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

[X1CHAPTER 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.**]**

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, CHAPTER 4.