

## SCHEDULE 1

Activities, installations and mobile plant

### **PART 2**

Activities

#### CHAPTER 4

The Chemical Industry

#### *SECTION 4.5*

*Pharmaceutical Production*

#### **Part A(1)**

- (a) Producing pharmaceutical products using a chemical or biological process.
- (b) Formulating such products if this may result in the release into water of any substance listed in paragraph 7 of Part 1 of this Schedule in a quantity which, in any 12-month period, is greater than the background quantity by more than the amount specified in that paragraph for that substance.

**Changes to legislation:**

There are outstanding changes not yet made by the legislation.gov.uk editorial team to The Environmental Permitting (England and Wales) Regulations 2010. Any changes that have already been made by the team appear in the content and are referenced with annotations.

[View outstanding changes](#)

**Changes and effects yet to be applied to :**

- Regulations excluded by [S.I. 2016/853 art. 3\(1\)\(a\)](#)
- Regulations excluded by [S.I. 2016/880 art. 6\(2\)\(a\)](#)
- Regulations excluded by [S.I. 2020/706 art. 7\(3\)\(a\)](#)
- Regulations excluded in part by [S.I. 2016/844 art. 3\(1\)\(a\)](#)
- Regulations modified by [2014 c. 20 Sch. 1 para. 6](#)
- Regulations revoked in part by [S.I. 2016/1154 Sch. 28](#)

**Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:**

Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

- Pt. 7 Ch. 1A inserted by [S.I. 2012/630 reg. 9](#)
- Pt. 7 Ch. 6 inserted by [S.I. 2012/630 reg. 11](#)
- Sch. 1 Pt. 2 Section 1.1 para. 1A inserted by [S.I. 2015/918 reg. 4\(2\)](#)
- Sch. 1 Pt. 1 para. 3(g) and word inserted by [S.I. 2013/390 reg. 19\(4\)\(c\)](#)
- Sch. 1 Pt. 1 para. 6(2)(a) omitted by [S.I. 2013/390 reg. 19\(6\)](#)
- Sch. 1 Pt. 1 para. 3(f) word omitted by [S.I. 2013/390 reg. 19\(4\)\(c\)](#)
- Sch. 1 Pt. 1 para. 2(2)(3) words omitted by [S.I. 2013/390 reg. 19\(3\)](#)
- Sch. 1 Pt. 2 s. 1.2(2) substituted by [S.I. 2011/2933 reg. 2\(3\)\(d\)](#)
- Sch. 1 Pt. 2 s. 1.2 words inserted by [S.I. 2011/2933 reg. 2\(2\)\(b\)](#)
- Sch. 1 Pt. 2 s. 1.2 words inserted by [S.I. 2011/2933 reg. 2\(3\)\(c\)](#)
- Sch. 1 Pt. 2 s. 1.2 words substituted by [S.I. 2011/2933 reg. 2\(2\)\(a\)](#)
- Sch. 1 Pt. 2 s. 1.2 words substituted by [S.I. 2011/2933 reg. 2\(3\)\(a\)](#)
- Sch. 1 Pt. 2 s. 1.2 words substituted by [S.I. 2011/2933 reg. 2\(3\)\(b\)](#)
- Sch. 2 para. 2(6) added by [S.I. 2016/475 reg. 23\(3\)](#)
- Sch. 2 para. 5(b)(iii) inserted by [S.I. 2014/255 reg. 12\(c\)](#)
- Sch. 2 para. 1(2)(3) inserted by [S.I. 2014/2852 reg. 9\(a\)\(ii\)](#)
- Sch. 2 para. 4A inserted by [S.I. 2014/2852 reg. 9\(d\)](#)
- Sch. 2 para. 5A inserted by [S.I. 2014/2852 reg. 9\(f\)](#)
- Sch. 2 para. 5B inserted by [S.I. 2016/475 reg. 23\(4\)](#)
- Sch. 2 para. 6(2A) inserted by [S.I. 2016/475 reg. 23\(5\)](#)
- Sch. 2 Pt. 1 para. 11A inserted by [S.I. 2013/755 Sch. 4 para. 385](#)
- Sch. 3 Pt. 4 added by [S.I. 2016/475 Sch. 1](#)
- Sch. 3 Pt. 1 Ch. 3 Section 2 para. 16(2) Table entry inserted by [S.I. 2012/630 reg. 13\(3\)\(d\)\(ii\)](#)
- Sch. 3 Pt. 1 Ch. 3 Section 2 para. 23(2) Table 1 entry inserted by [S.I. 2012/630 reg. 13\(3\)\(f\)](#)
- Sch. 3 Pt. 1 Ch. 3 Section 2 para. 24(2) Table entry inserted by [S.I. 2012/630 reg. 13\(3\)\(g\)](#)
- Sch. 3 Pt. 1 Ch. 3 Section 2 para. 25(2) Table entry inserted by [S.I. 2012/630 reg. 13\(3\)\(g\)](#)
- Sch. 3 Pt. 1 Ch. 3 Section 2 para. 30(2) Table entry inserted by [S.I. 2012/630 reg. 13\(3\)\(i\)](#)
- Sch. 3 Pt. 1 Ch. 3 Section 2 para. 27(4) inserted by [S.I. 2012/630 reg. 13\(3\)\(h\)\(ii\)](#)
- Sch. 3 Pt. 1 Ch. 2 Section 1 para. 3(d) inserted by [S.I. 2013/390 reg. 45\(a\)](#)
- Sch. 3 Pt. 1 Ch. 6 Section 6.8 para. 1(g) revoked by [S.I. 2011/600 Sch. 3](#) (This amendment not applied to legislation.gov.uk. [S.I. 2011/600](#) is revoked and the

