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 II

REGISTRATION OF SUBSTANCES

CHAPTER 1

General obligation to register and information requirements

Article 5

No data, no market

Subject to Articles 6, 7, 21 and 23, substances on their own, in **[**F1mixtures**]** or in articles shall not be manufactured in the Community or placed on the market unless they have been registered in accordance with the relevant provisions of this Title where this is required.

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 6

General obligation to register substances on their own or in [F1mixtures]

1 Save where this Regulation provides otherwise, any manufacturer or importer of a substance, either on its own or in one or more **[**F1mixture**]** (s), in quantities of one tonne or more per year shall submit a registration to the Agency.

2 For monomers that are used as on-site isolated intermediates or transported isolated intermediates, Articles 17 and 18 shall not apply.

3 Any manufacturer or importer of a polymer shall submit a registration to the Agency for the monomer substance(s) or any other substance(s), that have not already been registered by an actor up the supply chain, if both the following conditions are met:

a the polymer consists of 2 % weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);

b the total quantity of such monomer substance(s) or other substance(s) makes up one tonne or more per year.

4 A submission for registration shall be accompanied by the fee required in accordance with Title IX.

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 7

Registration and notification of substances in articles

1 Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if both the following conditions are met:

a the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;

b the substance is intended to be released under normal or reasonably foreseeable conditions of use.

A submission for registration shall be accompanied by the fee required in accordance with Title IX.

2 Any producer or importer of articles shall notify the Agency, in accordance with paragraph 4 of this Article, if a substance meets the criteria in Article 57 and is identified in accordance with Article 59(1), if both the following conditions are met:

a the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;

b the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w).

3 Paragraph 2 shall not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions to the recipient of the article.

4 The information to be notified shall include the following:

a the identity and contact details of the producer or importer as specified in section 1 of Annex VI, with the exception of their own use sites;

b the registration number(s) referred to in Article 20(1), if available;

c the identity of the substance as specified in sections 2.1 to 2.3.4 of Annex VI;

d the classification of the substance(s) as specified in sections 4.1 and 4.2 of Annex VI;

e a brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article(s);

f the tonnage range of the substance(s), such as 1 to 10 tonnes, 10 to 100 tonnes and so on.

5 The Agency may take decisions requiring producers or importers of articles to submit a registration, in accordance with this Title, for any substance in those articles, if all the following conditions are met:

a the substance is present in those articles in quantities totalling over one tonne per producer or importer per year;

b the Agency has grounds for suspecting that:

(i) the substance is released from the articles, and

(ii) the release of the substance from the articles presents a risk to human health or the environment;

c the substance is not subject to paragraph 1.

A submission for registration shall be accompanied by the fee required in accordance with Title IX.

6 Paragraphs 1 to 5 shall not apply to substances that have already been registered for that use.

7 From 1 June 2011 paragraphs 2, 3 and 4 of this Article shall apply six months after a substance is identified in accordance with Article 59(1).

8 Any measures for the implementation of paragraphs 1 to 7 shall be adopted in accordance with the procedure referred to in Article 133(3).

Article 8

Only representative of a non-Community manufacturer

1 A natural or legal person established outside the Community who manufactures a substance on its own, in **[**F1mixtures**]** or in articles, formulates a **[**F1mixture**]** or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on importers under this Title.

2 The representative shall also comply with all other obligations of importers under this Regulation. To this end, he shall have a sufficient background in the practical handling of substances and the information related to them and, without prejudice to Article 36, shall keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet referred to in Article 31.

3 If a representative is appointed in accordance with paragraphs 1 and 2, the non-Community manufacturer shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Regulation.

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 9

Exemption from the general obligation to register for product and process orientated research and development (PPORD)

1 Articles 5, 6, 7, 17, 18 and 21 shall not apply for a period of five years to a substance manufactured in the Community or imported for the purposes of product and process orientated research and development by a manufacturer or importer or producer of articles, by himself or in cooperation with listed customers and in a quantity which is limited to the purpose of product and process orientated research and development.

