Manual of
EUROPEAN
ENVIRONMENTAL
POLICY

Manual of European Environmental Policy

The following pages are a section from the Manual of European Environmental Policy written by the Institute for European Environmental Policy.

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This section is the text of the Manual as published in 2012. It is therefore important to note the following:

- The contents have not been updated since 2012 and no guarantee is given of the accuracy of the contents given potential subsequent developments.
- The sections include links to external websites (e.g. to legal texts). These links continue to work as long as those links are not broken by those websites.
- The sections also include the original links that enabled interactivity within the published on-line version of the Manual. These links no longer work.

The Manual should be cited as follows:

Farmer, A.M. (2012) (Editor). Manual of European Environmental Policy. 1043pp. Routledge, London.

Institute for European Environmental Policy

Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Formal references	
Regulation (EC) No 1907/2006 (OJ L309 24.11.2009)	Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
Proposed – COM(2003)644	
Amended by	
(OJ L136 29.05.2007)	Corrigenda to REACH
Regulation (EC) No 440/2008 (OJ L142 31.5.2008)	Regulation laying down test methods pursuant to REACH
Regulation (EC) No 134/2009 (OJ L46 17.2.2009)	Amendment to Annex XI
Regulation (EC) No 552/2009 (OJ L164 26.6.2009)	Amendment to Annex XVII
Regulation (EC) No 761/2009 (OJ L220 24.8.2009)	Amendment to Regulation (EC) No 440/2008
Regulation (EU) No 276/2010 (OJ L86 1.4.2010)	Amendment to Annex XVII
Regulation (EU) No 453/2010 (OJ L133 31.5.2010)	Replaces Annex I
Regulation (EU) No 1152/2010 (OJ L324 9.12.2010)	Amendment to Regulation (EC) No 440/2008
Regulation (EU) No 143/2011 (OJ L44 18.2.2011)	Amends Annex IV with six substances
Corrigenda (OJ L49 24.2.2011)	Corrigenda to Regulation No 143/2011
Regulation (EU) No 207/2011 (OJ L 58 3.3.2011)	Amendment to Annex XVII
Regulation (EU) No 252/2011 (OJ L69 16.3.2011)	Amendment to Annex I
Regulation (EU) No 253/2011 (OJ L69 16.3.2011)	Amendment to Annex III
Regulation (EU) No 494/2011 (OJ L134 21.5.2011)	Amendment to Annex XVII
Corrigenda (OJ L136 24.5.2011)	Corrigenda to Regulation (EU) No 494/2011
Regulation (EU) No 109/2012 (OJ L37 10.2.2012	Amendment to Annex XVII
Regulation (EU) No 125/2012 (OJ L41 15.2.2012	Amendment to Annex XIV
Regulation repeals	
Repeal of:	1 June 2007
Directive 91/155/EEC (Information to be included in safety data sheets).	
Deletion of:	1 June 2007
Article 14 (provision of safety data sheets) of Directive 1999/45/EEC (Classification, packaging and labelling of dangerous preparations).	
Repeals of:	1 June 2008
Directive 93/105/EC Information required for Technical Dossiers);	
Directive 2000/21/EC (amending the Dangerous Substances Directive);	

Regulation (EEC) No 793/93 (Evaluation and control of the risks of existing substances); and Regulation (EC) No 1488/94 (principles for risk assessment of existing substances).	
Directive 79/117/EEC	Directive prohibiting the placing on the market and use of plant protection products containing certain active substances.
Part of Directive 91/414/EEC	Directive concerning the placing of plant protection products on the market.
Binding dates	
Entry into force of REACH	1 June 2007
Titles applying:	1 June 2007
I – Scope, definitions	
IV – Information in supply chain	
IX – Fees and Charges	
X – European Chemicals Agency	
XIII – Competent Authorities	
XIV – Enforcement	
XV – Transitional arrangements	
Article 32 – provision of information down the supply chain on substances not requiring a Safety Data Sheet.	At first delivery of such substances after 1 June 2007
Article 67 – compliance with existing Marketing and Use restrictions for substances listed in Annex XVII	From 1 June 2007 until 1 June 2013
Article 115 – harmonization of classification and labelling at Community level for CMRs categories 1, 2 and 3, and respiratory sensitizers.	From 1 June 2007
Titles applying:	1 June 2008
II – Registration	
III – Sharing of data	
V – Obligations of downstream users	
VI – Evaluation	
VII – Authorisation	
XI – Classification and labelling inventory	
XII – Information	
Article 74 – European Commission Regulation specifying REACH fees and charges adopted.	By 1 June 2008
Article 118(3) – practical application to REACH of Regulation (EC) No 1049/2001 (regarding public access to European Parliament, Council and Commission documents).	By 1 June 2008
Article 128 – free movement of goods within scope of REACH	1 June 2008
Article 136 – transitional measures regarding existing substances.	1 June 2008
Article 138(4) – Commission review of REACH Annexes I, IV and V.	By 1 June 2008
Article 28 – pre-registration of phase-in (existing)	1 June 2008 until 1 December