- provisions revoked by those Regulations are revived by S.I. 2011/2377, reg. 28(1)(2))
- Sch. 3 Pt. 1 Ch. 6 Section 6.8 para. 1(i) revoked by [S.I. 2011/600 Sch. 3](#) (This amendment not applied to legislation.gov.uk. S.I. 2011/600 is revoked and the provisions revoked by those Regulations are revived by S.I. 2011/2377, reg. 28(1)(2))
  - Sch. 3 Pt. 1 Ch. 2 Section 2 para. 1(2) Table 2 substituted by [S.I. 2012/630 reg. 13\(2\)\(a\)](#)
  - Sch. 3 Pt. 1 Ch. 2 Section 2 para. 8(2) Table substituted by [S.I. 2012/630 reg. 13\(2\)\(b\)](#)
  - Sch. 3 Pt. 1 Ch. 2 Section 2 para. 16(4) substituted by [S.I. 2012/630 reg. 13\(2\)\(f\)](#)
  - Sch. 3 Pt. 1 Ch. 3 Section 2 para. 11(1) substituted by [S.I. 2012/630 reg. 13\(3\)\(c\)\(i\)](#)
  - Sch. 3 Pt. 1 Ch. 3 Section 2 para. 11(3)(f) substituted by [S.I. 2012/630 reg. 13\(3\)\(c\)\(ii\)](#)
  - Sch. 3 Pt. 1 Ch. 3 Section 2 para. 16 Title substituted by [S.I. 2012/630 reg. 13\(3\)\(d\)](#)
  - Sch. 3 Pt. 1 Ch. 3 Section 2 para. 19 Title substituted by [S.I. 2012/630 reg. 13\(3\)\(e\)](#)
  - Sch. 3 Pt. 1 Ch. 3 Section 2 para. 27 Title substituted by [S.I. 2012/630 reg. 13\(3\)\(h\)](#)
  - Sch. 3 Pt. 1 Ch. 3 Section 2 para. 27(3)(d) substituted by [S.I. 2012/630 reg. 13\(3\)\(h\)\(i\)](#)
  - Sch. 3 Pt. 1 Ch. 4 Section 2 para. 6(2) substituted by [S.I. 2013/390 reg. 45\(b\)\(ii\)](#)
  - Sch. 3 Pt. 1 Ch. 3 section 2 para. 1(5) substituted by [S.I. 2015/1360 reg. 7\(3\)\(b\)\(i\)\(bb\)](#)
  - Sch. 3 Pt. 1 Ch. 3 Section 2 para. T22(4) substituted by [S.I. 2011/2377 Sch. 2 para. 17\(7\)\(b\)](#)
  - Sch. 3 Pt. 1 Ch. 3 Section 2 para. T22(4) substituted by [S.I. 2011/600 Sch. 2 para. 54](#) (This amendment not applied to legislation.gov.uk. S.I. 2011/600 is revoked and the amendments made by Sch. 2 thereof are undone by S.I. 2011/2377, reg. 28(1)(3))
