

## SCHEDULE 1

Regulation 2(1)

### AMENDMENTS TO SUBORDINATE LEGISLATION

#### **Health and Safety (Enforcing Authority) Regulations 1998**

1.—(1) The Health and Safety (Enforcing Authority) Regulations 1998<sup>(1)</sup> are amended as follows.

(2) In regulation 2(1), in the definition of “hazardous substance or mixture”, for “laid down” substitute “as provided for”.

#### **Health and Safety (Enforcing Authority) Regulations (Northern Ireland) 1999**

2.—(1) The Health and Safety (Enforcing Authority) Regulations (Northern Ireland) 1999<sup>(2)</sup> are amended as follows.

(2) In regulation 2(1), in the definition of “hazardous substance or mixture”, for “laid down” substitute “as provided for”.

#### **Control of Substances Hazardous to Health Regulations 2002**

3.—(1) The Control of Substances Hazardous to Health Regulations 2002<sup>(3)</sup> are amended as follows.

(2) In regulation 2(1), in paragraph (a) of the definition of “substance hazardous to health”, for “laid down” substitute “as provided for”.

#### **Dangerous Substances and Explosive Atmospheres Regulations 2002**

4.—(1) The Dangerous Substances and Explosive Atmospheres Regulations 2002<sup>(4)</sup> are amended as follows.

(2) In regulation 2, in paragraph (a) of the definition of “dangerous substance”, for “laid down” substitute “as provided for”.

#### **Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003**

5.—(1) The Control of Substances Hazardous to Health Regulations (Northern Ireland) 2003<sup>(5)</sup> are amended as follows.

(2) In regulation 2(1), in paragraph (a) of the definition of “substance hazardous to health”, for “laid down” substitute “as provided for”.

#### **Dangerous Substances and Explosive Atmospheres Regulations (Northern Ireland) 2003**

6.—(1) The Dangerous Substances and Explosive Atmospheres Regulations (Northern Ireland) 2003<sup>(6)</sup> are amended as follows.

(2) In regulation 2, in paragraph (a) of the definition of “dangerous substance”, for “laid down” substitute “as provided for”.

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(1) [S.I. 1998/494](#), amended by [S.I. 2015/21](#).

(2) [S.R. 1999 No. 90](#); amended by [S.R. 2015 No. 265](#).

(3) [S.I. 2002/2677](#), amended by [S.I. 2015/21](#).

(4) [S.I. 2002/2776](#), amended by [S.I. 2015/21](#).

(5) [S.R. 2003 No. 34](#), amended by [S.R. 2015 No. 265](#).

(6) [S.R. 2003 No. 152](#), amended by [S.R. 2015 No. 265](#).

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## Plant Protection Products (Fees and Charges) Regulations 2011

7. The Plant Protection Products (Fees and Charges) Regulations 2011<sup>(7)</sup> are amended in accordance with paragraphs 8 to 16.

8.—(1) Regulation 2(1) is amended as follows.

(2) Omit the definition of “the Directive”.

(3) After the definition of “liability period” insert—

““MRL compliance” means compliance with the requirements of Article 18 of the MRL Regulation;”.

(4) After the definition of “the MRL Regulation” insert—

““MRL supplementary information requirement” means information requested in accordance with Article 14(3) of the MRL Regulation;”.

(5) After the definition of “Regulation 1107/2009” insert—

““standalone MRL application” means an application which is only for the setting, modification or deletion of a maximum residue level of an active substance;”.

9. Omit regulation 3.

10.—(1) Regulation 4 is amended as follows.

(2) In paragraph (2) after “applications for import tolerances” insert “and standalone MRL applications”.

(3) After paragraph (2) insert—

“(2A) A United Kingdom competent authority may charge fees for the evaluation of supplementary information provided in accordance with Article 14(3) of the MRL Regulation and such fees are payable in accordance with Schedule 3.”

11. In regulation 6—

(a) for the heading substitute “Charge for work under the Plant Protection Products (Sustainable Use) Regulations 2012”;

(b) for “within the scope of the Directive” substitute “under the Plant Protection Products (Sustainable Use) Regulations 2012<sup>(8)</sup>”.

12. In regulation 7(2)—

(a) omit “or”;

(b) at the end insert “or regulation 4(2A) and Schedule 3”.

13. In regulation 8(6) in the definition of “total costs incurred”—

(a) omit “or”;

(b) at the end insert “or regulation 4(2A) and Schedule 3”.