2 For the purpose of paragraph 1, the manufacturer or importer or producer of articles shall notify the Agency of the following information:

a the identity of the manufacturer or importer or producer of articles as specified in section 1 of Annex VI;

b the identity of the substance, as specified in section 2 of Annex VI;

c the classification of the substance as specified in section 4 of Annex VI, if any;

d the estimated quantity as specified in section 3.1 of Annex VI;

e the list of customers referred to in paragraph 1, including their names and addresses.

The notification shall be accompanied by the fee required in accordance with Title IX.

The period set out in paragraph 1 shall begin at receipt of the notification at the Agency.

3 The Agency shall check the completeness of the information supplied by the notifier and Article 20(2) shall apply adapted as necessary. The Agency shall assign a number to the notification and a notification date, which shall be the date of receipt of the notification at the Agency, and shall forthwith communicate that number and date to the manufacturer, or importer, or producer of articles concerned. The Agency shall also communicate this information to the competent authority of the Member State(s) concerned.

4 The Agency may decide to impose conditions with the aim of ensuring that the substance or the **[**F1mixture**]** or article in which the substance is incorporated will be handled only by staff of listed customers as referred to in paragraph 2(e) in reasonably controlled conditions, in accordance with the requirements of legislation for the protection of workers and the environment, and will not be made available to the general public at any time either on its own or in a **[**F1mixture**]** or article and that remaining quantities will be re-collected for disposal after the exemption period.

In such cases, the Agency may ask the notifier to provide additional necessary information.

5 In the absence of any indication to the contrary, the manufacturer or importer of the substance or the producer or importer of articles may manufacture or import the substance or produce or import the articles not earlier than two weeks after the notification.

6 The manufacturer or importer or producer of articles shall comply with any conditions imposed by the Agency in accordance with paragraph 4.

7 The Agency may decide to extend the five-year exemption period by a further maximum of five years or, in the case of substances to be used exclusively in the development of medicinal products for human or veterinary use, or for substances that are not placed on the market, for a further maximum of ten years, upon request if the manufacturer or importer

or producer of articles can demonstrate that such an extension is justified by the research and development programme.

8 The Agency shall forthwith communicate any draft decisions to the competent authorities of each Member State in which the manufacture, import, production or product and process orientated research takes place.

When taking decisions as provided for in paragraphs 4 and 7, the Agency shall take into account any comments made by such competent authorities.

9 The Agency and the competent authorities of the Member States concerned shall always keep confidential the information submitted in accordance with paragraphs 1 to 8.

10 An appeal may be brought, in accordance with Articles 91, 92 and 93, against Agency decisions under paragraphs 4 and 7 of this Article.

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 10

Information to be submitted for general registration purposes

A registration required by Article 6 or by Article 7(1) or (5) shall include all the following information:

(a) a technical dossier including:

(i) the identity of the manufacturer(s) or importer(s) as specified in section 1 of Annex VI;

(ii) the identity of the substance as specified in section 2 of Annex VI;

(iii) information on the manufacture and use(s) of the substance as specified in section 3 of Annex VI; this information shall represent all the registrant's identified use(s). This information may include, if the registrant deems appropriate, the relevant use and exposure categories;

(iv) the classification and labelling of the substance as specified in section 4 of Annex VI;

(v) guidance on safe use of the substance as specified in Section 5 of Annex VI;

(vi) study summaries of the information derived from the application of Annexes VII to XI;

(vii) robust study summaries of the information derived from the application of Annexes VII to XI, if required under Annex I;

(viii) an indication as to which of the information submitted under (iii), (iv), (vi), (vii) or subparagraph (b) has been reviewed by an assessor chosen by the manufacturer or importer and having appropriate experience;

(ix) proposals for testing where listed in Annexes IX and X;

(x) for substances in quantities of 1 to 10 tonnes, exposure information as specified in section 6 of Annex VI;

(xi) a request as to which of the information in Article 119(2) the manufacturer or importer considers should not be made available on the Internet in accordance with Article 77(2)(e), including a justification as to why publication could be harmful for his or any other concerned party's commercial interests.