  - Sch. 3 Pt. 1 Ch. 3 Section 2 para. 1(5) substituted by [S.I. 2015/1417 reg. 4\(5\)\(a\)\(ii\)](#)
  - Sch. 3 Pt. 1 Ch. 2 Section 2 para. 8(3)(d)(e) substituted for Sch. 3 Pt. 1 Ch. 2 Section 2 para. 8(3)(d) by [S.I. 2012/630 reg. 13\(2\)\(c\)](#)
  - Sch. 3 Pt. 1 Ch. 3 Section 2 para. 19(3)(a)(aa) substituted for Sch. 3 Pt. 1 Ch. 3 Section 2 para. 19(3)(a) by [S.I. 2012/630 reg. 13\(3\)\(e\)\(ii\)](#)
  - Sch. 3 Pt. 1 Ch. 5 Section 2 para. 1(3)(d)-(f) substituted for Sch. 3 Pt. 1 Ch. 5 Section 2 para. 1(3)(d)(e) by [S.I. 2012/630 reg. 13\(4\)](#)
  - Sch. 3 Pt. 1 Ch. 2 Section 2 para. 10(2) Table word substituted by [S.I. 2012/630 reg. 13\(2\)\(d\)\(ii\)](#)
  - Sch. 3 Pt. 1 Ch. 3 Section 2 para. 6(2) Table word substituted by [S.I. 2012/630 reg. 13\(3\)\(b\)](#)
  - Sch. 3 Pt. 1 Ch. 2 Section 2 para. 10(3)(f) words added by [S.I. 2012/630 reg. 13\(2\)\(e\)](#)
  - Sch. 3 Pt. 1 Ch. 2 Section 2 para. 10(2) table words inserted by [S.I. 2012/630 reg. 13\(2\)\(d\)\(i\)](#)
  - Sch. 3 Pt. 1 Ch. 3 Section 2 para. 16(1) words inserted by [S.I. 2012/630 reg. 13\(3\)\(d\)\(i\)](#)
  - Sch. 3 Pt. 1 Ch. 3 Section 2 para. 19(1) words inserted by [S.I. 2012/630 reg. 13\(3\)\(e\)\(i\)](#)
  - Sch. 3 Pt. 1 Ch. 3 Section 2 para. 5(2) Table words substituted by [S.I. 2012/630 reg. 13\(3\)\(a\)\(i\)](#)
  - Sch. 3 Pt. 1 Ch. 3 Section 2 para. 5(2) Table words substituted by [S.I. 2012/630 reg. 13\(3\)\(a\)\(ii\)](#)
  - Sch. 3 Pt. 1 Ch. 3 Section 2 para. 5(2) Table words substituted by [S.I. 2012/630 reg. 13\(3\)\(a\)\(iii\)](#)
  - Sch. 3 Pt. 1 Ch. 3 Section 2 para. 16(3)(a) words substituted by [S.I. 2012/630 reg. 13\(3\)\(d\)\(iii\)](#)
  - Sch. 3 Pt. 1 Ch. 4 Section 2 para. 6(1) words substituted by [S.I. 2013/390 reg. 45\(b\)\(i\)](#)
  - Sch. 3 Pt. 1 Ch. 4 Section 2 para. 6(4)(a) words substituted by [S.I. 2013/390 reg. 45\(b\)\(iii\)](#)

