

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)

[^{X1} TITLE VIII

RESTRICTIONS ON THE MANUFACTURING, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, [^{F3}MIXTURES] AND ARTICLES

[^{X1} CHAPTER 2

Restrictions process

Article 68

Introducing new and amending current restrictions

1 When there is an unacceptable risk to human health or the environment, arising from the manufacture, use or placing on the market of substances, ^{F1}... Annex XVII shall be amended [^{F2}by regulations made by the Secretary of State which provide for the adoption of new restrictions or the amendment of] current restrictions in Annex XVII, for the manufacture, use or placing on the market of substances on their own, in [^{F3}mixtures] or in articles, pursuant to the procedure set out in Articles 69 to 73. [^{F4}In exercising the power to make regulations under this paragraph, the Secretary of State] shall take into account the socio-economic impact of the restriction, including the availability of alternatives.

The first subparagraph shall not apply to the use of a substance as an on-site isolated intermediate.

[^{F32} For a substance on its own, in a mixture or in an article which meets the criteria for classification in the hazard classes carcinogenicity, germ cell mutagenicity or reproductive toxicity, category 1A or 1B, and could be used by consumers [^{F5}the Secretary of State may propose restrictions. The function of proposing restrictions is subject to the consent requirement in Article 4A. The Secretary of State may, by regulations, amend Annex 17 to give effect to a proposed restriction.] Articles 69 to 73 shall not apply.]

[^{F63} Regulations under paragraph 2 of this Article are to be made by statutory instrument; and a statutory instrument containing regulations made under paragraph 2 of this Article is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under paragraph 2 of this Article is subject to the consent requirement in Article 4A.]

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)

Textual Amendments

- F1** Words in Art. 68(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. 54(2)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F2** Words in Art. 68(1) substituted (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. 54(2)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F3** Substituted by 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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (Text with EEA relevance).
- F4** Words in Art. 68(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. 54(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F5** Words in Art. 68(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. 54(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F6** Art. 68(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. 54(4)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 69

Preparation of a proposal

1 If [^{F7}an appropriate authority] considers that the manufacture, placing on the market or use of a substance on its own, in a [^{F3}mixture] or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed, it shall ask the Agency to prepare a dossier which conforms to the requirements of Annex XV.

2 After the date referred to in Article 58(1)(c)(i) for a substance listed in Annex XIV, the Agency shall consider whether the use of that substance in articles poses a risk to human health or the environment that is not adequately controlled. If the Agency considers that the risk is not adequately controlled, it shall prepare a dossier which conforms to the requirements of Annex XV.

3 Within 12 months of the receipt of the request from [^{F8}an appropriate authority] in paragraph 1 and if this dossier demonstrates that action ^{F9}... is necessary, beyond any measures already in place, the Agency shall suggest restrictions, in order to initiate the restrictions process.

[^{F10} 4 If the Agency considers that the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed, the Agency must prepare a dossier which conforms to the requirements and format of the relevant sections of Annex 15. If this dossier demonstrates that action is necessary, beyond any measures already in place, the Agency must initiate the restrictions process and must inform those who submitted a registration for that substance.

The Agency must refer to any dossier, chemical safety report or risk assessment submitted to it under this Regulation. The Agency must also refer to any relevant risk assessment submitted for other regulatory purposes. To this end other public bodies carrying out a similar task must provide information to the Agency on request.]

[^{F11}5 The Agency must maintain a list of substances for which a dossier conforming to the requirements of Annex 15 is planned or underway for the purposes of a proposed restriction.]

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)

[^{F12}5A The Agency or an appropriate authority may propose the re-examination of an existing restriction listed in Annex 17.

If the Agency is proposing the re-examination, it must notify the appropriate authorities of the proposal. If an appropriate authority is proposing a re-examination, it must notify the Agency and the other appropriate authorities of the proposal. Where a re-examination is proposed (by the Agency or an appropriate authority), the Secretary of State must decide, on the basis of evidence presented by whoever proposed the re-examination, whether the re-examination should take place. That function of deciding whether the re-examination should take place is subject to the consent requirement in Article 4A. If the Secretary of State decides that the re-examination should take place, the Agency must carry out the re-examination.]

6 Without prejudice to Articles 118 and 119, the Agency shall make publicly available on its website all dossiers conforming with Annex XV including the restrictions suggested pursuant to paragraphs 3 and 4 of this Article without delay, clearly indicating the date of publication. The Agency shall invite all interested parties to submit individually or jointly within six months of the date of publication:

- a comments on dossiers and the suggested restrictions;
- b a socio-economic analysis, or information which can contribute to one, of the suggested restrictions, examining the advantages and drawbacks of the proposed restrictions. It shall conform to the requirements in Annex XVI.