14.—(1) Schedule 1 is amended as follows.

(2) In paragraph 1—

(a) in the table—

(i) in item 4 in the second column, after “application<sup>(2)</sup>” omit “(3)”;

(ii) omit items 5, 5a and 5b;

<sup>(7)</sup> [S.I. 2011/2132](#), amended by [S.I. 2016/254](#).

<sup>(8)</sup> [S.I. 2012/1657](#), amended by [S.I. 2016/765](#), [2018/942](#).

- (iii) in item 11 in the second column, for “for lead zonal re-registration and new product applications” substitute “to discuss potential product applications”;
- (iv) omit item 12;
- (b) in the notes following the table—
  - (i) omit notes (3), (5) and (6);
  - (ii) in note (7) for “items 1-5, 10, 11 and 12” substitute “items 1-4, 10 and 11”;
  - (iii) in note (16) omit “to the United Kingdom to act as lead zonal rapporteur”;
  - (iv) omit note (17);
  - (v) in note (18) for “the United Kingdom” substitute “a United Kingdom competent authority”.
- (3) In paragraph 2—
  - (a) in the heading, for “or synergist” substitute “, synergist or basic substance”;
  - (b) in the first sentence, for “or synergist” substitute “, synergist or basic substance”;
  - (c) in the table—
    - (i) in the heading before item 1, for “or synergist” substitute “, synergist or basic substance”;
    - (ii) omit item 2;
    - (iii) in item 3 for the words in the second column substitute “Co-ordination of scientific advice and public consultation and finalising the draft assessment report”;
    - (iv) in items 7 and 10, for the words in the second column substitute “Co-ordination of scientific advice and public consultation, and finalising the draft assessment report”;
    - (v) in item 12, in the second column, after “synergist,” insert “basic substance,”;
  - (d) in the notes following the table—
    - (i) omit note (2);
    - (ii) in note (3)—
      - (aa) at the beginning insert “In relation to active substances, safeners or synergists,”;
      - (bb) after the first sentence insert “In relation to basic substances, a full data package comprises the complete dossier (the information referred to in Article 23(3) of Regulation 1107/2009) to support one or more uses of the basic substance.”;
      - (cc) in the second sentence after “the product” insert “or basic substance”;
    - (iii) in note (4)—
      - (aa) omit paragraph (c);
      - (bb) in paragraph (d) at the beginning insert “in relation to active substances, safeners or synergists,”;
      - (cc) omit paragraph (e);
      - (dd) in paragraphs (f) and (g), at the beginning insert “in relation to active substances, safeners or synergists,”;
      - (ee) after paragraph (g) insert—
        - “(h) in relation to basic substances, resubmissions (for example where the previous application for approval under Regulation 1107/2009 has been unsuccessful and a new application is made

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in an attempt to address all the concerns raised from that earlier submission);

(i) in relation to basic substances, data to support a change to the conditions of approval of the basic substance.”;

(iv) for the final sentence substitute—

“The evaluation of scientific peer reviewed open literature on the active substance or basic substance and its relevant metabolites will be treated as a partial data package.”

(4) Omit paragraph 4 (including the table, and the notes following the table, in that paragraph).

**15.—**(1) Schedule 2 is amended as follows.

(2) In the Schedule heading, for “fee” substitute “fees and standalone MRL application fees”.

(3) After the Schedule heading insert the paragraph heading “Fees for import tolerances”.

(4) The existing content of the Schedule 2 (after the Schedule heading) becomes paragraph 1.

(5) In that paragraph—

(a) in the first sentence, for “product-related applications” substitute “import tolerances”;

(b) in the table, before item 1 insert—

“A1	Preliminary consideration of an application to determine whether the application can proceed further	229
A2	Co-ordination of applications	1,872”

(c) in the notes following the table—

(i) for note (1) substitute—

“(1) This category is mainly for active substances not currently approved in respect of the part of the United Kingdom to which the application relates. In certain cases it may also include active substances still being reviewed if toxicological endpoints have not yet been agreed and accepted in respect of that part of the United Kingdom.”;

(ii) in note (2)—

(aa) for “plant protection products” substitute “active substances”;

(bb) for “at a European level” substitute “and accepted in respect of the part of the United Kingdom to which the application relates”;

(iii) in note (3)—

(aa) for “plant protection products” substitute “active substances”;

(bb) for “at European level” substitute “and accepted in respect of the part of the United Kingdom to which the application relates”;

(iv) after note (3) insert—

“Fees for multiple import tolerances for the same active substance are calculated on a modular basis with a charge applied for each crop.”