- Sch. 3 Pt. 1 Ch. 4 Section 2 para. 6(4)(b) words substituted by [S.I. 2013/390 reg. 45\(b\)\(iv\)](#)
- Sch. 3 Pt. 1 Ch. 3 section 2 para. 1(3)(e) words substituted by [S.I. 2015/1360 reg. 7\(3\)\(b\)\(i\)\(aa\)](#)
- Sch. 3 Pt. 1 Ch. 3 section 2 para. 15(2) table words substituted by [S.I. 2015/1360 reg. 7\(3\)\(b\)\(ii\)](#)
- Sch. 3 Pt. 1 Ch. 5 section 2 para. 1(2) table words substituted by [S.I. 2015/1360 reg. 7\(3\)\(c\)](#)
- Sch. 3 Pt. 1 Ch. 3 Section 2 para. T13(2) Table words substituted by [S.I. 2011/2377 Sch. 2 para. 17\(6\)](#) (note previous omission of words)
- Sch. 3 Pt. 1 Ch. 3 Section 2 para. T22(3)(b) words substituted by [S.I. 2011/2377 Sch. 2 para. 17\(7\)\(a\)](#) (note previous omission of para.)
- Sch. 3 Pt. 1 Ch. 3 Section 2 para. T13(2) words substituted by [S.I. 2011/600 Sch. 2 para. 53](#) (This amendment not applied to [legislation.gov.uk](#). [S.I. 2011/600](#) is revoked and the amendments made by Sch. 2 thereof are undone by [S.I. 2011/2377](#), reg. 28(1)(3))
- Sch. 3 Pt. 1 Ch. 3 Section 2 para. 1(3)(e) words substituted by [S.I. 2015/1417 reg. 4\(5\)\(a\)\(i\)](#)
- Sch. 3 Pt. 1 Ch. 3 Section 2 para. 11(3)(c) words substituted by [S.I. 2015/1417 reg. 4\(5\)\(b\)](#)
- Sch. 3 Pt. 1 Ch. 3 Section 2 para. 15(2) table words substituted by [S.I. 2015/1417 reg. 4\(5\)\(c\)](#)
- Sch. 3 Pt. 1 Ch. 5 Section 2 para. 1(2) table words substituted by [S.I. 2015/1417 reg. 4\(6\)](#)
- Sch. 3 Pt. 2 para. 2A inserted by [S.I. 2014/2852 reg. 10\(b\)](#)
- Sch. 3 Pt. 3 para. 4 inserted by [S.I. 2014/255 reg. 13](#)
- Sch. 3 Pt. 3 para. 3A inserted by [S.I. 2014/2852 reg. 11\(b\)](#)
- Sch. 5 para. 9(1A) inserted by [S.I. 2014/255 reg. 14\(b\)\(ii\)](#)
- Sch. 5 Pt. 1 para. 5(1)(e) and word added by [S.I. 2016/475 reg. 25\(3\)\(b\)](#)
- Sch. 5 Pt. 1 para. 5(4)(e) and word added by [S.I. 2016/475 reg. 25\(4\)\(b\)](#)
- Sch. 5 Pt. 1 para. 14(3) added by [S.I. 2016/475 reg. 25\(7\)](#)
- Sch. 5 Pt. 1 para. 20 inserted by [S.I. 2013/390 reg. 46\(7\)](#)
