SCHEDULE 1

AMENDMENTS TO SUBORDINATE LEGISLATION

Health and Safety and Nuclear (Fees) Regulations 2016

46.—(1) The Health and Safety and Nuclear (Fees) Regulations 2016(**1**) 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—

"**Fees payable for activities under the CLP Regulation**

21A.—(1) The Agency(**2**) 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.

(**1**) S.I. 2016/253.

(**2**) 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.

(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—

"1 *Activity*	*2* *Fee per person per day worked*
(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
(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

"1 *Activity*	*2* *Fee per person per day worked*
(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

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