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

CHAPTER 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).

CHAPTER 2

Definitions and general provision

Article 3

Definitions

For the purposes of this Regulation:

1. substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

2. **[**[F1]mixture**]**: means a mixture or solution composed of two or more substances;

3. article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

4. producer of an article: means any natural or legal person who makes or assembles an article within the Community;

5. polymer: means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:

   (a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;

   (b) less than a simple weight majority of molecules of the same molecular weight.

   In the context of this definition a ‘monomer unit’ means the reacted form of a monomer substance in a polymer;

6. monomer: means a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process;

7. registrant: means the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance;

8. manufacturing: means production or extraction of substances in the natural state;

9. manufacturer: means any natural or legal person established within the Community who manufactures a substance within the Community;

10. import: means the physical introduction into the customs territory of the Community;

11. importer: means any natural or legal person established within the Community who is responsible for import;

12. placing on the market: means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market;

13. downstream user: means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a **[**F1mixture**]**, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user;

14. distributor: means any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a **[**F1mixture**]**, for third parties;

15. intermediate: means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as synthesis):

    (a) non-isolated intermediate: means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipework for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture;

    (b) on-site isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities;

    (c) transported isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites;

16. site: means a single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared;

17. actors in the supply chain: means all manufacturers and/or importers and/or downstream users in a supply chain;

18. Agency: means the European Chemicals Agency as established by this Regulation;

19. competent authority: means the authority or authorities or bodies established by the Member States to carry out the obligations arising from this Regulation;

20. phase-in substance: means a substance which meets at least one of the following criteria:

    (a) it is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS);

    (b) **[**F2it was manufactured in the Community, or in the countries acceding to the European Union on 1 January 1995, on 1 May 2004, on 1 January 2007 or on 1 July 2013, but not placed on the market by the manufacturer or importer, at least once in the 15 years before the entry into force of this Regulation, provided the manufacturer or importer has documentary evidence of this;

    (c) it was placed on the market in the Community, or in the countries acceding to the European Union on 1 January 1995, on 1 May 2004, on 1 January 2007 or on 1 July 2013, by the manufacturer or importer before the entry into force of this Regulation and it was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC in the version of Article 8(1) resulting from the amendment effected by Directive 79/831/EEC, but it does not meet the definition of a polymer as set out in this Regulation, provided the manufacturer or importer has documentary evidence of this, including proof that the substance was placed on the market by any manufacturer or importer between 18 September 1981 and 31 October 1993 inclusive;**]**

21. notified substance: means a substance for which a notification has been submitted and which could be placed on the market in accordance with Directive 67/548/EEC;

22. product and process orientated research and development: means any scientific development related to product development or the further development of a substance, on its own, in **[**F1mixtures**]** or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance;

23. scientific research and development: means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than one tonne per year;

24. use: means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;

25. registrant's own use: means an industrial or professional use by the registrant;

26. identified use: means a use of a substance on its own or in a **[**F1mixture**]**, or a use of a **[**F1mixture**]**, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user;

27. full study report: means a complete and comprehensive description of the activity performed to generate the information. This covers the complete scientific paper as

published in the literature describing the study performed or the full report prepared by the test house describing the study performed;

28. robust study summary: means a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report;

29. study summary: means a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study;

30. per year: means per calendar year, unless stated otherwise, for phase-in substances that have been imported or manufactured for at least three consecutive years, quantities per year shall be calculated on the basis of the average production or import volumes for the three preceding calendar years;

31. restriction: means any condition for or prohibition of the manufacture, use or placing on the market;

32. supplier of a substance or a **[**[F1]mixture**]**: means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a **[**[F1]mixture**]**, or a **[**[F1]mixture**]**;

33. supplier of an article: means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market;

34. recipient of a substance or a **[**[F1]mixture**]**: means a downstream user or a distributor being supplied with a substance or a **[**[F1]mixture**]**;

35. recipient of an article: means an industrial or professional user, or a distributor, being supplied with an article but does not include consumers;

36. SME: means small and medium-sized enterprises as defined in the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises[(13)];

37. exposure scenario: means the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate;

38. use and exposure category: means an exposure scenario covering a wide range of processes or uses, where the processes or uses are communicated, as a minimum, in terms of the brief general description of use;

39. substances which occur in nature: means a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means;

40. not chemically modified substance: means a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities;

41. alloy: means a metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means.

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).

F2 Substituted by Council Regulation (EU) No 517/2013 of 13 May 2013 adapting certain regulations and decisions in the fields of free movement of goods, freedom of movement for persons, company law, competition policy, agriculture, food safety, veterinary and phytosanitary policy, transport policy, energy, taxation, statistics, trans-European networks, judiciary and fundamental rights, justice, freedom and security, environment, customs union, external relations, foreign, security and defence policy and institutions, by reason of the accession of the Republic of Croatia.

Article 4

General provision

Any manufacturer, importer, or where relevant downstream user, may, whilst retaining full responsibility for complying with his obligations under this Regulation, appoint a third party representative for all proceedings under Article 11, Article 19, Title III and Article 53 involving discussions with other manufacturers, importers, or where relevant downstream users. In these cases, the identity of a manufacturer or importer or downstream user who has appointed a representative shall not normally be disclosed by the Agency to other manufacturers, importers, or, where relevant, downstream users.**]**

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).**]**

(13) **[**[X1]OJ L 124, 20.5.2003, p. 36.**]**

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 31/01/2020.

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 I.