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 I

GENERAL ISSUES

[X1CHAPTER 1

Aim, scope and application

Article 1

Aim and scope

1 The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.

2 This Regulation lays down provisions on substances and **[**F1mixtures**]** within the meaning of Article 3. These provisions shall apply to the manufacture, placing on the market or use of such substances on their own, in **[**F1mixtures**]** or in articles and to the placing on the market of **[**F1mixtures**]**.

3 This Regulation is based on the principle that it is for manufacturers, importers and downstream users to ensure that they manufacture, place on the market or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.

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 2

Application

1 This Regulation shall not apply to:

a radioactive substances within the scope of Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation[(1)];

b substances, on their own, in a **[**[F1]mixture**]** or in an article, which are subject to customs supervision, provided that they do not undergo any treatment or processing, and which are in temporary storage, or in a free zone or free warehouse with a view to re-exportation, or in transit;

c non-isolated intermediates;

d the carriage of dangerous substances and dangerous substances in dangerous **[**[F1]mixtures**]** by rail, road, inland waterway, sea or air.

2 Waste as defined in Directive 2006/12/EC of the European Parliament and of the Council[(2)] is not a substance, **[**[F1]mixture**]** or article within the meaning of Article 3 of this Regulation.

3 Member States may allow for exemptions from this Regulation in specific cases for certain substances, on their own, in a **[**[F1]mixture**]** or in an article, where necessary in the interests of defence.

4 This Regulation shall apply without prejudice to:

a Community workplace and environmental legislation, including Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work[(3)], Council Directive 96/61/EC of 24 September 1996 concerning integrated pollution prevention and control[(4)]; Directive 98/24/EC, Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy[(5)] and Directive 2004/37/EC;

b Directive 76/768/EEC as regards testing involving vertebrate animals within the scope of that Directive.

5 The provisions of Titles II, V, VI and VII shall not apply to the extent that a substance is used:

a in medicinal products for human or veterinary use within the scope of Regulation (EC) No 726/2004, Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products[(6)] and Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[(7)];

b in food or feedingstuffs in accordance with Regulation (EC) No 178/2002 including use:

(i) as a food additive in foodstuffs within the scope of Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption[(8)];

(ii) as a flavouring in foodstuffs within the scope of Council Directive 88/388/EEC of 22 June 1988 on the approximation of the laws of the Member States relating to flavourings for use in foodstuffs and to source materials for their production[(9)] and Commission Decision 1999/217/EC of 23 February 1999 adopting a register of flavouring substances used in or on foodstuffs drawn up in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council[(10)];

(iii) as an additive in feedingstuffs within the scope of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[(11)];

(iv) in animal nutrition within the scope of Council Directive 82/471/EEC of 30 June 1982 concerning certain products used in animal nutrition[(12)].

6 The provisions of Title IV shall not apply to the following **[**[F1]mixtures**]** in the finished state, intended for the final user:

a medicinal products for human or veterinary use, within the scope of Regulation (EC) No 726/2004 and Directive 2001/82/EC and as defined in Directive 2001/83/EC;

b cosmetic products as defined in Directive 76/768/EEC;

c medical devices which are invasive or used in direct physical contact with the human body in so far as Community measures lay down provisions for the classification and labelling of dangerous substances and **[**[F1]mixtures**]** which ensure the same level of information provision and protection as Directive 1999/45/EC;

d food or feedingstuffs in accordance with Regulation (EC) No 178/2002 including use:

(i) as a food additive in foodstuffs within the scope of Directive 89/107/EEC;

(ii) as a flavouring in foodstuffs within the scope of Directive 88/388/EEC and Decision 1999/217/EC;

(iii) as an additive in feedingstuffs within the scope of Regulation (EC) No 1831/2003;

(iv) in animal nutrition within the scope of Directive 82/471/EEC.

7 The following shall be exempted from Titles II, V and VI:

a substances included in Annex IV, as sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties;

b substances covered by Annex V, as registration is deemed inappropriate or unnecessary for these substances and their exemption from these Titles does not prejudice the objectives of this Regulation;

c substances on their own or in **[**[F1]mixtures**]**, registered in accordance with Title II, exported from the Community by an actor in the supply chain and re-imported into the Community by the same or another actor in the same supply chain who shows that:

(i) the substance being re-imported is the same as the exported substance;

(ii) he has been provided with the information in accordance with Articles 31 or 32 relating to the exported substance;

d substances, on their own, in **[**[F1]mixtures**]** or in articles, which have been registered in accordance with Title II and which are recovered in the Community if:

(i) the substance that results from the recovery process is the same as the substance that has been registered in accordance with Title II; and

(ii) the information required by Articles 31 or 32 relating to the substance that has been registered in accordance with Title II is available to the establishment undertaking the recovery.

8 On-site isolated intermediates and transported isolated intermediates shall be exempted from:

a Chapter 1 of Title II, with the exception of Articles 8 and 9; and
b Title VII.

9 The provisions of Titles II and VI shall not apply to polymers.**]**

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 159, 29.6.1996, p. 1.**]**

(2) **[**[X1]OJ L 114, 27.4.2006, p. 9.**]**

(3) **[**[X1]OJ L 183, 29.6.1989, p. 1. Directive as amended by Regulation (EC) No 1882/2003.**]**

(4) **[**[X1]OJ L 257, 10.10.1996, p. 26. Directive as last amended by Regulation (EC) No 166/2006 of the European Parliament and of the Council (OJ L 33, 4.2.2006, p. 1).**]**

(5) **[**[X1]OJ L 327, 22.12.2000, p. 1. Directive as amended by Decision No 2455/2001/EC (OJ L 331, 15.12.2001, p. 1).**]**

(6) **[**[X1]OJ L 311, 28.11.2001, p. 1. Directive as last amended by Directive 2004/28/EC (OJ L 136, 30.4.2004, p. 58).**]**

(7) **[**[X1]OJ L 311, 28.11.2001, p. 67. Directive as last amended by Regulation (EC) No 1901/2006.**]**

(8) **[**[X1]OJ L 40, 11.2.1989, p. 27. Directive as last amended by Regulation (EC) No 1882/2003.**]**

(9) **[**[X1]OJ L 184, 15.7.1988, p. 61. Directive as last amended by Regulation (EC) No 1882/2003.**]**

(10) **[**[X1]OJ L 84, 27.3.1999, p. 1. Decision as last amended by Decision 2006/253/EC (OJ L 91, 29.3.2006, p. 48).**]**

(11) **[**[X1]OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).**]**

(12) **[**[X1]OJ L 213, 21.7.1982, p. 8. Directive as last amended by Commission Directive 2004/116/EC (OJ L 379, 24.12.2004, p. 81).**]**

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.