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 VII

AUTHORISATION

[X1CHAPTER 1

Authorisation requirement

Article 55

Aim of authorisation and considerations for substitution

The aim of this Title is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end all manufacturers, importers and downstream users applying for authorisations shall analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.

Article 56

General provisions

1 A manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself if that substance is included in Annex XIV, unless:

a the use(s) of that substance on its own or in a **[**F1mixture**]** or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been authorised in accordance with Articles 60 to 64; or

b the use(s) of that substance on its own or in a **[**F1mixture**]** or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been exempted from the authorisation requirement in Annex XIV itself in accordance with Article 58(2); or

c the date referred to in Article 58(1)(c)(i) has not been reached; or

d the date referred to in Article 58(1)(c)(i) has been reached and he made an application 18 months before that date but a decision on the application for authorisation has not yet been taken; or

e in cases where the substance is placed on the market, authorisation for that use has been granted to his immediate downstream user.

2 A downstream user may use a substance meeting the criteria set out in paragraph 1 provided that the use is in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use.

3 Paragraphs 1 and 2 shall not apply to the use of substances in scientific research and development. Annex XIV shall specify if paragraphs 1 and 2 apply to product and process orientated research and development as well as the maximum quantity exempted.

4 Paragraphs 1 and 2 shall not apply to the following uses of substances:

a uses in plant protection products within the scope of Directive 91/414/EEC;

b uses in biocidal products within the scope of Directive 98/8/EC;

c use as motor fuels covered by Directive 98/70/EC of the European Parliament and of the Council of 13 October 1998 relating to the quality of petrol and diesel fuels[1];

d uses as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems.

5 In the case of substances that are subject to authorisation only because they meet the criteria in Article 57(a), (b) or (c) or because they are identified in accordance with Article 57(f) only because of hazards to human health, paragraphs 1 and 2 of this Article shall not apply to the following uses:

a uses in cosmetic products within the scope of Directive 76/768/EEC;

b uses in food contact materials within the scope of Regulation (EC) No 1935/2004.

6 Paragraphs 1 and 2 shall not apply to the use of substances when they are present in **[**[F1]mixtures**]**:

a for substances referred to in Article 57(d), (e) and (f), below a concentration limit of 0,1 % weight by weight (w/w);

[[F1]b for all other substances, below the lowest of the concentration limits specified in Directive 1999/45/EC or in Part 3 of Annex VI to Regulation (EC) No 1272/2008 which result in the classification of the mixture as dangerous.**]**

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 57

Substances to be included in Annex XIV

The following substances may be included in Annex XIV in accordance with the procedure laid down in Article 58:

(a) substances meeting the criteria for classification as carcinogenic category 1 or 2 in accordance with Directive 67/548/EEC;

(b) substances meeting the criteria for classification as mutagenic category 1 or 2 in accordance with Directive 67/548/EEC;

(c) substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EEC;

(d) substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII of this Regulation;

(e) substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII of this Regulation;

(f) substances — such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) — for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a) to (e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.

Article 58

Inclusion of substances in Annex XIV

1 Whenever a decision is taken to include in Annex XIV substances referred to in Article 57, such a decision shall be taken in accordance with the procedure referred to in Article 133(4). It shall specify for each substance:

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

b the intrinsic property (properties) of the substance referred to in Article 57;

c transitional arrangements:

(i) the date(s) from which the placing on the market and the use of the substance shall be prohibited unless an authorisation is granted (hereinafter referred to as the sunset date) which should take into account, where appropriate, the production cycle specified for that use;

(ii) a date or dates at least 18 months before the sunset date(s) by which applications must be received if the applicant wishes to continue to use the substance or place it on the market for certain uses after the sunset date(s); these continued uses shall be allowed after the sunset date until a decision on the application for authorisation is taken;

d review periods for certain uses, if appropriate;

e uses or categories of uses exempted from the authorisation requirement, if any, and conditions for such exemptions, if any.

2 Uses or categories of uses may be exempted from the authorisation requirement provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled. In the establishment of such exemptions, account shall be taken, in particular, of the proportionality of risk to human health and the environment related to the nature of the substance, such as where the risk is modified by the physical form.