(6) After that paragraph insert—

#### **“Fees for standalone MRL applications**

**2.** Fees for standalone MRL applications are in accordance with the following table.

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<i>Item</i>	<i>Category</i>	<i>Fee (£)</i>
1	Preliminary consideration of an application to determine whether the application can proceed further	229
2	Co-ordination of applications	1,872
3	Full human health description <sup>(1)</sup>	16,224
4	Metabolism and residues evaluation <sup>(2)</sup>	6,760
5	Residues evaluation <sup>(3)</sup>	2,028

#### Notes

(1) This category is mainly for active substances not currently approved in respect of the part of the United Kingdom to which the application relates. In certain cases it may also include active substances still being reviewed if toxicological endpoints have not yet been agreed and accepted in respect of that part of the United Kingdom.

(2) This category is for active substances where toxicological endpoints have already been agreed and accepted in respect of the part of the United Kingdom to which the application relates but the residue definition has only been established for crop groups unrelated to the intended use.

(3) This category is for active substances where relevant toxicological endpoints and residue definition have already been agreed and accepted in respect of the part of the United Kingdom to which the application relates.

Fees for multiple standalone applications for the same active substance are calculated on a modular basis with a charge applied for each crop or combination of maximum residue levels.”

#### 16. After Schedule 2 insert—

#### “SCHEDULE 3

Regulation 4(2A)

#### Maximum residue level supplementary information fees

Fees for the evaluation of supplementary information provided in accordance with Article 14(3) of the MRL Regulation are in accordance with the following table.

<i>Item</i>	<i>Category</i>	<i>Fee (£)</i>
1	Preliminary consideration of application to determine whether the application can proceed further	229
2	Co-ordination of applications	1,872
3	Simple reasoned case <sup>(1)</sup>	416
4	Analytical method <sup>(2)</sup>	416
5	Toxicology <sup>(3)</sup>	3,120
6	Metabolism and residues evaluation <sup>(4)</sup>	6,760
7	Residues evaluation <sup>(5)</sup>	2,028

#### Notes

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(1) This category is for an MRL supplementary information requirement to provide additional information on aspects of the data already evaluated or to provide evidence of the commercial availability of standards for MRL compliance.

(2) This category is for an MRL supplementary information requirement to provide an analytical method for MRL compliance.

(3) This category is for an MRL supplementary information requirement to address the toxicological relevance of a metabolite identified in plants or products of animal origin.

(4) This category is for an MRL supplementary information requirement to address plant or livestock metabolism or any other nature of residue study.

(5) This category is for an MRL supplementary information requirement to provide additional residue trials or any other magnitude of residue study including monitoring data.

Fees for multiple submissions to address MRL supplementary information for the same active substance are calculated on a modular basis with a charge applied for each MRL supplementary information requirement. Large or novel studies to address MRL supplementary information requirements will incur an additional fee, as a multiple of the original fee, if significant extra work is required over and above the usual level for the module in question.”

### **Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013**

17. The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations 2013<sup>(9)</sup> are amended in accordance with paragraphs 18 to 29.

18. In regulation 4(1)—

- (a) in the definition of “the Biocides Regulation”, for “Annexes I to IV” substitute “Annexes II to IV”;
- (b) omit the definition of “the Commission”;
- (c) in the definition of “competent authority”, for “a Member State” substitute “the United Kingdom”;
- (d) in the definition of “the PIC Regulation”, for “Annexes I, II, V and VI” substitute “Annexes II and VI”.

19. In regulation 6(1) omit “of Article 43”.

20. For regulation 7 substitute—

“7.—(1) For the purposes of the PIC Regulation, the Designated National Authority is—

- (a) in England, Scotland and Wales, the Great Britain Executive;
- (b) in Northern Ireland, the Northern Ireland Executive.

(2) The Designated National Authority is responsible for controlling the export and import of chemicals listed in Parts 1, 2 and 3 of the UK PIC list, in accordance with Article 18 of the PIC Regulation.

(3) In paragraph (2), the “UK PIC list” means the list established and maintained in accordance with Articles 7 and 23 of the PIC Regulation.”

21. In regulation 8—

- (a) in paragraph (2) omit “or Member State”;
- (b) for paragraph (4) substitute—

<sup>(9)</sup> [S.I. 2013/1506](#).

