

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Text with EEA relevance)

[<sup>X1</sup> TITLE III U.K.]

**DATA SHARING AND AVOIDANCE OF UNNECESSARY TESTING**

[<sup>X1</sup> CHAPTER 2 U.K.]

[<sup>F1</sup>Rules for registrants of substances]

*Article 26 U.K.*

**Duty to inquire prior to registration**

1 Every potential registrant <sup>F2</sup>... shall inquire from the Agency whether a registration has already been submitted for the same substance. He shall submit all the following information to the Agency with the inquiry:

- a his identity as specified in Section 1 of Annex VI, with the exception of the use sites;
- b the identity of the substance, as specified in Section 2 of Annex VI;
- c which information requirements would require new studies involving vertebrate animals to be carried out by him;
- d which information requirements would require other new studies to be carried out by him.

2 If the same substance has previously not been registered, the Agency shall inform the potential registrant accordingly.

3 If [<sup>F3</sup>there is a previous registration of the same substance that is less than 12 years old], the Agency shall inform the potential registrant without delay of the names and addresses of the previous registrant(s) and of the relevant summaries or robust study summaries, as the case may be, already submitted by them.

[<sup>F4</sup>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.]

Studies involving vertebrate animals shall not be repeated.

*Status: Point in time view as at 31/12/2020.*

*Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council, CHAPTER 2. (See end of Document for details)*

The Agency shall simultaneously inform the previous registrants of the name and address of the potential registrant. The available studies shall be shared with the potential registrant in accordance with Article 27.

4 If several potential registrants have made an inquiry in respect of the same substance, the Agency shall inform all potential registrants without delay of the name and address of the other potential registrants.

#### Textual Amendments

- F2** Words in Art. 26(1) omitted (31.12.2020) by virtue of The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 24(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F3** Words in Art. 26(3) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 24(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F4** Words in Art. 26(3) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 24(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

### Article 27 U.K.

#### Sharing of existing data in the case of registered substances

1 Where [<sup>F5</sup>there is a previous registration of a substance that is less than 12 years old] as referred to in Article 26(3), the potential registrant:

- a shall, in the case of information involving tests on vertebrate animals; and
- b may, in the case of information not involving tests on vertebrate animals,

request from the previous registrant(s) the information he requires with respect to Article 10(a)(vi) and (vii) in order to register.

[<sup>F6</sup> 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.]

3 The previous registrant and potential registrant(s) shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way. This may be facilitated by following cost sharing guidance based on those principles which is adopted by the Agency in accordance with Article 77(2)(g). Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements.

4 On agreement on the sharing of the information, the previous registrant shall [<sup>F7</sup>, within two weeks of receipt of payment,] make available to the new registrant the agreed information and shall give the new registrant the permission to refer to the previous registrant's full study report.

[<sup>F8</sup> 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 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).]

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*Changes to legislation: There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council, CHAPTER 2 . (See end of Document for details)*

6 Within one month from the receipt of the information referred to in paragraph 5, the Agency shall give the potential registrant permission to refer to the information requested by him in his registration dossier, subject to the potential registrant providing, upon request by the Agency, proof that he has paid the previous registrant(s) for that information a share of cost incurred. The previous registrant(s) shall have a claim on the potential registrant for a proportionate share of the cost incurred by him. Calculation of the proportionate share may be facilitated by the guidance adopted by the Agency in accordance with Article 77(2)(g). Provided he makes the full study report available to the potential registrant, the previous registrant(s) shall have a claim on the potential registrant for an equal share of the cost incurred by him, which shall be enforceable in the national courts.

7 An appeal may be brought, in accordance with Articles 91, 92 and 93, against Agency decisions under paragraph 6 of this Article.

8 The registration waiting period in accordance with Article 21(1) for the new registrant shall be extended by a period of four months, if the previous registrant so requests. ]

#### Textual Amendments

- F5** Words in Art. 27(1) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 25(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F6** Art. 27(2) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 25(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F7** Words in Art. 27(4) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 25(4)**; 2020 c. 1, Sch. 5 para. 1(1)
- F8** Art. 27(5) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 25(5)**; 2020 c. 1, Sch. 5 para. 1(1)

#### Editorial Information

- X1** Substituted by Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (Official Journal of the European Union L 396 of 30 December 2006).

#### Textual Amendments

- F1** Title 3 Ch. 2 title substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 23**; 2020 c. 1, **Sch. 5 para. 1(1)**

**Status:**

Point in time view as at 31/12/2020.

**Changes to legislation:**

There are currently no known outstanding effects for the Regulation (EC) No 1907/2006 of the European Parliament and of the Council, CHAPTER 2 .