

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 VI

EVALUATION

[^{X1} CHAPTER 2

Substance evaluation

Article 44

Criteria for substance evaluation

1 [^{F1}The] Agency shall in cooperation with the [^{F2}appropriate authorities] develop criteria for prioritising substances with a view to further evaluation. Prioritisation shall be on a risk-based approach. The criteria shall consider:

- a hazard information, for instance structural similarity of the substance with known substances of concern or with substances which are persistent and liable to bio-accumulate, suggesting that the substance or one or more of its transformation products has properties of concern or is persistent and liable to bio-accumulate;
- b exposure information;
- c tonnage, including aggregated tonnage from the registrations submitted by several registrants.

2 The Agency shall use the criteria in paragraph 1 for the purpose of compiling a draft ^{F3}... rolling action plan which shall cover a period of three years and shall specify substances to be evaluated each year. Substances shall be included if there are grounds for considering (either on the basis of a dossier evaluation carried out by the Agency or on the basis of any other appropriate source, including information in the registration dossier) that a given substance constitutes a risk to human health or the environment. [^{F4}The Agency must submit its draft rolling action plan to the appropriate authorities within 12 months of IP completion day and give the appropriate authorities the opportunity to comment on it. The Agency must submit a draft annual update to its rolling action plan by 31 May in each subsequent year and give the appropriate authorities the opportunity to comment on it. The Agency must adopt a final rolling annual action plan for each year (after taking account of any comments made on the draft by the appropriate authorities) and must publish it on its website.]

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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)

Textual Amendments

- F1 Word in Art. 44(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. 34(2)(a); 2020 c. 1, Sch. 5 para. 1(1)
F2 Words in Art. 44(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. 34(2)(b); 2020 c. 1, Sch. 5 para. 1(1)
F3 Word in Art. 44(2) 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. 34(3)(a)(i); 2020 c. 1, Sch. 5 para. 1(1)
F4 Words in Art. 44(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. 34(3)(a)(ii) (as amended by S.I. 2019/1144, regs. 1, 3(2)(a)(b) (as amended by S.I. 2020/1577, regs. 1(1)(a), 13(2)) and S.I. 2020/1313, regs. 1(3), 6(2)); 2020 c. 1, Sch. 5 para. 1(1)
F5 Words in Art. 44(2) 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. 34(3)(b); 2020 c. 1, Sch. 5 para. 1(1)

Article 45

[F6Evaluation of substances on the rolling action plan]

1 The Agency shall be responsible for F7... ensuring that substances on the F8... rolling action plan are evaluated. F9...

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Textual Amendments

- F6 Art. 45 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. 35(2); 2020 c. 1, Sch. 5 para. 1(1)
F7 Words in Art. 45(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. 35(3)(a)(i); 2020 c. 1, Sch. 5 para. 1(1)
F8 Word in Art. 45(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. 35(3)(a)(ii); 2020 c. 1, Sch. 5 para. 1(1)
F9 Words in Art. 45(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. 35(3)(b); 2020 c. 1, Sch. 5 para. 1(1)
F10 Art. 45(2)-(5) 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. 35(4); 2020 c. 1, Sch. 5 para. 1(1)

Article 46

Requests for further information and check of information submitted

1 If the [F11Agency] considers that further information is required, including, if appropriate, information not required in Annexes VII to X, it shall prepare a draft decision, stating reasons, requiring the registrant(s) to submit the further information and setting a deadline for its submission. A draft decision shall be prepared within 12 months of the

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publication of the ^{F12}... rolling action plan on the Agency's website for substances to be evaluated that year. The decision shall be taken in accordance with the procedure laid down in Articles 50 and 52.

2 The registrant shall submit the information required to the Agency by the deadline set.

3 The [^{F13}Agency] shall examine any information submitted, and shall draft any appropriate decisions in accordance with this Article, if necessary, within 12 months of the information being submitted.

4 The [^{F14}Agency] shall finish its evaluation activities within 12 months of the start of the evaluation of the substance or within 12 months of the information being submitted under paragraph 2 ^{F15}.... If this deadline is exceeded, the evaluation shall be deemed to be finished.

Textual Amendments

- F11** Word in Art. 46(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. 36(2)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F12** Word in Art. 46(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. 36(2)(b)**; 2020 c. 1, Sch. 5 para. 1(1)
- F13** Word in Art. 46(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. 36(3)**; 2020 c. 1, Sch. 5 para. 1(1)
- F14** Word in Art. 46(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. 36(4)(a)**; 2020 c. 1, Sch. 5 para. 1(1)
- F15** Words in Art. 46(4) 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. 36(4)(b)**; 2020 c. 1, Sch. 5 para. 1(1)

Article 47

Coherence with other activities

1 An evaluation of a substance shall be based on all relevant information submitted on that particular substance and on any previous evaluation under this Title. Where information on intrinsic properties of a substance has been generated by reference to structurally related substance(s), the evaluation may also cover these related substances. In cases where a decision on an evaluation has been previously taken in accordance with Article 51 or Article 52, any draft decision requiring further information under Article 46 may be justified only by a change of circumstances or acquired knowledge.

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Textual Amendments

- F16** Art. 47(2) 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. 37**; 2020 c. 1, Sch. 5 para. 1(1)

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[^{F17} Article 48

Follow-up to substance evaluation

Once the substance evaluation has been completed, the Agency must consider how to use the information obtained from this evaluation for the purposes of Article 59(3) and Article 69(4). The Agency must inform the appropriate authorities and the registrant of its conclusions as to whether or how to use the information obtained.]]

Textual Amendments

F17 Art. 48 substituted (31.12.2020) by [The REACH etc. \(Amendment etc.\) \(EU Exit\) Regulations 2019](#) (S.I. 2019/758), reg. 1(1), **Sch. 1 para. 38**; 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 .