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 III

DATA SHARING AND AVOIDANCE OF UNNECESSARY TESTING

CHAPTER 1

Objectives and general rules

Article 25

Objectives and general rules

1 In order to avoid animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. It is also necessary to take measures limiting duplication of other tests.

2 The sharing and joint submission of information in accordance with this Regulation shall concern technical data and in particular information related to the intrinsic properties of substances. Registrants shall refrain from exchanging information concerning their market behaviour, in particular as regards production capacities, production or sales volumes, import volumes or market shares.

3 Any study summaries or robust study summaries of studies submitted in the framework of a registration under this Regulation at least 12 years previously can be used for the purposes of registration by another manufacturer or importer.

CHAPTER 2

Rules for non-phase-in substances and registrants of phase-in substances who have not pre-registered

Article 26

Duty to inquire prior to registration

1 Every potential registrant of a non-phase-in substance, or potential registrant of a phase-in substance who has not pre-registered in accordance with Article 28, shall inquire from the Agency whether a registration has already been submitted for the same substance. He shall submit all the following information to the Agency with the inquiry:

a his identity as specified in Section 1 of Annex VI, with the exception of the use sites;

b the identity of the substance, as specified in Section 2 of Annex VI;

c which information requirements would require new studies involving vertebrate animals to be carried out by him;

d which information requirements would require other new studies to be carried out by him.

2 If the same substance has previously not been registered, the Agency shall inform the potential registrant accordingly.

3 If the same substance has previously been registered less than 12 years earlier, the Agency shall inform the potential registrant without delay of the names and addresses of the previous registrant(s) and of the relevant summaries or robust study summaries, as the case may be, already submitted by them.

Studies involving vertebrate animals shall not be repeated.

The Agency shall simultaneously inform the previous registrants of the name and address of the potential registrant. The available studies shall be shared with the potential registrant in accordance with Article 27.

4 If several potential registrants have made an inquiry in respect of the same substance, the Agency shall inform all potential registrants without delay of the name and address of the other potential registrants.

Article 27

Sharing of existing data in the case of registered substances

1 Where a substance has previously been registered less than 12 years earlier as referred to in Article 26(3), the potential registrant:

a shall, in the case of information involving tests on vertebrate animals; and

b may, in the case of information not involving tests on vertebrate animals,

request from the previous registrant(s) the information he requires with respect to Article 10(a)(vi) and (vii) in order to register.

2 When a request for information has been made according to paragraph 1, the potential and the previous registrant(s) as referred to in paragraph 1 shall make every effort to reach an agreement on the sharing of the information requested by the potential registrant(s) with respect to Article 10(a)(vi) and (vii). Such an agreement may be replaced by submission of the matter to an arbitration board and acceptance of the arbitration order.

3 The previous registrant and potential registrant(s) shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way. This may be facilitated by following cost sharing guidance based on those principles which is adopted by the Agency in accordance with Article 77(2)(g). Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements.

4 On agreement on the sharing of the information, the previous registrant shall make available to the new registrant the agreed information and shall give the new registrant the permission to refer to the previous registrant's full study report.

5 If there is failure to reach such an agreement, the potential registrant(s) shall inform the Agency and the previous registrant(s) thereof at the earliest one month after receipt, from the Agency, of the name and address of the previous registrant(s).

6 Within one month from the receipt of the information referred to in paragraph 5, the Agency shall give the potential registrant permission to refer to the information requested by him in his registration dossier, subject to the potential registrant providing, upon request by the Agency, proof that he has paid the previous registrant(s) for that information a share of cost incurred. The previous registrant(s) shall have a claim on the potential registrant for a proportionate share of the cost incurred by him. Calculation of the proportionate share may be facilitated by the guidance adopted by the Agency in accordance with Article 77(2)(g). Provided he makes the full study report available to the potential registrant, the previous registrant(s) shall have a claim on the potential registrant for an equal share of the cost incurred by him, which shall be enforceable in the national courts.

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

8 The registration waiting period in accordance with Article 21(1) for the new registrant shall be extended by a period of four months, if the previous registrant so requests.

CHAPTER 3

Rules for phase-in-substances

Article 28

Duty to pre-register for phase-in substances

1 In order to benefit from the transitional regime provided for in Article 23 each potential registrant of a phase-in substance in quantities of one tonne or more per year, including without limitation intermediates, shall submit all the following information to the Agency:

a the name of the substance as specified in Section 2 of Annex VI, including its EINECS and CAS number or, if not available, any other identity codes;

b his name and address and the name of the contact person and, where appropriate, the name and address of the person representing him in accordance with Article 4 as specified in Section 1 of Annex VI;

c the envisaged deadline for the registration and the tonnage band;

d the name(s) of substance(s) as specified in Section 2 of Annex VI, including their EINECS and CAS number or, if not available, any other identity codes, for which the available information is relevant for the application of Sections 1.3 and 1.5 of Annex XI.

2 The information referred to in paragraph 1 shall be submitted within a time period starting on 1 June 2008 and ending on 1 December 2008.

