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)

[X1TITLE VI

EVALUATION

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:

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.

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;

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.

CHAPTER 2

Substance evaluation

Article 44

Criteria for substance evaluation

1 In order to ensure a harmonised approach, the Agency shall in cooperation with the Member States 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 Community 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. The Agency shall submit the first draft rolling action plan to the Member States by 1 December 2011. The Agency shall submit draft annual updates to the rolling action plan to the Member States by 28 February each year.

The Agency shall adopt the final Community rolling action plan on the basis of an opinion from the Member State Committee set up under Article 76(1)(e) (hereinafter referred to as the Member State Committee) and shall publish the plan on its website, identifying the Member State who will carry out the evaluation of the substances listed therein as determined according to Article 45.

Article 45

Competent authority

1 The Agency shall be responsible for coordinating the substance evaluation process and ensuring that substances on the Community rolling action plan are evaluated. In doing so, the Agency shall rely on the competent authorities of Member States. In carrying out an evaluation of a substance, the competent authorities may appoint another body to act on their behalf.

2 A Member State may choose (a) substance(s) from the draft Community rolling action plan, with the aim of becoming a competent authority for the purposes of Articles 46, 47 and

48. In the event of a substance from the draft Community rolling action plan not being chosen by any Member State, the Agency shall ensure that the substance is evaluated.

3 In cases where two or more Member States have expressed an interest in evaluating the same substance and they cannot agree who should be the competent authority, the competent authority for the purposes of Articles 46, 47 and 48 shall be determined in accordance with the following procedure.

The Agency shall refer the matter to the Member State Committee, in order to agree which authority shall be the competent authority, taking into account the Member State in which the manufacturer(s) or importer(s) is located, the respective proportions of total Community gross domestic product, the number of substances already being evaluated by a Member State and the expertise available.

If, within 60 days of the referral, the Member State Committee reaches unanimous agreement, the Member States concerned shall adopt substances for evaluation accordingly.

If the Member State Committee fails to reach a unanimous agreement, the Agency shall submit the conflicting opinions to the Commission, which shall decide which authority shall be the competent authority, in accordance with the procedure referred to in Article 133(3), and the Member States concerned shall adopt substances for evaluation accordingly.

4 The competent authority identified in accordance with paragraphs 2 and 3 shall evaluate the allocated substances in accordance with this Chapter.

5 A Member State may notify the Agency at any time of a substance not on the Community rolling action plan, whenever it is in possession of information which suggests that the substance is a priority for evaluation. The Agency shall decide whether to add this substance to the Community rolling action plan on the basis of an opinion from the Member State Committee. If the substance is added to the Community rolling action plan, the proposing Member State, or another Member State who agrees, shall evaluate that substance.

Article 46

Requests for further information and check of information submitted

1 If the competent authority 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 publication of the Community 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 competent authority 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 competent authority 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, and notify the Agency accordingly. If this deadline is exceeded, the evaluation shall be deemed to be finished.

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.

2 In order to ensure a harmonised approach to requests for further information, the Agency shall monitor draft decisions under Article 46 and shall develop criteria and priorities. Where appropriate, implementing measures shall be adopted in accordance with the procedure referred to in Article 133(3).

Article 48

Follow-up to substance evaluation

Once the substance evaluation has been completed, the competent authority shall consider how to use the information obtained from this evaluation for the purposes of Article 59(3), Article 69(4) and Article 115(1). The competent authority shall inform the Agency of its conclusions as to whether or how to use the information obtained. The Agency shall in turn inform the Commission, the registrant and the competent authorities of the other Member States.

CHAPTER 3

Evaluation of intermediates

Article 49

Further information on on-site isolated intermediates

For on-site isolated intermediates that are used in strictly controlled conditions, neither dossier nor substance evaluation shall apply. However, where the competent authority of the Member State in whose territory the site is located considers that a risk to human health or the environment, equivalent to the level of concern arising from the use of substances meeting the criteria in Article 57, arises from the use of an on-site isolated intermediate and that risk is not properly controlled, it may:

(a) require the registrant to submit further information directly related to the risk identified. This request shall be accompanied by a written justification;

(b) examine any information submitted and, if necessary, recommend any appropriate risk reduction measures to address the risks identified in relation to the site in question.

The procedure provided for in the first paragraph may be undertaken only by the competent authority referred to therein. The competent authority shall inform the Agency of the results of such an evaluation, which shall then inform the competent authorities of the other Member States and make the results available to them.