Except in cases covered under Article 25(3), Article 27(6) or Article 30(3), the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (vi) and (vii) for the purpose of registration;

(b) a chemical safety report when required under Article 14, in the format specified in Annex I. The relevant sections of this report may include, if the registrant considers appropriate, the relevant use and exposure categories.

Article 11

Joint submission of data by multiple registrants

1 When a substance is intended to be manufactured in the Community by one or more manufacturers and/or imported by one or more importers, and/or is subject to registration under Article 7, the following shall apply.

Subject to paragraph 3, the information specified in Article 10(a)(iv), (vi), (vii) and (ix), and any relevant indication under Article 10(a)(viii) shall first be submitted by the one registrant acting with the agreement of the other assenting registrant(s) (hereinafter referred to as the lead registrant).

Each registrant shall subsequently submit separately the information specified in Article 10(a)(i), (ii), (iii) and (x), and any relevant indication under Article 10(a)(viii).

The registrants may decide themselves whether to submit the information specified in Article 10(a)(v) and (b) and any relevant indication under Article 10(a)(viii) separately or whether one registrant is to submit this information on behalf of the others.

2 Each registrant need only comply with paragraph 1 for items of information specified in Article 10(a)(iv), (vi), (vii) and (ix) that are required for the purposes of registration within his tonnage band in accordance with Article 12.

3 A registrant may submit the information referred to in Article 10(a)(iv), (vi), (vii) or (ix) separately if:

a it would be disproportionately costly for him to submit this information jointly; or

b submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or

c he disagrees with the lead registrant on the selection of this information.

If points (a), (b) or (c) apply, the registrant shall submit, along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of

information was likely to lead to substantial commercial detriment or the nature of the disagreement, as the case may be.

4 A submission for registration shall be accompanied by the fee required in accordance with Title IX.

Article 12

Information to be submitted depending on tonnage

1 The technical dossier referred to in Article 10(a) shall include under points (vi) and (vii) of that provision all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant and as a minimum the following:

a the information specified in Annex VII for non-phase-in substances, and for phase-in substances meeting one or both of the criteria specified in Annex III, manufactured or imported in quantities of one tonne or more per year per manufacturer or importer;

b the information on physicochemical properties specified in Annex VII, section 7 for phase-in substances manufactured or imported in quantities of one tonne or more per year per manufacturer or importer which do not meet either of the criteria specified in Annex III;

c the information specified in Annexes VII and VIII for substances manufactured or imported in quantities of 10 tonnes or more per year per manufacturer or importer;

d the information specified in Annexes VII and VIII and testing proposals for the provision of the information specified in Annex IX for substances manufactured or imported in quantities of 100 tonnes or more per year per manufacturer or importer;

e the information specified in Annexes VII and VIII and testing proposals for the provision of the information specified in Annexes IX and X for substances manufactured or imported in quantities of 1 000 tonnes or more per year per manufacturer or importer.

2 As soon as the quantity of a substance per manufacturer or importer that has already been registered reaches the next tonnage threshold, the manufacturer or importer shall inform the Agency immediately of the additional information he would require under paragraph 1. Article 26(3) and (4) shall apply adapted as necessary.

3 This Article shall apply to producers of articles adapted as necessary.

Article 13

General requirements for generation of information on intrinsic properties of substances

1 Information on intrinsic properties of substances may be generated by means other than tests, provided that the conditions set out in Annex XI are met. In particular for human toxicity, information shall be generated whenever possible by means other than vertebrate animal tests, through the use of alternative methods, for example, *in vitro* methods or qualitative or quantitative structure-activity relationship models or from information from structurally related substances (grouping or read-across). Testing in accordance with Annex VIII, Sections 8.6 and 8.7, Annex IX and Annex X may be omitted where justified by information on exposure and implemented risk management measures as specified in Annex XI, section 3.

