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 XV

TRANSITIONAL AND FINAL PROVISIONS

Article 128

Free movement

1 Subject to paragraph 2, Member States shall not prohibit, restrict or impede the manufacturing, import, placing on the market or use of a substance, on its own, in a **[**F1mixture**]** or in an article, falling within the scope of this Regulation, which complies with this Regulation and, where appropriate, with Community acts adopted in implementation of this Regulation.

2 Nothing in this Regulation shall prevent Member States from maintaining or laying down national rules to protect workers, human health and the environment applying in cases where this Regulation does not harmonise the requirements on manufacture, placing on the market or use.

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 129

Safeguard clause

1 Where a Member State has justifiable grounds for believing that urgent action is essential to protect human health or the environment in respect of a substance, on its own, in a **[**F1mixture**]** or in an article, even if satisfying the requirements of this Regulation, it may take appropriate provisional measures. The Member State shall immediately inform the Commission, the Agency and the other Member States thereof, giving reasons for its decision and submitting the scientific or technical information on which the provisional measure is based.

2 The Commission shall take a decision in accordance with the procedure referred to in Article 133(3) within 60 days of receipt of the information from the Member State. This decision shall either:

a authorise the provisional measure for a time period defined in the decision; or

b require the Member State to revoke the provisional measure.

3 If, in the case of a decision as referred to in paragraph 2(a), the provisional measure taken by the Member State consists in a restriction on the placing on the market or use of a substance, the Member State concerned shall initiate a Community restrictions procedure by submitting to the Agency a dossier, in accordance with Annex XV, within three months of the date of the Commission decision.

4 In the case of a decision as referred to in paragraph 2(a), the Commission shall consider whether this Regulation needs to be adapted.

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 130

Statement of reasons for decisions

The competent authorities, the Agency and the Commission shall state the reasons for all decisions they take under this Regulation.

Article 131

Amendments to the Annexes

The Annexes may be amended in accordance with the procedure referred to in Article 133(4).

Article 132

Implementing legislation

The measures necessary to put the provisions of this Regulation efficiently into effect shall be adopted in accordance with the procedure referred to in Article 133(3).

Article 133

Committee procedure

1 The Commission shall be assisted by a Committee.

2 Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

3 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

4 Where reference is made to this paragraph, Article 5a(1) to (4), and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

5 The Committee shall adopt its Rules of Procedure.

Article 134

Preparation of establishment of the Agency

1 The Commission shall afford the necessary support towards the establishment of the Agency.

2 For that purpose, until such time as the Executive Director takes up his duties following his appointment by the Management Board of the Agency in accordance with Article 84, the Commission, on behalf of the Agency, and using the budget provided for the latter, may:

a appoint personnel, including a person who shall fulfil the administrative functions of the Executive Director on an interim basis; and

b conclude other contracts.

Article 135

Transitional measures regarding notified substances

1 The requests to notifiers to provide further information to the competent authority in accordance with Article 16(2) of Directive 67/548/EEC, shall be considered as decisions adopted in accordance with Article 51 of this Regulation.

2 The requests to a notifier to provide further information for a substance in accordance with Article 16(1) of Directive 67/548/EEC, shall be considered as decisions adopted in accordance with Article 52 of this Regulation.

Such substance shall be regarded as being included in the Community rolling action plan in accordance with Article 44(2) of this Regulation and shall be regarded as being chosen in accordance with Article 45(2) of this Regulation by the Member State whose competent authority has requested further information in accordance with Article 7(2) and Article 16(1) of Directive 67/548/EEC.

Article 136

Transitional measures regarding existing substances

1 The requests to manufacturers and importers to submit information to the Commission made by a Commission Regulation in application of Article 10(2) of Regulation (EEC) No 793/93, shall be considered as decisions adopted in accordance with Article 52 of this Regulation.

The competent authority for the substance shall be the competent authority from the Member State identified as rapporteur in accordance with Article 10(1) of Regulation (EEC) No 793/93 and shall carry out the tasks of Article 46(3) and Article 48 of this Regulation.

2 The requests to manufacturers and importers to submit information to the Commission made by a Commission Regulation in application of Article 12(2) of Regulation (EEC) No 793/93, shall be considered as decisions adopted in accordance with Article 52 of this Regulation. The Agency shall identify the competent authority for the substance to carry out the tasks of Article 46(3) and Article 48 of this Regulation.

3 A Member State whose rapporteur has not forwarded by 1 June 2008 the risk evaluation and, where appropriate, the strategy for limiting the risks, in accordance with Article 10(3) of Regulation (EEC) No 793/93, shall:

a document information on hazard and risk in accordance with Annex XV, Part B of this Regulation;

b apply Article 69(4) of this Regulation on the basis of the information referred to in point (a); and

c prepare a documentation of how it considers that any other risks identified would need to be addressed by action other than an amendment of Annex XVII of this Regulation.

The information referred to above shall be submitted to the Agency by 1 December 2008.