3 Prior to a decision to include substances in Annex XIV, the Agency shall, taking into account the opinion of the Member State Committee, recommend priority substances to be included specifying for each substance the items set out in paragraph 1. Priority shall normally be given to substances with:

a PBT or vPvB properties; or

b wide dispersive use; or

c high volumes.

The number of substances included in Annex XIV and the dates specified under paragraph 1 shall also take account of the Agency's capacity to handle applications in the time provided for. The Agency shall make its first recommendation of priority substances to be included in Annex XIV by 1 June 2009. The Agency shall make further recommendations at least every second year with a view to including further substances in Annex XIV.

4 Before the Agency sends its recommendation to the Commission it shall make it publicly available on its website, clearly indicating the date of publication, taking into account Articles 118 and 119 on access to information. The Agency shall invite all interested parties to submit comments within three months of the date of publication, in particular on uses which should be exempt from the authorisation requirement.

The Agency shall update its recommendation, taking into account the comments received.

5 Subject to paragraph 6, after inclusion of a substance in Annex XIV, this substance shall not be subjected to new restrictions under the procedure outlined in Title VIII covering the risks to human health or the environment from the use of the substance on its own, in a **[**[F1]mixture**]** or incorporation of a substance in an article arising from the intrinsic properties specified in Annex XIV.

6 A substance listed in Annex XIV may be subjected to new restrictions under the procedure outlined in Title VIII covering the risks to human health or the environment from the presence of the substance in (an) article(s).

7 Substances for which all uses have been prohibited under Title VIII or by other Community legislation shall not be included in Annex XIV or shall be removed from it.

8 Substances which as a result of new information no longer meet the criteria of Article 57 shall be removed from Annex XIV in accordance with the procedure referred to in Article 133(4).

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 59

Identification of substances referred to in Article 57

1 The procedure set out in paragraphs 2 to 10 of this Article shall apply for the purpose of identifying substances meeting the criteria referred to in Article 57 and establishing a candidate list for eventual inclusion in Annex XIV. The Agency shall indicate, within this list, the substances that are on its work programme according to Article 83(3)(e).

2 The Commission may ask the Agency to prepare a dossier in accordance with relevant Sections of Annex XV for substances which in its opinion meet the criteria set out in Article 57.

[[F1]The dossier may be limited, if appropriate, to a reference to an entry in Part 3 of Annex VI to Regulation (EC) No 1272/2008.**]** The Agency shall make this dossier available to the Member States.

3 Any Member State may prepare a dossier in accordance with Annex XV for substances which in its opinion meet the criteria set out in Article 57 and forward it to the Agency. **[**[F1]The dossier may be limited, if appropriate, to a reference to an entry in Part 3 of Annex VI to Regulation (EC) No 1272/2008.**]** The Agency shall make this dossier available within 30 days of receipt to the other Member States.

4 The Agency shall publish on its website a notice that an Annex XV dossier has been prepared for a substance. The Agency shall invite all interested parties to submit comments within a specified deadline to the Agency.

5 Within 60 days of circulation, the other Member States or the Agency may comment on the identification of the substance in relation to the criteria in Article 57 in the dossier to the Agency.

6 If the Agency does not receive or make any comments, it shall include this substance on the list referred to in paragraph 1. The Agency may include this substance in its recommendations under Article 58(3).

7 When comments are made or received, the Agency shall refer the dossier to the Member State Committee within 15 days of the end of the 60-day period referred to in paragraph 5.

8 If, within 30 days of the referral, the Member State Committee reaches a unanimous agreement on the identification, the Agency shall include the substance in the list referred to in paragraph 1. The Agency may include that substance in its recommendations under Article 58(3).

9 If the Member State Committee fails to reach a unanimous agreement, the Commission shall prepare a draft proposal on the identification of the substance within three months of receipt of the opinion of the Member State Committee. A final decision on the identification of the substance shall be taken in accordance with the procedure referred to in Article 133(3).

10 The Agency shall publish and update the list referred to in paragraph 1 on its website without delay after a decision on inclusion of a substance has been taken.**]**

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).

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).

(1) **[**[X1]OJ L 350, 28.12.1998, p. 58. Directive as amended by Regulation (EC) No 1882/2003.**]**

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 20/01/2009.

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.