- Sch. 5 Pt. 1 para. 15(3)(aa) inserted by [S.I. 2016/475 reg. 25\(8\)](#)
- Sch. 5 Pt. 1 para. 16(3)(ba)(bb) inserted by [S.I. 2016/475 reg. 25\(9\)](#)
- Sch. 5 Pt. 1 para. 2(1)(b) substituted by [S.I. 2012/630 reg. 14\(c\)](#)
- Sch. 5 Pt. 1 para. 2(2)(3) substituted for Sch. 5 Pt. 1 para. 2(2) by [S.I. 2016/475 reg. 25\(2\)](#)
- Sch. 5 Pt. 1 para. 5(4) word omitted by [S.I. 2016/475 reg. 25\(4\)\(a\)](#)
- Sch. 5 Pt. 1 para. 14(1)(a) words inserted by [S.I. 2016/475 reg. 25\(6\)](#)
- Sch. 5 Pt. 1 para. 5(1)(c) words omitted by [S.I. 2013/390 reg. 46\(2\)](#)
- Sch. 5 Pt. 1 para. 5(5) words omitted by [S.I. 2013/390 reg. 46\(4\)\(b\)](#)
- Sch. 5 Pt. 1 para. 5(4)(d) words substituted by [S.I. 2013/390 reg. 46\(3\)](#)
- Sch. 5 Pt. 1 para. 5(5) words substituted by [S.I. 2013/390 reg. 46\(4\)\(a\)](#)
- Sch. 5 Pt. 1 para. 5(5) words substituted by [S.I. 2013/390 reg. 46\(4\)\(c\)](#)
- Sch. 5 Pt. 1 para. 10(4) words substituted by [S.I. 2013/390 reg. 46\(5\)\(a\)\(i\)](#)
- Sch. 5 Pt. 1 para. 10(4) words substituted by [S.I. 2013/390 reg. 46\(5\)\(a\)\(ii\)](#)
- Sch. 5 Pt. 1 para. 10(4) words substituted by [S.I. 2013/390 reg. 46\(5\)\(a\)\(iii\)](#)
- Sch. 5 Pt. 1 para. 10(5) words substituted by [S.I. 2013/390 reg. 46\(5\)\(b\)](#)
- Sch. 5 Pt. 1 para. 16(3)(d) words substituted by [S.I. 2013/390 reg. 46\(6\)](#)
- Sch. 5 Pt. 1 para. 13(3) words substituted by [S.I. 2016/475 reg. 25\(5\)](#)
- Sch. 7 para. 4(b) omitted by [S.I. 2013/390 reg. 47\(1\)\(d\)](#)
- Sch. 7A inserted by [S.I. 2013/390 reg. 47\(2\)](#)
- Sch. 8 para. 1A inserted by [S.I. 2015/918 reg. 5\(3\)](#)
- Sch. 8 para. 1(1) words inserted by [S.I. 2015/918 reg. 5\(2\)](#)
- Sch. 8A inserted by [S.I. 2015/918 reg. 6](#)
- Sch. 8A para. 11 heading inserted by [S.I. 2015/934 reg. 2\(a\)](#)
- Sch. 8A para. 11 words inserted by [S.I. 2015/934 reg. 2\(b\)](#)
- Sch. 9 para. 3(4)(c) and word inserted by [S.I. 2013/390 reg. 49\(4\)](#)