2 These methods shall be regularly reviewed and improved with a view to reducing testing on vertebrate animals and the number of animals involved. The Commission, following

consultation with relevant stakeholders, shall, as soon as possible, make a proposal, if appropriate, to amend the Commission Regulation on test methods adopted in accordance with the procedure referred to in Article 133(4), and the Annexes of this Regulation, if relevant, so as to replace, reduce or refine animal testing. Amendments to that Commission Regulation shall be adopted in accordance with the procedure specified in paragraph 3 and amendments to the Annexes of this Regulation shall be adopted in accordance with the procedure referred to in Article 131.

3 Where tests on substances are required to generate information on intrinsic properties of substances, they shall be conducted in accordance with the test methods laid down in a Commission Regulation or in accordance with other international test methods recognised by the Commission or the Agency as being appropriate. The Commission shall adopt that Regulation, designed to amend the non-essential elements of this Regulation by supplementing it, in accordance with the procedure referred to in Article 133(4).

Information on intrinsic properties of substances may be generated in accordance with other test methods provided that the conditions set out in Annex XI are met.

4 Ecotoxicological and toxicological tests and analyses shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable.

5 If a substance has already been registered, a new registrant shall be entitled to refer to the study summaries or robust study summaries, for the same substance submitted earlier, provided that he can show that the substance that he is now registering is the same as the one previously registered, including the degree of purity and the nature of impurities, and that the previous registrant(s) have given permission to refer to the full study reports for the purpose of registration.

A new registrant shall not refer to such studies in order to provide the information required in Section 2 of Annex VI.

Article 14

Chemical safety report and duty to apply and recommend risk reduction measures

1 Without prejudice to Article 4 of Directive 98/24/EC, a chemical safety assessment shall be performed and a chemical safety report completed for all substances subject to registration in accordance with this Chapter in quantities of 10 tonnes or more per year per registrant.

The chemical safety report shall document the chemical safety assessment which shall be conducted in accordance with paragraphs 2 to 7 and with Annex I for either each substance on its own or in a **[**[F1]mixture**]** or in an article or a group of substances.

[[F1]2 A chemical safety assessment in accordance with paragraph 1 need not be performed for a substance which is present in a mixture if the concentration of the substance in the mixture is less than:

a the cut-off value referred to in Article 11, paragraph 3 of Regulation (EC) No 1272/2008;

b 0,1 % weight by weight (w/w), if the substance meets the criteria in Annex XIII to this Regulation.**]**

3 A chemical safety assessment of a substance shall include the following steps:

a human health hazard assessment;

b physicochemical hazard assessment;

c environmental hazard assessment;

d persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) assessment.

[[F1]4 If, as a result of carrying out steps (a) to (d) of paragraph 3, the registrant concludes that the substance fulfils the criteria for any of the following hazard classes or categories set out in Annex I to Regulation (EC) No 1272/2008:

a hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F;

b hazard classes 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10;

c hazard class 4.1;

d hazard class 5.1,

or is assessed to be a PBT or vPvB, the chemical safety assessment shall include the following additional steps:**]**

a exposure assessment including the generation of exposure scenario(s) (or the identification of relevant use and exposure categories if appropriate) and exposure estimation;

b risk characterisation.

The exposure scenarios (where appropriate the use and exposure categories), exposure assessment and risk characterisation shall address all identified uses of the registrant.

5 The chemical safety report need not include consideration of the risks to human health from the following end uses:

a in food contact materials within the scope of Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food[(1)];

b in cosmetic products within the scope of Directive 76/768/EEC.

6 Any registrant shall identify and apply the appropriate measures to adequately control the risks identified in the chemical safety assessment, and where suitable, recommend them in the safety data sheets which he supplies in accordance with Article 31.

7 Any registrant required to conduct a chemical safety assessment shall keep his chemical safety report available and up to date.