Article 137

Transitional measures regarding restrictions

1 By 1 June 2010, the Commission shall, if necessary, prepare a draft amendment to Annex XVII in accordance with either of the following:

a any risk evaluation and recommended strategy for limiting risks that has been adopted at Community level in accordance with Article 11 of Regulation (EEC) No 793/93 as far as it includes proposals for restrictions in accordance with Title VIII of this Regulation but for which a decision under Directive 76/769/EEC has not yet been taken;

b any proposal, which has been submitted to the relevant institutions but has not yet been adopted, concerning the introduction or the amendment of restrictions under Directive 76/769/EEC.

2 Until 1 June 2010, any dossier referred to in Article 129(3) shall be submitted to the Commission. The Commission shall, if necessary, prepare a draft amendment to Annex XVII.

3 Any amendment to the restrictions adopted under Directive 76/769/EEC from 1 June 2007 shall be incorporated in Annex XVII with effect from 1 June 2009.

Article 138

Review

1 By 1 June 2019, the Commission shall carry out a review to assess whether or not to extend the application of the obligation to perform a chemical safety assessment and to document it in a chemical safety report to substances not covered by this obligation because they are not subject to registration or subject to registration but manufactured or imported in quantities of less than 10 tonnes per year. However, for substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction, category 1 or 2, in accordance with Directive 67/548/EEC, the review shall be carried out by 1 June 2014. When carrying out the review the Commission shall take into account all relevant factors, including:

a the costs for manufacturers and importers of drawing up the chemical safety reports;

b the distribution of costs between actors in the supply chain and the downstream user;

c the benefits for human health and the environment.

On the basis of these reviews, the Commission may, if appropriate, present legislative proposals to extend this obligation.

2 The Commission may present legislative proposals as soon as a practicable and cost-efficient way of selecting polymers for registration on the basis of sound technical and valid scientific criteria can be established, and after publishing a report on the following:

a the risks posed by polymers in comparison with other substances;

b the need, if any, to register certain types of polymer, taking account of competitiveness and innovation on the one hand and the protection of human health and the environment on the other.

3 The report, referred to in Article 117(4), on the experience acquired with the operation of this Regulation shall include a review of the requirements relating to registration of substances manufactured or imported only in quantities starting at one tonne but less than 10 tonnes per year per manufacturer or importer. On the basis of that review, the Commission may present legislative proposals to modify the information requirements for substances manufactured or imported in quantities of one tonne or more up to 10 tonnes per year per manufacturer or importer, taking into account the latest developments, for example in relation to alternative testing and (quantitative) structure-activity relationships ((Q)SARs).

4 The Commission shall carry out a review of Annexes I, IV and V by 1 June 2008, with a view to proposing amendments, if appropriate, to them in accordance with the procedure referred to in Article 131.

5 The Commission shall carry out a review of Annex XIII by 1 December 2008, to assess the adequacy of the criteria for identifying substances which are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative, with a view to proposing an amendment to it, if appropriate, in accordance with the procedure referred to in Article 133(4).

6 By 1 June 2012 the Commission shall carry out a review to assess whether or not to amend the scope of this Regulation to avoid overlaps with other relevant Community provisions. On the basis of that review, the Commission may, if appropriate, present a legislative proposal.

7 By 1 June 2013 the Commission shall carry out a review to assess whether or not, taking into account latest developments in scientific knowledge, to extend the scope of Article 60(3) to substances identified under Article 57(f) as having endocrine disrupting properties. On the basis of that review the Commission may, if appropriate, present legislative proposals.

8 By 1 June 2019, the Commission shall carry out a review to assess whether or not to extend the scope of Article 33 to cover other dangerous substances, taking into account the practical experience in implementing that Article. On the basis of that review, the Commission may, if appropriate, present legislative proposals to extend that obligation.

9 In accordance with the objective of promoting non-animal testing and the replacement, reduction or refinement of animal testing required under this Regulation, the Commission shall review the testing requirements of Section 8.7 of Annex VIII by 1 June 2019. On the basis of this review, while ensuring a high level of protection of health and the environment, the Commission may propose an amendment in accordance with the procedure referred to in Article 133(4).

Article 139

Repeals

Directive 91/155/EEC shall be repealed.

Directives 93/105/EC and 2000/21/EC and Regulations (EEC) No 793/93 and (EC) No 1488/94 shall be repealed with effect from 1 June 2008.

Directive 93/67/EEC shall be repealed with effect from 1 August 2008.

Directive 76/769/EEC shall be repealed with effect from 1 June 2009.

References to the repealed acts shall be construed as references to this Regulation.

Article 140

Amendment of Directive 1999/45/EC

Article 14 of Directive 1999/45/EC shall be deleted.

Article 141

Entry into force and application

1 This Regulation shall enter into force on 1 June 2007.

2 Titles II, III, V, VI, VII, XI and XII as well as Articles 128 and 136 shall apply from 1 June 2008.

3 Article 135 shall apply from 1 August 2008.

4 Title VIII and Annex XVII shall apply from 1 June 2009.**]**

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, TITLE XV.