substances of 1 tonne+ per year.	2008
Article 135 – transitional measures regarding notified substances.	1 August 2008
Article 7 – registration and notification of substances in articles.	1 December 2008
Article 126 – Member States' provision on penalties for non-compliance with REACH.	By 1 December 2008
Article 138(5) – Commission review of REACH Annex XIII (adequacy of criteria identifying PBT and vPvB substances).	By 1 December 2008
Title applying:	1 June 2009
VIII – Restrictions	
Article 58(3) – European Chemicals Agency's first recommendation of priority substances to be included in Annex XIV (list of substances subject to authorisation).	By 1 June 2009
Article 67(3) – Commission to compile and publish an inventory of Annex XVII restrictions.	By 1 June 2009
Article 137(3) – Commission to incorporate into Annex XVII any amendments to Directive 76/769/EEC restrictions adopted from 1 June 2007.	1 June 2009
Repeals of:	1 June 2009
Directive 93/67/EEC (Risk assessment for new notified substances);	
Directive 76/769/EEC (Restrictions on the marketing and use of certain dangerous substances and preparations).	
Annex XVII – List of restricted substances and conditions of restriction.	1 June 2009
Article 117(1) – First of five-yearly Member State reports to Commission on the operation of REACH.	By 1 June 2010
Article 23(1) – registration provisions for phase-in substances for CMR (category 1 or 2) and toxic (R50/53) over 1 tonne + per year, and other substances over 1,000 tonnes per year.	1 December 2010
Article 116 – transitional arrangements for obligations in Article 113 to notify the ECHA of substances subject to registration and/or dangerous substances classified as such under existing legislation.	1 December 2010
Article 117(2) – First of five-yearly European Chemicals Agency reports to Commission on operation of REACH.	By 1 June 2011
Article 117(3) – First of three-yearly European Chemicals Agency reports to Commission on use of non-animal testing strategies.	By 1 June 2011
Article 44(2) – European Chemicals Agency to prepare first draft three-year Community rolling action plan of substances to be evaluated each year.	1 December 2011
Article 117(4) – First of five-yearly general report by Commission on operation of REACH, and funding for development and evaluation of alternative test methods.	By 1 June 2012

Article 138(3) – Commission review of registration requirements for substances of 1–10 tonnes per year, for Article 117(4) reports.	By 1 June 2012
Article 138(6) – Commission review of scope of REACH, to avoid overlaps with other legislation.	By 1 June 2012
Article 43(2)(a) – European Chemicals Agency to prepare draft decisions for testing proposals in registrations received by 1 December 2010, complying with Annexes IX and X.	By 1 December 2012
Article 23(2) – registration provisions for phase-in substances of 100 tonnes or more per year.	1 June 2013
Article 138(7) – Commission review of whether to exclude endocrine disrupting substances from 'adequate control' authorisations.	By 1 June 2013
Article 138(1) – Commission review of whether to require chemical safety assessments for CMRs category 1 or 2.	By 1 June 2014
Article 43(2)(b) – European Chemicals Agency to prepare draft decisions for testing proposals in registrations received by 1 June 2013, complying with Annex IX only.	By 1 June 2016
Article 23(3) – registration provisions for phase-in substances of 1 tonne or more per year.	1 June 2018
Article 138(1) – Commission review of whether to require chemical safety assessments for substances exempt from REACH, or in quantities of less than 10 tonnes per year.	By 1 June 2019
Article 138(8) – Commission review whether to extend duty to communicate information on substances in articles to other dangerous substances, in addition to CMRs, PBTs, vPvBs and endocrine disruptors already covered.	By 1 June 2019
Article 138(9) – Commission review of reproductive toxicity testing requirements (Annex VIII, section 8.7), to ensure minimization of animal testing.	By 1 June 2019
Article 43(2)(c) – European Chemicals Agency to prepare draft decisions for any testing proposals in registrations received by 1 June 2018.	By 1 June 2022