- Sch. 9 para. 3(3)(b)-(f) substituted for Sch. 9 para. 3(3)(b)(c) by S.I. 2013/390 reg. 49(3)
- Sch. 9 para. 3(2)(a) words omitted by S.I. 2013/390 reg. 49(2)
- Sch. 9A inserted by S.I. 2014/255 reg. 16Sch.
- Sch. 10 para. 5(4)(5) inserted by S.I. 2013/766 reg. 2(3)
- Sch. 13A inserted by S.I. 2013/390 reg. 50(2)
- Sch. 15A inserted by S.I. 2013/390 reg. 52(2)
- Sch. 17A inserted by S.I. 2013/390 reg. 53(2)
- Sch. 18 Pt. 2 para. 2 substituted by S.I. 2016/149 reg. 4
- Sch. 19 para. 3 inserted by S.I. 2014/255 reg. 18
- Sch. 23 Pt. 7 para. 25 Table 4 words inserted by S.I. 2012/630 reg. 16(4)(b)
- Sch. 23 Pt. 7 para. 10(1)(c) words omitted by S.I. 2012/630 reg. 16(4)(a)
- Sch. 23A inserted by S.I. 2015/324 reg. 2(4)Sch.
- Sch. 23A para. 1(1A) inserted by S.I. 2016/475 reg. 28
- Sch. 23ZA inserted by S.I. 2016/475 Sch. 2
- Sch. 24 para. 1(2)(ca) inserted by S.I. 2014/255 reg. 20(b)
- Sch. 26 para. 2 revoked by 2013 c. 32 Sch. 12 para. 30
- reg. 2(6) inserted by S.I. 2013/390 reg. 4(15)
- reg. 8(1)(h)(i) inserted by S.I. 2013/390 reg. 9(1)
- reg. 8(1)(j) added by S.I. 2016/475 reg. 6(1)
- reg. 8(2)(d) added by S.I. 2016/475 reg. 6(2)
- reg. 8(4)(e)(f) inserted by S.I. 2013/390 reg. 9(2)
- reg. 8(4)(g) added by S.I. 2016/475 reg. 6(3)
- reg. 9(g)(h) added by S.I. 2016/475 reg. 7
- reg. 12(6)(7) inserted by S.I. 2013/390 reg. 10
- reg. 17(2)(d) and word inserted by S.I. 2012/630 reg. 4(b)
- reg. 17(2)(ba) inserted by S.I. 2016/475 reg. 9(a)
- reg. 18(1)(aa) inserted by S.I. 2016/475 reg. 10
- reg. 19(b)-(d) substituted for reg. 19(b)(c) by S.I. 2012/630 reg. 5
- reg. 20(5)(c) and word inserted by S.I. 2014/255 reg. 4(b)
- reg. 20(7)(8) added by S.I. 2016/475 reg. 11
- reg. 21(6A) inserted by S.I. 2014/255 reg. 5(a)
- reg. 21(8) inserted by S.I. 2012/630 reg. 7(c)
- reg. 24(1)(d) added by S.I. 2016/475 reg. 13(a)
- reg. 24(1)(ba) inserted by S.I. 2014/255 reg. 6
- reg. 32(1)-(1C) substituted for reg. 32(1)-(1B) by S.I. 2014/255 reg. 8
- reg. 32(1A)(1B) inserted by S.I. 2013/755 Sch. 4 para. 377(3)
- reg. 32(2)(c)(d) inserted by S.I. 2013/390 reg. 13(1)(b)
- reg. 33(6)(aa) inserted by S.I. 2013/755 Sch. 4 para. 378(3)(b)
- reg. 35(2)(r) added by S.I. 2016/475 reg. 15(b)
- reg. 35(2)(ba) inserted by S.I. 2015/918 reg. 3
- reg. 35(2)(ca) inserted by S.I. 2014/255 reg. 9
- reg. 36(3A) inserted by S.I. 2016/475 reg. 16(b)
- reg. 36(4)-(6) substituted for reg. 36(4) by S.I. 2013/390 reg. 15(d)
- reg. 37(2A) inserted by S.I. 2016/475 reg. 17(b)
- reg. 37(3A) inserted by S.I. 2015/1756 reg. 3(a)
- reg. 37(3A) words inserted by S.I. 2016/475 reg. 17(c)
- reg. 37(3B) inserted by S.I. 2016/475 reg. 17(d)
- reg. 37(4)(a)(i)-(v) substituted for reg. 37(4)(a)(i)-(iii) by S.I. 2015/1756 reg. 3(b)(ii)
- reg. 37(7A) inserted by S.I. 2015/1756 reg. 3(c)
- reg. 39(1A) inserted by S.I. 2016/475 reg. 19(b)
- reg. 40(4)(5) inserted by S.I. 2013/390 reg. 16
- reg. 44A inserted by S.I. 2015/324 reg. 2(3)
- reg. 57(6) inserted by S.I. 2015/1756 reg. 5(c)
- reg. 57A inserted by S.I. 2016/475 reg. 21
- reg. 66A66B inserted by S.I. 2016/475 reg. 22

– reg. 108(2A) inserted by [S.I. 2013/755 Sch. 4 para. 383\(3\)](#)