“(4) The duties referred to in paragraph (3) are those contained in Articles 6(1), 7(1), 13(1) and (2)(b), 20(1), 26(1), 29(1), 31(1), 50(2), 54(1) and (2), 59(2), 62(1), 63(1), (2) and (3), 64(2), 71(3), the second subparagraph of 89(3), 93 and 95(1) of the Biocides Regulation.”

**22.** In regulation 13—

(a) for paragraph (1) substitute—

“(1) In this regulation, “essential use active substance” means an active substance in respect of which the Secretary of State or a Devolved Authority has granted a derogation for essential use under Article 22 of Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council.”;

(b) in paragraph (5)(c), for “Commission” substitute “Secretary of State or Devolved Authority”;

(c) in paragraph (6), for “Commission makes a decision or adopts a regulation” substitute “Secretary of State or Devolved Authority issues a decision”.

**23.—**(1) Regulation 14 is amended as follows.

(2) In paragraph (2)—

(a) omit sub-paragraphs (f), (g), (k) and (l);

(b) before paragraph (m) insert—

“(la) to reject an application for non-payment of fees under Article 54(3);

(lb) to establish technical equivalence under Article 54(4);

(lc) to reject an application for failure to provide additional information under Article 54(5);”;

(c) after paragraph (n) insert—

“(na) to give a prospective applicant data under Article 63(3);”.

(3) Omit paragraph (3).

(4) In paragraph (4)—

(a) in sub-paragraph (a)—

(i) for “(g)” substitute “(e)”;

(ii) after “(j),” insert “(la), (lc),”;

(b) in sub-paragraph (b) omit “and 2(l)”;

(c) in sub-paragraph (d) omit “, (k)”.

(5) In paragraph (7), for “Commission or another competent authority” substitute “Secretary of State or a Devolved Authority”.

**24.** In regulation 17, for “Member State” substitute “Secretary of State”.

**25.** In regulation 21—

(a) for the heading, substitute “Duties on the Designated National Authority and the Secretary of State”;

(b) for “a designated national authority or the Member State” substitute “the Designated National Authority or the Secretary of State”.

**26.** In regulation 30(1)—

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- (a) in sub-paragraph (a), omit “or”;
  - (b) omit sub-paragraph (b).
- 27.** In regulation 38 omit paragraph (2).
- 28.** In Schedule 2—
- (a) in paragraph 1, in the definition of “Plant protection product”, after “91/414/EEC” insert “as it had effect immediately before exit day”;
  - (b) after paragraph 10 insert—
 

“**11.** For the purposes of regulation 13 of these Regulations, essential use derogations granted by the Commission before exit day (under either Regulation 1062/2014 or its predecessor Regulation 1451/2007 on the second phase of the 10-year work programme referred to in Article 16(2) of [Directive 98/8/EC](#) of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market) are deemed to have been granted by the Secretary of State subject to the same terms and conditions.”
- 29.** In Schedule 3, in paragraph 7, omit sub-paragraphs (c) and (d).

### **Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013**

**30.** The Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013(**10**) are amended in accordance with paragraphs 31 to 39.

- 31.** In regulation 4(1)—
- (a) in the definition of “the Biocides Regulation”, for “Annexes I to IV” substitute “Annexes II to IV”;
  - (b) omit the definition of “the Commission”;
  - (c) in the definition of “competent authority”, for “a Member State” substitute “the United Kingdom”.
- 32.** In regulation 6 omit “of Article 43”.
- 33.** In regulation 7—
- (a) in paragraph (2) omit “or Member State”;
  - (b) for paragraph (4) substitute—
 

“(4) The duties referred to in paragraph (3) are those contained in Articles 6(1), 7(1), 13(1) and (2)(b), 20(1), 26(1), 29(1), 31(1), 50(2), 54(1) and (2), 59(2), 62(1), 63(1), (2) and (3), 64(2), 71(3), the second sub-paragraph of 89(3), 93 and 95(1) of the Biocides Regulation.”
- 34.** In regulation 12—
- (a) for paragraph (1) substitute—
 

“(1) In this regulation, “essential use active substance” means an active substance in respect of which the Secretary of State or a Devolved Authority has granted a derogation for essential use under Article 22 of Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and the Council.”;

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(10) [S.R. 2013 No.206](#).



- (b) in paragraph (5)(c), for “Commission” substitute “Secretary of State or Devolved Authority”;
- (c) in paragraph (6), for “Commission makes a decision or adopts a regulation” substitute “Secretary of State or Devolved Authority issues a decision”.

