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 XII

INFORMATION

Article 117

Reporting

1 Every five years, Member States shall submit to the Commission a report on the operation of this Regulation in their respective territories, including sections on evaluation and enforcement as described in Article 127.

The first report shall be submitted by 1 June 2010.

2 Every five years, the Agency shall submit to the Commission a report on the operation of this Regulation. The Agency shall include in its report information on the joint submission of information in accordance with Article 11 and an overview of the explanations given for submitting information separately.

The first report shall be submitted by 1 June 2011.

3 Every three years the Agency, in accordance with the objective of promoting non-animal testing methods, shall submit to the Commission a report on the status of implementation and use of non-animal test methods and testing strategies used to generate information on intrinsic properties and for risk assessment to meet the requirements of this Regulation.

The first report shall be submitted by 1 June 2011.

4 Every five years, the Commission shall publish a general report on:

a the experience acquired with the operation of this Regulation, including the information referred to in paragraphs 1, 2 and 3 and;

b the amount and distribution of funding made available by the Commission for the development and evaluation of alternative test methods.

The first report shall be published by 1 June 2012.

Article 118

Access to information

1 Regulation (EC) No 1049/2001 shall apply to documents held by the Agency.

2 Disclosure of the following information shall normally be deemed to undermine the protection of the commercial interests of the concerned person:

a details of the full composition of a preparation;

b without prejudice to Article 7(6) and Article 64(2), the precise use, function or application of a substance or preparation, including information about its precise use as an intermediate;

c the precise tonnage of the substance or preparation manufactured or placed on the market;

d links between a manufacturer or importer and his distributors or downstream users.

Where urgent action is essential to protect human health, safety or the environment, such as emergency situations, the Agency may disclose the information referred to in this paragraph.

3 The Management Board shall adopt the practical arrangements for implementing Regulation (EC) No 1049/2001, including appeals or remedies necessary for reviewing a partial or full rejection of a confidentiality request, by 1 June 2008.

4 Decisions taken by the Agency pursuant to Article 8 of Regulation (EC) No 1049/2001 may form the subject of a complaint to the Ombudsman or of an action before the Court of Justice, under the conditions laid down in Articles 195 and 230 of the Treaty respectively.

Article 119

Electronic public access

1 The following information held by the Agency on substances whether on their own, in preparations or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 77(2)(e):

a the name in the IUPAC Nomenclature, for dangerous substances within the meaning of Directive 67/548/EEC, without prejudice to paragraph 2(f) and (g);

b if applicable, the name of the substance as given in EINECS;

c the classification and labelling of the substance;

d physicochemical data concerning the substance and on pathways and environmental fate;

e the result of each toxicological and ecotoxicological study;

f any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC) established in accordance with Annex I;

g the guidance on safe use provided in accordance with Sections 4 and 5 of Annex VI;

h analytical methods if requested in accordance with Annexes IX or X which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.

2 The following information on substances whether on their own, in preparations or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 77(2)(e) except where a party submitting the information submits a justification in accordance with Article 10(a)(xi), accepted as valid by the Agency, as to why such publication is potentially harmful for the commercial interests of the registrant or any other party concerned:

a if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous;

b the total tonnage band (i.e. 1 to 10 tonnes, 10 to 100 tonnes, 100 to 1 000 tonnes or over 1 000 tonnes) within which a particular substance has been registered;

c the study summaries or robust study summaries of the information referred to in paragraph 1(d) and (e);

d information, other than that listed in paragraph 1, contained in the safety data sheet;

e the trade name(s) of the substance;

f the name in the IUPAC Nomenclature for non-phase-in substances which are dangerous within the meaning of Directive 67/548/EEC for a period of six years;

g the name in the IUPAC Nomenclature for dangerous substances within the meaning of Directive 67/548/EEC that are only used as one or more of the following:

(i) as an intermediate;

(ii) in scientific research and development;

(iii) in product and process orientated research and development.

Article 120

Cooperation with third countries and international organisations

Notwithstanding Articles 118 and 119, information received by the Agency under this Regulation may be disclosed to any government or national authority of a third country or an international organisation in accordance with an agreement concluded between the Community and the third party concerned under Regulation (EC) No 304/2003 of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals[1] or under Article 181a(3) of the Treaty, provided that both the following conditions are met:

(a) the purpose of the agreement is cooperation on the implementation or management of legislation concerning chemicals covered by this Regulation;

(b) the third party protects the confidential information as mutually agreed.**]**

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 63, 6.3.2003, p. 1. Regulation as last amended by Commission Regulation (EC) No 777/2006 (OJ L 136, 24.5.2006, p. 9).**]**

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 XII.