

SCHEDULE 1

Amendment of Titles 1 To 15

PART 3

Amendment of Title 3: Data sharing and avoidance of unnecessary testing

Chapter 1 of Title 3

22. In Article 25(3), after “this Regulation” insert “, or under EU REACH before exit day”.

Chapter 2 of Title 3

23. For the title of Chapter 2, substitute “Rules for registrants of substances”.

- 24.—(1) Article 26 is amended as follows.

(2) In paragraph 1, omit “of a non-phase-in substance, or potential registrant of a phase-in substance who has not pre-registered in accordance with Article 28,”.

- (3) In paragraph 3—

- (a) in the first subparagraph, for “the same substance has previously been registered less than 12 years earlier” substitute “there is a previous registration of the same substance that is less than 12 years old”;

- (b) after the first subparagraph, insert—

“A registration of a substance is less than 12 years old if—

- (a) in a case where the registration came into existence under Article 127A, the existing EU registration (as defined in Article 127D) began less than 12 years before the potential registrant’s enquiry to the Agency;
- (b) in any other case, the registration under this Regulation began less than 12 years before the potential registrant’s enquiry to the Agency.”.

- 25.—(1) Article 27 is amended as follows.

(2) In paragraph 1, for “a substance has previously been registered less than 12 years earlier” substitute “there is a previous registration of a substance that is less than 12 years old”.

- (3) For paragraph 2 substitute—

“2. Within one month of a request for information being made according to paragraph 1, the owner of the study shall provide proof of the cost of the information to the potential registrant(s) requesting it. The potential and the previous registrant(s) as referred to in paragraph 1 shall make every effort to reach an agreement on the sharing of the information requested by the potential registrant(s) with respect to Article 10(a)(vi) and (vii). Such an agreement may be replaced by submission of the matter to an arbitration board and acceptance of the arbitration order.”.

(4) In paragraph 4, after “the previous registrant shall” insert “, within two weeks of receipt of payment,”.

- (5) For paragraph 5 substitute—

“5. If the previous registrant as referred to in paragraph 1 refuses to provide either proof of the cost of that study or the study itself to a potential registrant, or there is failure to

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reach an agreement referred to in paragraph 4, the potential registrant(s) shall inform the Agency and the previous registrant(s) thereof at the earliest one month after receipt, from the Agency, of the name and address of the previous registrant(s).”.

Chapter 3 of Title 3

26. Omit Articles 28 to 30.