**35.**—(1) Regulation 13 is amended as follows.

(2) In paragraph (2)

- (a) omit sub-paragraphs (f), (g), (k) and (l);
- (b) before paragraph (m) insert—
  - “(la) to reject an application for non-payment of fees under Article 54(3);
  - (lb) to establish technical equivalence under Article 54(4);
  - (lc) to reject an application for failure to provide additional information under Article 54(5);”;
- (c) after paragraph (n) insert—
  - “(na) to give a prospective applicant data under Article 63(3)”.

(3) Omit paragraph (3).

(4) In paragraph (4)—

- (a) in sub-paragraph (a)—
  - (i) for “(g)” substitute “(e)”;
  - (ii) after “(j),” insert “(la), (lc),”;
- (b) in sub-paragraph (b) omit “and 2(l)”;
- (c) in sub-paragraph (d) omit “, (k)”.

(5) In paragraph (7), for “Commission or another competent authority” substitute “Secretary of State or a Devolved Authority”.

**36.** In regulation 16 for “Member State” substitute “Secretary of State”.

**37.** In regulation 18(1)—

- (a) in sub-paragraph (a), omit “or”;
- (b) omit sub-paragraph (b).

**38.** In Schedule 1—

- (a) in paragraph 1, in the definition of “Plant protection product”, after “94/414/EEC” insert “as it had effect immediately before exit day”;
- (b) after paragraph 10 insert—

“**11.** For the purposes of regulation 12 of these Regulations, essential use derogations granted by the Commission before exit day (under either Regulation 1062/2014 or its predecessor Regulation 1451/2007 on the second phase of the 10-year work programme referred to in Article 16(2) of [Directive 98/8/EC](#) of the European Parliament and the Council concerning the placing of biocidal products on the market) are deemed to have been granted by the Secretary of State subject to the same terms and conditions.”

**39.** In Schedule 2, in paragraph 7, omit sub-paragraphs (c) and (d).

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## Genetically Modified Organisms (Contained Use) Regulations 2014

**40.**—(1) The Genetically Modified Organisms (Contained Use) Regulations 2014<sup>(11)</sup> are amended as follows.

(2) In regulation 3(2)—

(a) in sub-paragraph (a) omit paragraph (iii);

(b) in sub-paragraph (b), for paragraph (i) substitute—

“(i) a medicinal product for veterinary use marketed in accordance with the Veterinary Medicines Regulations 2013<sup>(12)</sup>”.

(3) After regulation 33 insert—

### “Transitional provision in relation to the withdrawal of the United Kingdom from the European Union

**33A.**—(1) Subject to paragraphs (2) and (3), these Regulations do not apply to any activity which is covered by a written consent given by a competent authority of an EEA State in accordance with Article 15(3), 17(6) or 18(2) of Directive (EC) No 2001/18 of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms<sup>(13)</sup>.

(2) The written consent referred to in paragraph (1) must be valid immediately before exit day.

(3) Any activity covered by the consent referred to in paragraph (1) must be conducted in accordance with any obligations, conditions or limitations attached to that consent.

(4) Subject to paragraphs (5) and (6), these Regulations do not apply to any genetically modified organisms which are cultured, stored, transported, destroyed, disposed of or used, where such organisms are, or are contained in, a medicinal product for human or veterinary use marketed in accordance with an authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

(5) The marketing authorisation referred to in paragraph (4) must be valid immediately before exit day.

(6) Any marketing authorisation referred to in paragraph (4) must be conducted in accordance with any obligations, conditions, restrictions, requirements or limitations attached to that authorisation.”

(4) In Schedule 3, in paragraph 3 for sub-paragraph (d) substitute—

“(d) consideration of relevant legislation, including legislation on the protection of workers from risks related to exposure to biological agents at work, other classification schemes referring to plant and animal pathogens, and other international and national classification schemes for genetically modified micro-organisms”.

## Control of Major Accident Hazards Regulations 2015

**41.**—(1) The Control of Major Accident Hazards Regulations 2015<sup>(14)</sup> are amended as follows.

<sup>(11)</sup> S.I. 2014/1663, amended by S.I. 2015/1637.

<sup>(12)</sup> S.I. 2013/2033, amended by S.I. 2014/599, 2018/761.

<sup>(13)</sup> OJNo. L 106, 17.04.2001, p.1.