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

Substances regarded as being registered

Article 15

Substances in plant protection and biocidal products

1 Active substances and co-formulants manufactured or imported for use in plant protection products only and included either in Annex I to Council Directive 91/414/EEC[(2)] or in Commission Regulation (EEC) No 3600/92[(3)], Commission Regulation (EC) No 703/2001[(4)], Commission Regulation (EC) No 1490/2002[(5)], or Commission Decision 2003/565/EC[(6)] and for any substance for which a Commission Decision on the completeness of the dossier has been taken pursuant to Article 6 of Directive 91/414/EEC shall be regarded as being registered and the registration as completed for manufacture or import for the use as a plant protection product and therefore as fulfilling the requirements of Chapters 1 and 5 of this Title.

2 Active substances manufactured or imported for use in biocidal products only and included either in Annexes I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market[(7)] or in Commission Regulation (EC) No 2032/2003[(8)] on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC, until the date of the decision referred to in the second subparagraph of Article 16(2) of Directive 98/8/EC, shall be regarded as being registered and the registration as completed for manufacture or import for the use in a biocidal product and therefore as fulfilling the requirements of Chapters 1 and 5 of this Title.

Article 16

Duties of the Commission, the Agency and registrants of substances regarded as being registered

1 The Commission or the relevant Community body shall make information equivalent to that required by Article 10 available to the Agency for substances regarded as registered according to Article 15. The Agency shall include this information or a reference thereto in its databases and notify the competent authorities thereof by 1 December 2008.

2 Articles 21, 22 and 25 to 28 shall not apply to uses of substances regarded as registered according to Article 15.

CHAPTER 3

Obligation to register and information requirements for certain types of isolated intermediates

Article 17

Registration of on-site isolated intermediates

1 Any manufacturer of an on-site isolated intermediate in quantities of one tonne or more per year shall submit a registration to the Agency for the on-site isolated intermediate.

2 A registration for an on-site isolated intermediate shall include all the following information, to the extent that the manufacturer is able to submit it without any additional testing:

a the identity of the manufacturer as specified in Section 1 of Annex VI;

b the identity of the intermediate as specified in Sections 2.1 to 2.3.4 of Annex VI;

c the classification of the intermediate as specified in Section 4 of Annex VI;

d any available existing information on physicochemical, human health or environmental properties of the intermediate. Where a full study report is available, a study summary shall be submitted;

e a brief general description of the use, as specified in Section 3.5 of Annex VI;

f details of the risk management measures applied.

Except in cases covered under Article 25(3), Article 27(6) or Article 30(3), the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (d) for the purpose of registration.

The registration shall be accompanied by the fee required in accordance with Title IX.

3 Paragraph 2 shall apply only to on-site isolated intermediates if the manufacturer confirms that the substance is only manufactured and used under strictly controlled conditions in that it is rigorously contained by technical means during its whole lifecycle. Control and procedural technologies shall be used to minimise emission and any resulting exposure.

If these conditions are not fulfilled, the registration shall include the information specified in Article 10.

Article 18

Registration of transported isolated intermediates

1 Any manufacturer or importer of a transported isolated intermediate in quantities of one tonne or more per year shall submit a registration to the Agency for the transported isolated intermediate.

2 A registration for a transported isolated intermediate shall include all the following information:

a the identity of the manufacturer or importer as specified in Section 1 of Annex VI;

b the identity of the intermediate as specified in Sections 2.1 to 2.3.4 of Annex VI;

c the classification of the intermediate as specified in Section 4 of Annex VI;

d any available existing information on physicochemical, human health or environmental properties of the intermediate. Where a full study report is available, a study summary shall be submitted;

e a brief general description of the use, as specified in Section 3.5 of Annex VI;

f information on risk management measures applied and recommended to the user in accordance with paragraph 4.

Except in cases covered under Article 25(3), Article 27(6) or Article 30(3), the registrant shall be in legitimate possession of or have permission to refer to the full study report summarised under (d) for the purpose of registration.

The registration shall be accompanied by the fee required in accordance with Title IX.

3 A registration for a transported isolated intermediate in quantities of more than 1 000 tonnes per year per manufacturer or importer shall include the information specified in Annex VII in addition to the information required under paragraph 2.

