

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)

[^{XI} TITLE VII

AUTHORISATION

CHAPTER 2

Granting of authorisations

[^{XI} Article 64

Procedure for authorisation decisions

1 The Agency shall acknowledge the date of receipt of the application. [^{F1}The Agency must give its draft opinion within ten months of the date of receipt of the application].

2 The Agency shall make available on its web-site broad information on uses, taking into account Articles 118 and 119 on access to information, for which applications have been received and for reviews of authorisations, with a deadline by which information on alternative substances or technologies may be submitted by interested third parties.

[^{F2} 3 In preparing its opinion, the Agency must first check that the application includes all the information specified in Article 62 that is relevant to its remit. If necessary, the Agency must request additional information to bring the application into conformity with the requirements of Article 62. The Agency may, if it deems it necessary, require the applicant or request third parties to submit, within a specified time period, additional information on possible alternative substances or technologies. The Agency, and any scientific adviser providing the Agency with scientific knowledge and advice in relation to the opinion, must take into account any information submitted by third parties.]

[^{F3}3A In paragraph 3 “scientific adviser” means a person who the Agency has commissioned (in compliance with the duty imposed by Article 77(A1)) to provide it with scientific knowledge and advice.]

4 The draft [^{F4}opinion] shall include the following elements:

- a ^{F5}... An assessment of the risk to human health and/or the environment arising from the use(s) of the substance, including the appropriateness and effectiveness of the risk management measures as described in the application and, if relevant, an assessment of the risks arising from possible alternatives;
- b ^{F6}... An assessment of the socio-economic factors and the availability, suitability and technical feasibility of alternatives associated with the use(s) of the substance as

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, Article 64 . (See end of Document for details)

described in the application, when an application is made in accordance with Article 62 and of any third party contributions submitted under paragraph 2 of this Article.

5 The Agency shall send [^{F7}its draft opinion] to the applicant by the end of the deadline set out in paragraph 1. Within one month of receipt of the draft opinion, the applicant may provide written notice that he wishes to comment. The draft opinion shall be deemed to have been received seven days after the Agency has sent it.

If the applicant does not wish to comment, the Agency shall send [^{F8}its final opinion to the appropriate authorities] and the applicant, within 15 days of the end of the period within which the applicant may comment or within 15 days of receipt of notice from the applicant that he does not intend to comment.

If the applicant wishes to comment, he shall send his written argumentation to the Agency within two months of the receipt of the draft opinion. The [^{F9}Agency] shall consider the comments and adopt [^{F10}its] final [^{F11}opinion] within two months of receipt of the written argumentation, taking this argumentation into account where appropriate. Within a further 15 days the Agency shall send the [^{F11}opinion], with the written argumentation attached, to the [^{F12}appropriate authorities] and the applicant.

6 The Agency shall determine in accordance with Articles 118 and 119 which parts of its [^{F13}opinion] and parts of any attachments thereto should be made publicly available on its website.

7 In cases covered by Article 63(1), the Agency shall treat the applications together, provided the deadlines for the first application can be met.

[^{F14} 8 The Secretary of State must make a decision granting or refusing the authorisation within six months of receipt of the opinion from the Agency.

The function in this paragraph of deciding whether to grant or refuse the authorisation is subject to the consent requirement in Article 4A.]

9 Summaries of the [^{F15}decisions of the Secretary of State], including the authorisation number and the reasons for the decision, in particular where suitable alternatives exist, shall be published [^{F16}by the Secretary of State] and shall be made publicly available in a database established and kept up to date by the Agency.

10 In cases covered by Article 63(2), the deadline set out in paragraph 1 of this Article shall be shortened to five months.]

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** Words in Art. 64(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. 50(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F2** Art. 64(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. 50(3)**; 2020 c. 1, Sch. 5 para. 1(1)

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- F3** Art. 64(3A) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(4)**; 2020 c. 1, Sch. 5 para. 1(1)
- F4** Word in Art. 64(4) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(5)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F5** Words in Art. 64(4)(a) 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. 50(5)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F6** Words in Art. 64(4)(b) 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. 50(5)(c)**; 2020 c. 1, Sch. 5 para. 1(1)
- F7** Words in Art. 64(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. 50(6)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F8** Words in Art. 64(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. 50(6)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F9** Word in Art. 64(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. 50(6)(c)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F10** Word in Art. 64(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. 50(6)(c)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F11** Word in Art. 64(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. 50(6)(c)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F12** Words in Art. 64(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. 50(6)(c)(iv)**; 2020 c. 1, Sch. 5 para. 1(1)
- F13** Word in Art. 64(6) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(7)**; 2020 c. 1, Sch. 5 para. 1(1)
- F14** Art. 64(8) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(8)**; 2020 c. 1, Sch. 5 para. 1(1)
- F15** Words in Art. 64(9) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(9)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F16** Words in Art. 64(9) substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 50(9)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)

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, Article 64 .