CHAPTER 4

Common provisions

Article 50

Registrants' and downstream users' rights

1 The Agency shall notify any draft decision under Articles 40, 41 or 46 to the registrant(s) or downstream user(s) concerned, informing them of their right to comment within 30 days of receipt. If the concerned registrant(s) or downstream user(s) wish to comment, they shall provide their comments to the Agency. The Agency in turn shall inform the competent authority of the submission of the comments without delay. The competent authority (for decisions taken under Article 46) and the Agency (for decisions taken under Articles 40 and 41) shall take any comments received into account and may amend the draft decision accordingly.

2 If a registrant has ceased the manufacture or import of the substance, or the production or import of an article, or the downstream user the use, he shall inform the Agency of this fact with the consequence that the registered volume in his registration, if appropriate, shall be put to zero and no further information may be requested with respect to that substance, unless the registrant notifies the restart of the manufacture or import of the substance or the production or import of the article, or the downstream user notifies the restart of the use. The Agency shall inform the competent authority of the Member State in which the registrant or downstream user is located.

3 The registrant may cease the manufacture or import of the substance or the production or import of the article, or the downstream user the use, upon receipt of the draft decision. In such cases, the registrant, or downstream user, shall inform the Agency of this fact with the consequence that his registration, or report, shall no longer be valid, and no further information may be requested with respect to that substance, unless he submits a new registration or report. The Agency shall inform the competent authority of the Member State in which the registrant or downstream user is located.

4 Notwithstanding paragraphs 2 and 3, further information may be required in accordance with Article 46 in either or both of the following cases:

a where the competent authority prepares a dossier in accordance with Annex XV concluding that there is a potential long-term risk to human health or the environment justifying the need for further information;

b where the exposure to the substance manufactured or imported by the registrant(s), or to the substance in the article produced or imported by the registrant(s), or to the substance used by the downstream user(s) contributes significantly to that risk.

The procedure in Articles 69 to 73 shall apply *mutatis mutandis*.

Article 51

Adoption of decisions under dossier evaluation

1 The Agency shall notify its draft decision in accordance with Articles 40 or 41, together with the comments of the registrant, to the competent authorities of the Member States.

2 Within 30 days of circulation, the Member States may propose amendments to the draft decision to the Agency.

3 If the Agency does not receive any proposals, it shall take the decision in the version notified under paragraph 1.

4 If the Agency receives a proposal for amendment, it may modify the draft decision. The Agency shall refer a draft decision, together with any amendments proposed, to the Member State Committee within 15 days of the end of the 30-day period referred to in paragraph 2.

5 The Agency shall forthwith communicate any proposal for amendment to any registrants or downstream users concerned and allow them to comment within 30 days. The Member State Committee shall take any comments received into account.

6 If, within 60 days of the referral, the Member State Committee reaches a unanimous agreement on the draft decision, the Agency shall take the decision accordingly.

7 If the Member State Committee fails to reach unanimous agreement, the Commission shall prepare a draft decision to be taken in accordance with the procedure referred to in Article 133(3).

8 An appeal may be brought, in accordance with Articles 91, 92 and 93, against Agency decisions under paragraphs 3 and 6 of this Article.

Article 52

Adoption of decisions under substance evaluation

1 The competent authority shall circulate its draft decision in accordance with Article 46, together with any comments by the registrant or downstream user, to the Agency and to the competent authorities of the other Member States.

2 The provisions of Article 51(2) to (8) shall apply *mutatis mutandis*.

Article 53

Cost sharing for tests without an agreement between registrants and/or downstream users

1 Where registrants or downstream users are required to perform a test as a result of a decision taken under this Title, those registrants or downstream users shall make every effort to reach an agreement as to who is to carry it out on behalf of the other registrants or downstream users 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 to perform the test on behalf of all of them.

2 If a registrant or downstream user performs a test on behalf of others, they shall all share the cost of that study equally.

3 In the case referred to in paragraph 1, the registrant or downstream user who performs the test shall provide each of the others concerned with a copy of the full study report.

4 The person performing and submitting the study shall have a claim against the others accordingly. Any person concerned shall be able to make a claim in order to prohibit another person from manufacturing, importing or placing the substance on the market if that other person either fails to pay his share of the cost or to provide security for that amount or fails to hand over a copy of the full study report of the study performed. All claims shall be enforceable in the national courts. Any person may choose to submit their claims for remuneration to an arbitration board and accept the arbitration order.

Article 54

Publication of information on evaluation

By 28 February of each year, the Agency shall publish on its website a report on the progress made over the previous calendar year towards discharging the obligations incumbent upon it in relation to evaluation. This report shall include, in particular, recommendations to potential registrants in order to improve the quality of future registrations.**]**

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).

Status:
Point in time view as at 10/12/2011.

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, TITLE VI.