

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 1

Dossier evaluation

Article 40

Examination of testing proposals

[^{F1}1 The Agency shall examine any testing proposal set out in a registration or a downstream user report for provision of the information specified in Annexes IX and X for a substance. Priority shall be given to registrations of substances which have or may have PBT, vPvB, sensitising and/or carcinogenic, mutagenic or toxic for reproduction (CMR) properties, or substances above 100 tonnes per year with uses resulting in widespread and diffuse exposure, provided they fulfil the criteria for any of the following hazard classes or categories set out in Annex I of Regulation (EC) No 1272/2008:

- a hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;
- b hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;
- c hazard class 4.1;
- d hazard class 5.1.]

2 Information relating to testing proposals involving tests on vertebrate animals shall be published on the Agency website. The Agency shall publish on its website the name of the substance, the hazard end-point for which vertebrate testing is proposed, and the date by which any third party information is required. It shall invite third parties to submit, using the format provided by the Agency, scientifically valid information and studies that address the relevant substance and hazard end-point, addressed by the testing proposal, within 45 days of the date of publication. All such scientifically valid information and studies received shall be taken into account by the Agency in preparing its decision in accordance with paragraph 3.

3 On the basis of the examination under paragraph 1, the Agency shall draft one of the following decisions and that decision shall be taken in accordance with the procedure laid down in Articles 50 and 51:

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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 1. (See end of Document for details)

- a a decision requiring the registrant(s) or downstream user(s) concerned to carry out the proposed test and setting a deadline for submission of the study summary, or the robust study summary if required by Annex I;
 - b a decision in accordance with point (a), but modifying the conditions under which the test is to be carried out;
 - c a decision in accordance with points (a), (b) or (d) but requiring registrant(s) or downstream user(s) to carry out one or more additional tests in cases of non-compliance of the testing proposal with Annexes IX, X and XI;
 - d a decision rejecting the testing proposal;
 - e a decision in accordance with points (a), (b) or (c), if several registrants or downstream users of the same substance have submitted proposals for the same test, giving them the opportunity to reach an agreement on who will perform the test on behalf of all of them and to inform the Agency accordingly within 90 days. If the Agency is not informed of such agreement within such 90 days, it shall designate one of the registrants or downstream users, as appropriate, to perform the test on behalf of all of them.
- 4 The registrant or downstream user shall submit the information required to the Agency by the deadline set.

Textual Amendments

- F1** 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 \(Text with EEA relevance\).](#)

Article 41

Compliance check of registrations

- 1 The Agency may examine any registration in order to verify any of the following:
- a that the information in the technical dossier(s) submitted pursuant to Article 10 complies with the requirements of Articles 10, 12 and 13 and with Annexes III and VI to X;
 - b that the adaptations of the standard information requirements and the related justifications submitted in the technical dossier(s) comply with the rules governing such adaptations set out in Annexes VII to X and with the general rules set out in Annex XI;
 - c that any required chemical safety assessment and chemical safety report comply with the requirements of Annex I and that the proposed risk management measures are adequate;
 - d that any explanation(s) submitted in accordance with Article 11(3) or Article 19(2) have an objective basis.
- 2 The list of dossiers being checked for compliance by the Agency shall be made available to Member States competent authorities.
- 3 On the basis of an examination made pursuant to paragraph 1, the Agency may, within 12 months of the start of the compliance check, prepare a draft decision requiring the registrant(s) to submit any information needed to bring the registration(s) into compliance with the relevant information requirements and specifying adequate time limits for the submission of further information. Such a decision shall be taken in accordance with the procedure laid down in Articles 50 and 51.

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

5 To ensure that registration dossiers comply with this Regulation, the Agency shall select a percentage of those dossiers, no lower than 5 % of the total received by the Agency for each tonnage band, for compliance checking. The Agency shall give priority, but not exclusively, to dossiers meeting at least one of the following criteria:

- a the dossier contains information in Article 10(a)(iv), (vi) and/or (vii) submitted separately as per Article 11(3); or
- b the dossier is for a substance manufactured or imported in quantities of one tonne or more per year and does not meet the requirements of Annex VII applying under either Article 12(1)(a) or (b), as the case may be; or
- c the dossier is for a substance listed in the Community rolling action plan referred to in Article 44(2).

6 Any third party may electronically submit information to the Agency relating to substances that appear on the list referred to in Article 28(4). The Agency shall consider this information together with the information submitted according to Article 124 when checking and selecting dossiers.

7 The Commission may, after consulting with the Agency, take a decision to vary the percentage of dossiers selected and amend or include further criteria in paragraph 5 in accordance with the procedure referred to in Article 133(4).

Article 42

Check of information submitted and follow-up to dossier evaluation

1 The Agency shall examine any information submitted in consequence of a decision taken under Articles 40 or 41, and draft any appropriate decisions in accordance with these Articles, if necessary.

2 Once the dossier evaluation is completed, the Agency shall notify the Commission and the competent authorities of the Member States of the information obtained and any conclusions made. The competent authorities shall use the information obtained from this evaluation for the purposes of Article 45(5), Article 59(3) and Article 69(4). The Agency shall use the information obtained from this evaluation for the purposes of Article 44.

Article 43

Procedure and time periods for examination of testing proposals

1 In the case of non phase-in substances, the Agency shall prepare a draft decision in accordance with Article 40(3) within 180 days of receiving a registration or downstream user report containing a testing proposal.

2 In the case of phase-in substances, the Agency shall prepare the draft decisions in accordance with Article 40(3):

- a by 1 December 2012 for all registrations received by 1 December 2010 containing proposals for testing in order to fulfil the information requirements in Annexes IX and X;
- b by 1 June 2016 for all registrations received by 1 June 2013 containing proposals for testing in order to fulfil the information requirements in Annex IX only;

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c by 1 June 2022 for any registrations containing testing proposals received by 1 June 2018.

3 The list of registration dossiers being evaluated under Article 40 shall be made available to Member States.]

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).

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