Textual Amendments

- F7** Words in Art. 69(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. 55(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F8** Words in Art. 69(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. 55(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F9** Words in Art. 69(3) 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. 55(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F10** Art. 69(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. 55(4)**; 2020 c. 1, Sch. 5 para. 1(1)
- F11** Art. 69(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. 55(5)**; 2020 c. 1, Sch. 5 para. 1(1)
- F12** Art. 69(5A) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 55(6)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 70

Agency opinion: [^{F13}risk assessment]

Within nine months of the date of publication referred to in Article 69(6), the [^{F14}Agency] shall formulate an opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment, based on its consideration of the relevant parts of the dossier. This opinion shall take account of the [^{F15}dossier], and the views of interested parties referred to in Article 69(6)(a).

Textual Amendments

- F13** Words in Art. 70 heading substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 56(2)**; 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, CHAPTER 2. (See end of Document for details)

- F14** Word in Art. 70 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 56(3)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F15** Word in Art. 70 substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 56(3)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 71

Agency opinion: [^{F16}socio-economic analysis]

1 Within 12 months of the date of publication referred to in Article 69(6), the [^{F17}Agency] shall formulate an opinion on the suggested restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. It shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account of the analyses or information according to Article 69(6)(b), if there are any. The Agency shall publish the draft opinion on its website without delay. The Agency shall invite interested parties to give their comments on the draft opinion no later than 60 days from the publication of that draft opinion.

2 The [^{F18}Agency] shall without delay adopt its opinion, taking into account where appropriate further comments received by the deadline set. This opinion shall take account of the comments and socio-economic analyses of interested parties submitted under Article 69(6) (b) and under paragraph 1 of this Article.

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Textual Amendments

- F16** Words in Art. 71 heading substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 57(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F17** Word in Art. 71(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. 57(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F18** Word in Art. 71(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. 57(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F19** Art. 71(3) 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. 57(4)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 72

Submission of an opinion to the [^{F20}appropriate authorities]

1 The Agency shall submit to the [^{F21}appropriate authorities] without delay [^{F22}its opinions on risk assessment and socio-economic analysis] on restrictions suggested for substances on their own, in [^{F3}mixtures] or in articles. If [^{F23}the Agency does] not formulate an opinion by the deadline set in Article 70 and Article 71(1) the Agency shall inform the [^{F24}appropriate authorities] accordingly, stating the reasons.

2 Without prejudice to Articles 118 and 119 the Agency shall publish [^{F25}its opinions] on its website without delay.

3 The Agency shall provide the [^{F26}appropriate authorities that request them] with all documents and evidence submitted to or considered by it.

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)

Textual Amendments

- F20** Words in Art. 72 heading substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 58(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F21** Words in Art. 72(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. 58(3)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F22** Words in Art. 72(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. 58(3)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F23** Words in Art. 72(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. 58(3)(b)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F24** Words in Art. 72(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. 58(3)(b)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F25** Words in Art. 72(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. 58(4)**; 2020 c. 1, Sch. 5 para. 1(1)
- F26** Words in Art. 72(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. 58(5)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 73

[^{F27}Restriction decisions]

1 If the conditions laid down in Article 68 are fulfilled, the [^{F28}Secretary of State must propose] a draft amendment to Annex XVII, within three months of receipt of [^{F29}the Agency's opinions]. [^{F30}The functions of deciding whether to propose a draft amendment, and of proposing a draft amendment, are subject to the consent requirement in Article 4A.]

Where the draft amendment diverges from the original proposal or if it does not take the opinions from the Agency into account, the [^{F31}Secretary of State] shall annex a detailed explanation of the reasons for the differences.

[^{F32}2 The Secretary of State may, by regulations, amend Annex 17 to include the draft amendment.

Regulations under this paragraph are to be made by statutory instrument; and a statutory instrument containing regulations made under this paragraph is subject to annulment in pursuance of a resolution of either House of Parliament.

The function of making regulations under this Article is subject to the consent requirement in Article 4A.]]

Textual Amendments

- F27** Art. 73 heading substituted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 59(2)**; 2020 c. 1, Sch. 5 para. 1(1)
- F28** Words in Art. 73(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. 59(3)(a)(i)**; 2020 c. 1, Sch. 5 para. 1(1)
- F29** Words in Art. 73(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. 59(3)(a)(ii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F30** Words in Art. 73(1) inserted (31.12.2020) by The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 59(3)(a)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)
- F31** Words in Art. 73(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. 59(3)(b)**; 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, CHAPTER 2. (See end of Document for details)

F32 Art. 73(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. 59(4)**; 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).

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 .