Purpose of the Regulation

Historically, the Regulation concerning Registration, Evaluation, Authorisation and Restriction of Chemicals (hereafter REACH) evolved from three earlier phases with their distinctive approaches towards chemicals. In the 1970s, *ad hoc* restrictions on the marketing and use of chemicals that were known to be harmful began to be introduced (often following accidents). The 1980s saw a systematic and proactive approach to new chemicals which were not allowed into the market before they had been tested. The 1990s developed the evaluation of existing chemicals but only about 140 chemicals were included into priority lists and of these only a few have been evaluated and even fewer restricted[1]. This disappointing progress

in evaluating existing chemicals was one of the main reasons for REACH, which introduces a single system for all chemicals and abolishes the distinction between 'new' (introduced into the market after 1981) and 'existing' chemicals (listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) before 1981). Consequently, REACH incorporates into its remit all existing chemicals about which sufficient information is often lacking for effective assessment and control. It also transfers the burden of proof of risk assessments of substances from the public authorities to industry and places much more responsibility on manufacturers, importers and downstream users to provide useful information about the chemicals on the market. REACH also calls for the progressive substitution of the most dangerous chemicals when suitable alternatives have been identified.

Summary of the legislation

Overview

REACH is the longest, most detailed and complicated item of EU environmental legislation. However, its essential elements can be stated as follows:

- all chemical substances manufactured or imported in quantities of 1 tonne or more must be registered with the European Chemicals Agency (ECHA) by the manufacturer/importer;
- the registration contains a dossier with information to enable the substance to be used safely;
- ECHA can evaluate dossiers and substances;
- downstream users are to contribute to the dossier;
- substances of very high concern are not to be used unless authorized;
- companies will be required to make efforts to find safer substitutes as part of the authorisation procedure; and
- the manufacture, marketing and use of substances can be restricted.

General issues (Title I)

The 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 only substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.

Article 2 lists the categories of substances and products exempted from the application of REACH. These are:

- Radioactive substances within the scope of Directive 96/29/EURATOM (see section on safety standards for radiation).
- Substances, on their own, in a preparation or in an article, which are subject to customs supervision (provided certain conditions are met);
- Non-isolated intermediates;
- Carriage of dangerous substances;
- Waste as defined in Directive 2006/12/EC (see section on Waste Framework Directive).
- Medicinal products (exempt from Titles II, V, VI and VII);

- Food and feeding stuffs;
- Exemptions in the interests of defence.

Annexes IV and V list the substances that are exempted from registration and evaluations. Annex IV substances are exempt because they are considered to cause minimum risk as a result of their intrinsic properties. For substances in Annex V the registration is deemed inappropriate or unnecessary. In March 2010 ECHA published a guidance document[2] on Annex V exemptions.

Article 3 defines substances, articles, intermediates and preparations in the following manner:

- *A 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.
- *A preparation* means a mixture or solution composed of two or more substances.
- *An 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.
- *An intermediate* means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance.
- *A phase-in substance* means a substance listed in EINECS or those that have been manufactured in the Community, but not placed on the Community market, in the last 15 years, or the 'no longer polymers' of Directive 67/548/EEC.
- *A notified substance* means a substance for which a notification as a 'new chemical' has been submitted and which could be placed on the market in accordance with Directive 67/548/EEC (see section on classification, labelling and packaging of chemical substances and mixtures).

ECHA has produced further guidance on intermediates[3], for monomers and polymers[4] and for substances in articles[5].

