foreseeable.
44. The PEC, or the qualitative estimation of exposure, shall be determined taking account of, in particular and where appropriate:
 - adequately measured exposure data,
 - the form in which the product is marketed,
 - the type of biocidal product,
 - the application method and application rate,
 - the physico-chemical properties,

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- breakdown/transformation products,
 - likely pathways to environmental compartments and potential for adsorption/desorption and degradation,
 - the frequency and duration of exposure,
 - long range environmental transportation.
45. When conducting the exposure assessment, special consideration shall be given to adequately measured, representative exposure data where such data are available. Where calculation methods are used for the estimation of exposure levels, adequate models shall be applied. The characteristics of these models shall be as listed in point 34. Where appropriate, on a case-by-case basis, relevant monitoring data from substances with analogous use and exposure patterns or analogous properties should also be considered.
46. For any given environmental compartment, the risk characterisation shall, as far as possible, entail comparison of the PEC with the PNEC so that a PEC/PNEC ratio may be derived.
47. If it has not been possible to derive a PEC/PNEC ratio, the risk characterisation shall entail a qualitative evaluation of the likelihood that an effect is occurring under the current conditions of exposure or will occur under the expected conditions of exposure.
48. The evaluating body shall conclude that the biocidal product does not comply with criterion (iv) under point (b) of Article 19(1) if it contains any substance of concern or relevant metabolites or breakdown or reaction products fulfilling the criteria for being PBT or vPvB in accordance with Annex XIII to Regulation (EC) No 1907/2006, or if it has endocrine-disrupting properties unless it is scientifically demonstrated that under relevant field conditions there is no unacceptable effect.

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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\(8\)](#)