<sup>(14)</sup> S.I. 2015/483.

(2) In regulation 2(1), in the definition of “the CLP Regulation”, for “Annex VI, Part 3 Table 3.1” substitute “the UK mandatory classification and labelling list established under Article 38A (which for the purposes of these Regulations is deemed to be part of Regulation (EC) No. 1272/2008)”.

#### **Explosives (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2015**

**42.**—(1) The Explosives (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2015<sup>(15)</sup> are amended as follows.

- (2) In regulation 3—
  - (a) in the definition of “the CLP Regulation” omit the words from “, of which” to the end;
  - (b) in the definition of “competent authority”, for “a Member State” substitute “the United Kingdom”.
- (3) In regulation 4 omit “of Article 43”.
- (4) In regulation 5(1) for “Member State” substitute “the Secretary of State”.
- (5) In regulation 7(1)—
  - (a) at the end of sub-paragraph (a), omit “or”;
  - (b) omit sub-paragraph (b).
- (6) In Schedule 1 in paragraph 7 omit sub-paragraphs (c) and (d).

#### **Biocidal Products (Fees and Charges) Regulations (Northern Ireland) 2015**

**43.**—(1) The Biocidal Products (Fees and Charges) Regulations (Northern Ireland) 2015<sup>(16)</sup> are amended as follows.

- (2) In regulation 2(1), after the definition of “the Executive” insert—
  - ““Regulation 354/2013” means Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council;
  - “Regulation 1062/2014” means Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council.”
- (3) Omit regulation 3.
- (4) In regulation 4, for paragraph (1) substitute—
  - “(1) The Executive shall charge fees for—
    - (a) work it carries out within the scope of the Biocides Regulation which relates to the activities listed in column 1 of the Table in the Schedule;
    - (b) work it carries out in order to evaluate an application for a change to an authorised product under Regulation 354/2013;
    - (c) work it carries out in order to determine an application to be a participant for the review of an active substance/product-type combination under Article 17 of Regulation 1062/2014; and

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<sup>(15)</sup> S.R. 2015 No. 236.

<sup>(16)</sup> S.R. 2015 No. 254

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- (d) work it carries out in order to evaluate an application under regulation 12 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013(17).”

(5) In the Schedule, for the table substitute—

“Table

<i>I</i>	<i>2</i>
<i>Activity</i>	<i>Fee per person per day worked</i>
(a) Validation of an application for approval of an active substance	£447
(b) Evaluation of an application to approve an active substance	£447
(c) Evaluation of an application to renew an active substance approval	£447
(d) Validation of an application to amend the conditions of approval of an active substance	£447
(e) Evaluation of an application to amend the conditions of approval of an active substance	£447
(f) Work relating to a request for inclusion of an active substance in the Simplified Active Substance List made on behalf of an economic operator	£447
(g) Validation of an application to amend the conditions of inclusion of an active substance in the Simplified Active Substance List	£447
(h) Evaluation of an application to amend the conditions of inclusion of an active substance in the Simplified Active Substance List	£447
(i) Meetings with applicants and prospective applicants	£447
(j) Evaluation of an application to authorise a biocidal product under the simplified procedure	£393
(k) Validation of an application for a national authorisation of a biocidal product	£393
(l) Evaluation of an application for a national authorisation of a biocidal product	£393
(m) Evaluation of an application to renew a national authorisation of a biocidal product	£393
(n) Determination of an application to amend an existing biocidal product authorisation	£393
(o) Evaluation of an application for an emergency use permit	£393
(p) Assessment of an application to be included in the list of suppliers maintained under Article 95 of Regulation 528/2012	£447
(q) Determination of a request that information on an active substance or product is not made publicly available	£447
(r) Determination of the classification of a proposed change to an authorised product in accordance with Regulation 354/2013	£393

(17) S.R. 2013 No. 206.

<i>I</i>	<i>2</i>
<i>Activity</i>	<i>Fee per person per day worked</i>
(s) Determination of an application to be a participant for the review of an active substance/product-type combination under Article 17 of Regulation 1062/2014	£447
(t) Assessment of technical equivalence	£447
(u) Evaluation of an application under regulation 12 of the Biocidal Products and Chemicals (Appointment of Authorities and Enforcement) Regulations (Northern Ireland) 2013	£393 <sup>2</sup>

### **The Control of Major Accident Hazards Regulations (Northern Ireland) 2015**

**44.**—(1) The Control of Major Accident Hazards Regulations (Northern Ireland) 2015<sup>(18)</sup> are amended as follows.