For the generation of this information, Article 13 shall apply.

4 Paragraphs 2 and 3 shall apply only to transported isolated intermediates if the manufacturer or importer confirms himself or states that he has received confirmation from the user that the synthesis of (an)other substance(s) from that intermediate takes place on other sites under the following strictly controlled conditions:

a the substance is rigorously contained by technical means during its whole lifecycle including manufacture, purification, cleaning and maintenance of equipment, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage;

b procedural and control technologies shall be used that minimise emission and any resulting exposure;

c only properly trained and authorised personnel handle the substance;

d in the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered;

e in cases of accident and where waste is generated, procedural and/or control technologies are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures;

f substance-handling procedures are well documented and strictly supervised by the site operator.

If the conditions listed in the first subparagraph are not fulfilled, the registration shall include the information specified in Article 10.

Article 19

Joint submission of data on isolated intermediates by multiple registrants

1 When an on-site isolated intermediate or transported isolated intermediate is intended to be manufactured in the Community by one or more manufacturers and/or imported by one or more importers, the following shall apply.

Subject to paragraph 2 of this Article, the information specified in Article 17(2)(c) and (d) and Article 18(2)(c) and (d) shall first be submitted by one manufacturer or importer acting with the agreement of the other assenting manufacturer(s) or importer(s) (hereinafter referred to as ‘the lead registrant’).

Each registrant shall subsequently submit separately the information specified in Article 17(2)(a), (b), (e) and (f) and Article 18(2)(a),(b), (e) and (f).

2 A manufacturer or importer may submit the information referred to in Article 17(2)(c) or (d) and Article 18(2)(c) or (d) separately if:

a it would be disproportionately costly for him to submit this jointly; or

b submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or

c he disagrees with the lead registrant on the selection of this information.

If points (a), (b) or (c) apply, the manufacturer or importer shall submit, along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment, or the nature of the disagreement, as the case may be.

3 A submission for registration shall be accompanied by the fee required in accordance with Title IX.

CHAPTER 4

Common provisions for all registrations

Article 20

Duties of the Agency

1 The Agency shall assign a submission number to each registration, which is to be used for all correspondence regarding the registration until the registration is deemed to be complete, and a submission date, which shall be the date of receipt of the registration at the Agency.

2 The Agency shall undertake a completeness check of each registration in order to ascertain that all the elements required under Articles 10 and 12 or under Articles 17 or 18, as well as the registration fee referred to in Article 6(4), Article 7(1) and (5), Article 17(2) or Article 18(2), have been provided. The completeness check shall not include an assessment of the quality or the adequacy of any data or justifications submitted.

The Agency shall undertake the completeness check within three weeks of the submission date, or within three months of the relevant deadline of Article 23, as regards registrations of phase-in substances submitted in the course of the two-month period immediately preceding that deadline.

If a registration is incomplete, the Agency shall inform the registrant, before expiry of the three-week or three-month period referred to in the second subparagraph, as to what further information is required in order for the registration to be complete, while setting a reasonable deadline for this. The registrant shall complete his registration and submit it to the Agency within the deadline set. The Agency shall confirm the submission date of the further information to the registrant. The Agency shall perform a further completeness check, considering the further information submitted.

The Agency shall reject the registration if the registrant fails to complete his registration within the deadline set. The registration fee shall not be reimbursed in such cases.

3 Once the registration is complete, the Agency shall assign a registration number to the substance concerned and a registration date, which shall be the same as the submission date. The Agency shall without delay communicate the registration number and registration date to the registrant concerned. The registration number shall be used for all subsequent correspondence regarding registration.

4 The Agency shall notify the competent authority of the relevant Member State within 30 days of the submission date, that the following information is available in the Agency database:

a the registration dossier together with the submission or registration number;

b the submission or registration date;

c the result of the completeness check; and

d any request for further information and deadline set in accordance with the third subparagraph of paragraph 2.

The relevant Member State shall be the Member State within which the manufacture takes place or the importer is established.