3 Registrants who do not submit the information required under paragraph 1 shall not be able to rely on Article 23.

4 The Agency shall by 1 January 2009 publish on its website a list of the substances referred to in paragraph 1(a) and (d). That list shall comprise only the names of the substances, including their EINECS and CAS number if available and other identity codes, and the first envisaged registration deadline.

5 After the publication of the list a downstream user of a substance not appearing on the list may notify the Agency of his interest in the substance, his contact details and the details of his current supplier. The Agency shall publish on its website the name of the substance and on request provide contact details of the downstream user to a potential registrant.

6 Potential registrants who manufacture or import for the first time a phase-in substance in quantities of one tonne or more per year or use for the first time a phase-in substance in the context of production of articles or import for the first time an article containing a phase-in substance that would require registration, after 1 December 2008, shall be entitled to rely on Article 23 provided that they submit the information referred to in paragraph 1 of this Article to the Agency within six months of first manufacturing, importing or using the substance in quantities of one tonne or more per year and no later than 12 months before the relevant deadline in Article 23.

7 Manufacturers or importers of phase-in substances in quantities of less than one tonne per year that appear on the list published by the Agency in accordance with paragraph 4 of this Article, as well as downstream users of those substances and third parties holding information on those substances, may submit the information referred to in paragraph 1 of this Article or any other relevant information to the Agency for those substances, with the intention of being part of the substance information exchange forum as referred to in Article 29.

Article 29

Substance Information Exchange Forums

1 All potential registrants, downstream users and third parties who have submitted information to the Agency in accordance with Article 28, or whose information is held by the Agency in accordance with Article 15, for the same phase-in substance, or registrants who have submitted a registration for that phase-in substance before the deadline set out in Article 23(3), shall be participants in a substance information exchange forum (SIEF).

2 The aim of each SIEF shall be to:

a facilitate, for the purposes of registration, the exchange of the information specified in Article 10(a) (vi) and (vii) between potential registrants, thereby avoiding the duplication of studies; and

b agree classification and labelling where there is a difference in the classification and labelling of the substance between potential registrants.

3 SIEF participants shall provide other participants with existing studies, react to requests by other participants for information, collectively identify needs for further studies for the purposes of paragraph 2(a) and arrange for such studies to be carried out. Each SIEF shall be operational until 1 June 2018.

Article 30

Sharing of data involving tests

1 Before testing is carried out in order to meet the information requirements for the purposes of registration, a SIEF participant shall inquire whether a relevant study is available by communicating within his SIEF. If a relevant study involving tests on vertebrate animals is available within the SIEF, a participant of that SIEF shall request that study. If a relevant study not involving tests on vertebrate animals is available within the SIEF, a SIEF participant may request that study.

Within one month of the request, the owner of the study shall provide proof of its cost to the participant(s) requesting it. The participant(s) and the owner shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non discriminatory way. This may be facilitated by following any cost sharing guidance which is based on those principles and is adopted by the Agency in accordance with Article 77(2)(g). If they cannot reach such an agreement, the cost shall be shared equally. The owner shall give permission to refer to the full study report for the purpose of registration within two weeks of receipt of payment. Registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements.

2 If a relevant study involving tests is not available within the SIEF, only one study shall be conducted per information requirement within each SIEF by one of its participants acting on behalf of the others. They shall take all reasonable steps to reach an agreement within a deadline set by the Agency as to who is to carry out the test on behalf of the other participants and to submit a summary or robust study summary to the Agency. If no agreement is reached, the Agency shall specify which registrant or downstream user shall perform the test. All participants of the SIEF who require a study shall contribute to the costs for the elaboration of the study with a share corresponding to the number of participating potential registrants. Those participants that do not carry out the study themselves shall have the right to receive the full study report within two weeks following payment to the participant that carried out the study.

3 If the owner of a study as referred to in paragraph 1 which involves testing on vertebrate animals refuses to provide either proof of the cost of that study or the study itself to (an) other participant(s), he shall not be able to proceed with registration until he provides the information to the other participants(s). The other participant(s) shall proceed with registration without fulfilling the relevant information requirement, explaining the reason for this in the registration dossier. The study shall not be repeated unless within 12 months of the date of registration of the other participant(s), the owner of this information has not provided it to them and the Agency decides that the test should be repeated by them. However, if a registration containing this information has already been submitted by another registrant, the Agency shall give the other participant(s) permission to refer to the information in his registration dossier(s). The other registrant shall have a claim on the other participant(s) for an equal share of the cost, provided he makes the full study report available to the other participant(s), which shall be enforceable in the national courts.

4 If the owner of a study as referred to in paragraph 1 which does not involve testing on vertebrate animals refuses to provide either proof of the cost of that study or the study itself to (an)other participant(s), the other SIEF participants shall proceed with registration as if no relevant study was available in the SIEF.

5 An appeal may be brought, in accordance with Articles 91, 92 and 93, against Agency decisions under paragraphs 2 or 3 of this Article.

6 The owner of the study who has refused to provide either proof of the cost or the study itself, as referred to in paragraph 3 or 4 of this Article, shall be penalised in accordance with Article 126.**]**

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 12/10/2008.

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 III.