(2) In regulation 2(1), in the definition of “the CLP Regulation”, for “Annex VI, Part 3 Table 3.1” substitute “the UK mandatory classification and labelling list established under Article 38A (which for the purposes of these Regulations is deemed to be part of Regulation (EC) No. 1272/2008)”.

### **Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015**

**45.**—(1) The Genetically Modified Organisms (Contained Use) Regulations (Northern Ireland) 2015<sup>(19)</sup> are amended as follows.

(2) In regulation 3(2)—

(a) in sub-paragraph (a)—

(i) in paragraph (ii) omit “or”;

(ii) omit paragraph (iii);

(b) in sub-paragraph (b), for paragraph (i) substitute—

“(i) a medicinal product for veterinary use marketed in accordance with the Veterinary Medicines Regulations 2013<sup>(20)</sup>”.

(3) After regulation 33 insert—

#### **“Transitional provision in relation to the withdrawal of the United Kingdom from the European Union**

**33A.**—(1) Subject to paragraphs (2) and (3), these Regulations do not apply to any activity which is covered by a written consent given by a competent authority of an EEA State in accordance with Article 15(3), 17(6) or 18(2) of Directive (EC) No 2001/18 of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms<sup>(21)</sup>.

(2) The written consent referred to in paragraph (1) must be valid immediately before exit day.

(3) Any activity covered by the consent referred to in paragraph (1) must be conducted in accordance with any obligations, conditions or limitations attached to that consent.

<sup>(18)</sup> S.R. 2015 No. 325.

<sup>(19)</sup> S.R. 2015 No. 339.

<sup>(20)</sup> S.I. 2013/2033 amended by S.I. 2014/599, 2018/761.

<sup>(21)</sup> OJ No L 106, 17.04.2001, p. 1.

**Draft Legislation:** This is a draft item of legislation and has not yet been made as a UK Statutory Instrument.  
 This draft has been replaced by a new draft, *The Chemicals (Health and Safety) and Genetically Modified Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019* ISBN 978-0-11-118153-9

(4) Subject to paragraphs (5) and (6), these Regulations do not apply to any genetically modified organisms which are cultured, stored, transported, destroyed, disposed of or used, where such organisms are, or are contained in, a medicinal product for human or veterinary use marketed in accordance with an authorisation under Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

(5) The marketing authorisation referred to in paragraph (4) must be valid immediately before exit day.

(6) Any marketing authorisation referred to in paragraph (4) must be conducted in accordance with any obligations, conditions, restrictions, requirements or limitations attached to that authorisation.”

(4) In Schedule 3, in paragraph 3 for sub-paragraph (d) substitute—

“(d) consideration of relevant legislation, including legislation on the protection of workers from risks related to exposure to biological agents at work, other classification schemes referring to plant and animal pathogens, and other international and national classification schemes for genetically modified micro-organisms;”.

## Health and Safety and Nuclear (Fees) Regulations 2016

**46.**—(1) The Health and Safety and Nuclear (Fees) Regulations 2016<sup>(22)</sup> are amended as follows.

(2) In regulation 21—

(a) omit paragraph (1);

(b) for paragraph (2) substitute—

“(2) Each competent authority must charge fees for—

(a) work it carries out within the scope of the Biocides Regulation which relates to the activities listed in column 1 of Schedule 15;

(b) work it carries out in order to evaluate an application for a change to an authorised product under Regulation 354/2013;

(c) work it carries out in order to determine an application to be a participant for the review of an active substance/product-type combination under Article 17 of Regulation 1062/2014; and

(d) work it carries out in order to evaluate an application under regulation 13 of the 2013 Biocidal Products and Chemicals Regulations.”;

(c) in paragraph (12), after the definition of “competent authority” insert—

““Regulation 354/2013” means Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council; and

“Regulation 1062/2014” means Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council.”

(3) After regulation 21 insert—

(22) [S.I. 2016/253](#).

## “Fees payable for activities under the CLP Regulation

**21A.**—(1) The Agency<sup>(23)</sup> may charge fees for work it carries out within the scope of the CLP Regulation which relates to the activities listed in column 1 of Schedule 16.

(2) Any fee payable under paragraph (1) must be calculated in accordance with paragraphs (3) to (9).

(3) Where a fee is payable under paragraph (1), the Agency must prepare and send to the person referred to in column 2 of Schedule 16 (“the applicant”) an estimate of the fee, which will be at least £5000.