If the manufacturer has production sites in more than one Member State, the relevant Member State shall be the one in which the head office of the manufacturer is established. The other Member States where the production sites are established shall also be notified.

The Agency shall forthwith notify the competent authority of the relevant Member State(s) when any further information submitted by the registrant is available on the Agency database.

5 An appeal may be brought, in accordance with Articles 91, 92 and 93, against Agency decisions under paragraph 2 of this Article.

6 Where additional information for a particular substance is submitted to the Agency by a new registrant, the Agency shall notify the existing registrants that this information is available on the database for the purposes of Article 22.

Article 21

Manufacturing and import of substances

1 A registrant may start or continue the manufacture or import of a substance or production or import of an article, if there is no indication to the contrary from the Agency in accordance with Article 20(2) within the three weeks after the submission date, without prejudice to Article 27(8).

In the case of registrations of phase-in substances, such a registrant may continue the manufacture or import of the substance or production or import of an article, if there is no indication to the contrary from the Agency in accordance with Article 20(2) within the three weeks after the submission date or, if submitted within the two-month period before the relevant deadline of Article 23, if there is no indication to the contrary from the Agency in accordance with Article 20(2) within the three months from that deadline, without prejudice to Article 27(8).

In the case of an update of a registration according to Article 22 a registrant may continue the manufacture or import of the substance, or the production or import of the article, if there is no indication to the contrary from the Agency in accordance with Article 20(2) within the three weeks after the update date, without prejudice to Article 27(8).

2 If the Agency has informed the registrant that he is to submit further information in accordance with the third subparagraph of Article 20(2), the registrant may start the manufacture or import of a substance or production or import of an article if there is no indication to the contrary from the Agency within the three weeks after receipt by the Agency of the further information necessary to complete his registration, without prejudice to Article 27(8).

3 If a lead registrant submits parts of the registration on behalf of one or more other registrants, as provided for in Articles 11 or 19, any of the other registrants may manufacture or import the substance or produce or import the articles only after the expiry of the time-limit laid down in paragraph 1 or 2 of this Article and provided that there is no indication to the contrary

from the Agency in respect of the registration of the lead registrant acting on behalf of the others and his own registration.

Article 22

Further duties of registrants

1 Following registration, a registrant shall be responsible on his own initiative for updating his registration without undue delay with relevant new information and submitting it to the Agency in the following cases:

a any change in his status, such as being a manufacturer, an importer or a producer of articles, or in his identity, such as his name or address;

b any change in the composition of the substance as given in Section 2 of Annex VI;

c changes in the annual or total quantities manufactured or imported by him or in the quantities of substances present in articles produced or imported by him if these result in a change of tonnage band, including cessation of manufacture or import;

d new identified uses and new uses advised against as in Section 3.7 of Annex VI for which the substance is manufactured or imported;

e new knowledge of the risks of the substance to human health and/or the environment of which he may reasonably be expected to have become aware which leads to changes in the safety data sheet or the chemical safety report;

f any change in the classification and labelling of the substance;

g any update or amendment of the chemical safety report or Section 5 of Annex VI;

h the registrant identifies the need to perform a test listed in Annex IX or Annex X, in which cases a testing proposal shall be developed;

i any change in the access granted to information in the registration.

The Agency shall communicate this information to the competent authority of the relevant Member State.

2 A registrant shall submit to the Agency an update of the registration containing the information required by the decision made in accordance with Articles 40, 41 or 46 or take into account a decision made in accordance with Articles 60 and 73, within the deadline specified in that decision. The Agency shall notify the competent authority of the relevant Member State that the information is available on its database.

3 The Agency shall undertake a completeness check according to Article 20(2) first and second subparagraphs of each updated registration. In cases where the update is in accordance with Article 12(2) and with paragraph 1(c) of this Article then the Agency shall check the completeness of the information supplied by the registrant and Article 20(2) shall apply adapted as necessary.

4 In cases covered by Articles 11 or 19, each registrant shall submit separately the information specified in paragraph 1(c) of this Article.