(4) The applicant must pay the Agency the amount of that estimate within 30 days of its issue.

(5) Upon completion of the work, the Agency must prepare a detailed statement of the work carried out and of the cost incurred by the Agency or any person acting on its behalf in carrying out that work.

(6) If the cost referred to in paragraph (5) is greater than the amount estimated in accordance with paragraph (3), the Agency must notify the amount of the difference to the applicant who must pay the amount of the difference, which will be the final fee payable, without delay.

(7) If the cost referred to in paragraph (5) is less than the amount estimated in accordance with paragraph (3), the fee must be adjusted accordingly and the amount of the difference must be paid without delay by the Agency to the applicant.

(8) Subject to paragraph (9), in estimating or stating the cost of carrying out any work, the Agency must determine that cost by reference to the daily rate per person specified in column 3 of Schedule 16 that corresponds to the activity listed in column 1.

(9) The daily rate per person must be adjusted pro rata for a period worked of less than 7.4 hours on any one day by—

- (a) dividing the daily rate by 14.8 to create a half-hourly rate; and
- (b) multiplying that figure by the number of half hours worked, rounded up or down to the nearest half hour.

(10) Any unpaid fees may be recovered by the Agency as a civil debt.

(11) For the purposes of this regulation and Schedule 16 “the CLP Regulation” means Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures.

(12) Expressions used in the CLP Regulation which are also used in this regulation or Schedule 16 have the same meaning in these Regulations as they have in the CLP Regulation.”

(4) In Schedule 15, for the table substitute—

<i>“1</i>	<i>2</i>
<i>Activity</i>	<i>Fee per person per day worked</i>
(a) Validation of an application for approval of an active substance	£465
(b) Evaluation of an application to approve an active substance	£465
(c) Evaluation of an application to renew an active substance approval	£465

<sup>(23)</sup> The definition of Agency in Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures is being amended to mean the Health and Safety Executive by amendments made elsewhere in these Regulations.

**Draft Legislation:** This is a draft item of legislation and has not yet been made as a UK Statutory Instrument.  
This draft has been replaced by a new draft, The Chemicals (Health and Safety) and Genetically Modified  
Organisms (Contained Use) (Amendment etc.) (EU Exit) Regulations 2019 ISBN 978-0-11-118153-9

“1	2
Activity	Fee per person per day worked
(d) Validation of an application to amend the conditions of approval of an active substance	£465
(e) Evaluation of an application to amend the conditions of approval of an active substance	£465
(f) Work relating to a request for inclusion of an active substance in the Simplified Active Substance List made on behalf of an economic operator	£465
(g) Validation of an application to amend the conditions of inclusion of an active substance in the Simplified Active Substance List	£465
(h) Evaluation of an application to amend the conditions of inclusion of an active substance in the Simplified Active Substance List	£465
(i) Meetings with applicants and prospective applicants	£465
(j) Evaluation of an application to authorise a biocidal product under the simplified procedure	£409
(k) Validation of an application for a national authorisation of a biocidal product	£409
(l) Evaluation of an application for a national authorisation of a biocidal product	£409
(m) Evaluation of an application to renew a national authorisation of a biocidal product	£409
(n) Determination of an application to amend an existing biocidal product authorisation	£409
(o) Evaluation of an application for an emergency use permit	£409
(p) Assessment of an application to be included in the list of suppliers maintained under Article 95 of the Biocides Regulation	£465
(q) Determination of a request that information on an active substance or product is not made publicly available	£465
(r) Determination of the classification of a proposed change to an authorised product in accordance with Regulation 354/2013	£409
(s) Determination of an application to be a participant for the review of an active substance/product-type combination under Article 17 of Regulation 1062/2014	£465
(t) Assessment of technical equivalence	£465
(u) Evaluation of an application under regulation 13 of the 2013 Biocidal Products and Chemicals Regulations	£409”

(5) After Schedule 15 insert—



“SCHEDULE 16

Regulation 21A

FEES FOR ACTIVITIES IN RESPECT OF WHICH A FEE IS  
PAYABLE AND DAILY RATE UNDER THE CLP REGULATION

<i>1</i>	<i>2</i>	<i>3</i>
<i>Activity</i>	<i>Person by whom fee is payable</i>	<i>Fee</i>
Consideration of a proposal submitted under sub paragraph (1) of paragraph 3 of Article 37A	Person submitting the application	£465”