5 An update shall be accompanied by the relevant part of the fee required in accordance with Title IX.

CHAPTER 5

Transitional provisions applicable to phase-in substances and notified substances

Article 23

Specific provisions for phase-in substances

1 Article 5, Article 6, Article 7(1), Article 17, Article 18 and Article 21 shall not apply until 1 December 2010 to the following substances:

a phase-in substances classified as carcinogenic, mutagenic or toxic to reproduction, category 1 or 2, in accordance with Directive 67/548/EEC and manufactured in the Community or imported, in quantities reaching one tonne or more per year per manufacturer or per importer, at least once after 1 June 2007;

b phase-in substances classified as very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment (R50/53) in accordance with Directive 67/548/EEC, and manufactured in the Community or imported in quantities reaching 100 tonnes or more per year per manufacturer or per importer, at least once after 1 June 2007;

c phase-in substances manufactured in the Community or imported, in quantities reaching 1 000 tonnes or more per year per manufacturer or per importer, at least once after 1 June 2007.

2 Article 5, Article 6, Article 7(1), Article 17, Article 18 and Article 21 shall not apply until 1 June 2013 to phase-in substances manufactured in the Community or imported, in quantities reaching 100 tonnes or more per year per manufacturer or per importer, at least once after 1 June 2007.

3 Article 5, Article 6, Article 7(1), Article 17, Article 18 and Article 21 shall not apply until 1 June 2018 to phase-in substances manufactured in the Community or imported, in quantities reaching one tonne or more per year per manufacturer or per importer, at least once after 1 June 2007.

4 Without prejudice to paragraphs 1 to 3, a registration can be submitted at any time before the relevant deadline.

5 This Article shall also apply to substances registered under Article 7 adapted as necessary.

Article 24

Notified substances

1 A notification in accordance with Directive 67/548/EEC shall be regarded as a registration for the purposes of this Title and the Agency shall assign a registration number by 1 December 2008.

2 If the quantity of a notified substance manufactured or imported per manufacturer or importer reaches the next tonnage threshold under Article 12, the additional required information corresponding to that tonnage threshold, as well as to all the lower tonnage thresholds, shall be submitted in accordance with Articles 10 and 12, unless it has already been submitted in accordance with those Articles.**]**

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 338, 13.11.2004, p. 4.**]**

(2) **[**[X1]Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1). Directive as last amended by Commission Directive 2006/136/EC (OJ L 349, 12.12.2006, p. 42).**]**

(3) **[**[X1]Commission Regulation (EEC) No 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (OJ L 366, 15.12.1992, p. 10). Regulation as last amended by Regulation (EC) No 2266/2000 (OJ L 259, 13.10.2000, p. 27).**]**

(4) **[**[X1]Commission Regulation (EC) No 703/2001 of 6 April 2001 laying down the active substances of plant protection products to be assessed in the second stage of the work programme referred to in Article 8(2) of Council Directive 91/414/EEC and revising the list of Member States designated as rapporteurs for those substances (OJ L 98, 7.4.2001, p. 6).**]**

(5) **[**[X1]Commission Regulation (EC) No 1490/2002 of 14 August 2002 laying down further detailed rules for the implementation of the third stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC (OJ L 224, 21.8.2002, p. 23). Regulation as last amended by Regulation (EC) No 1744/2004 (OJ L 311, 8.10.2004, p. 23).**]**

(6) **[**[X1]Commission Decision 2003/565/EC of 25 July 2003 extending the time period provided for in Article 8(2) of Council Directive 91/414/EEC (OJ L 192, 31.7.2003, p. 40).**]**

(7) **[**[X1]OJ L 123, 24.4.1998, p. 1. Directive as last amended by Commission Directive 2006/140/EC (OJ L 414, 30.12.2006, p. 78).**]**

(8) **[**[X1]OJ L 307, 24.11.2003, p. 1. Regulation as last amended by Regulation (EC) No 1849/2006 (OJ L 355, 15.12.2006, p. 63).**]**

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 01/01/2020.

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 II.