Registration (Title II)

Any manufacturer or importer of a substance in quantities of 1 tonne or more per year is required to submit a registration to ECHA. The registration provisions require the generation of data on the manufactured or imported substances, with a view to using these data to assess the risks related to these substances and to develop and recommend appropriate risk management measures. The registration requirements for different categories are described in more detail below.

A polymer must be registered when it contains more than 2 per cent (w/w) of the monomer substance and the total quantity of such monomer substance makes up 1 tonne or more per year. Articles must be registered when the substance in the article is intended to be released under normal or reasonably foreseeable conditions of use and the substance is present in the articles in quantities over 1 tonne per producer or importer per year. The producer or importer is also required to notify ECHA if a substance of very high concern (on the candidate list (see Title VII)), is present in the article above a concentration of 0.1 per cent (w/w) and present over 1 tonne, except where exposure to humans and environment can be excluded during normal conditions of use and disposal. A lighter registration is required for on-site and transported intermediates as described in Articles 17 and 18. If a substance has already been

registered, a new registrant is entitled to refer to the study summaries, for the same substance submitted earlier. Substances in plant protection and biocidal products are regarded as being already registered, as they are covered by other legislation. Notifications under Directive 67/548/EEC of 'new substances' are also considered as registrations for the purposes of REACH.

Transitional provisions applicable to phase-in substances and notified substances are described in Articles 23 and 24. To facilitate the transition to REACH, the registration provisions are applied in steps to phase-in substances in accordance with Directive 67/548/EEC and those in quantities.

Manufacturers and importers must obtain information on the substances they manufacture or import and use this information to assess the risks arising from their use and ensure that these risks are properly managed. To reflect this the manufacturers and importers are required to submit a technical dossier for substances in quantities of 1 tonne or more as well as a chemical safety report for substances in quantities of 10 tonnes or more. The technical dossier contains information on the properties, uses and on the classification of a substance as well as guidance on safe use, as described in Article 10. The information requirements are set out in the testing annexes that vary according to the tonnage in which the substance is manufactured or imported. Tonnage for phase-in-substances is calculated as a three-year average as long as they have been manufactured or imported for three consecutive years.

The chemical safety report is based on a chemical safety assessment in accordance with Article 14. The chemical safety assessment includes a human health assessment, physiochemical hazard assessment, environmental hazard assessment and an assessment of whether the substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB). If the substance meets the criteria for classification as dangerous in accordance with Directive 67/548/EEC or is assessed to be a PBT or vPvB, the chemical safety assessment has to include the additional steps of an exposure assessment and risk characterization. A chemical safety assessment is not required for a substance which is present in a preparation if the concentration of the substance in the preparations is less than the lowest of concentrations set in Directive 1999/45/EC, Directive 67/548/EEC, Title XI of this Regulation or 0.1 per cent (w/w) (as well as criteria set in Annex XIII).

Information on intrinsic properties of substances may be generated by means other than tests (as long as the provisions of Annex IX are met). This is especially true for human toxicity information, where the information has to be generated, whenever possible, by means other than a vertebrate animal test. These methods will be regularly reviewed and improved with a view to reducing testing on vertebrate animals and the number of animals involved.

When a substance or isolated intermediate is intended to be manufactured by one or more manufacturer and/or imported by one or more importer, the registrants may decide whether to submit the information separately or whether one registrant is to submit the information on behalf of the others. A registrant may also submit the information separately based on disproportionate costs, commercially sensitive information or if the registrant disagrees with the lead registrant on the selection of the information.

ECHA is required to undertake a completeness check of each registration but this will not include an assessment of the quality or adequacy of any data or justifications submitted. The completeness check has to be undertaken by ECHA within three weeks of the submission

date or within three months of the relevant deadline as regards registrations of phase-in substances submitted in the course of the two-month period immediately preceding the deadline. If a registration is incomplete, ECHA has to inform the registrant and set a reasonable deadline for the submission of further information. ECHA has to reject the registration if the registrant fails to complete his registration within the deadline set. Following registration, a registrant is responsible for updating the registration without 'undue delay' with any relevant new information.

The latest guidance document[6] on the registration process was published in November 2009.. In addition ECHA provides further guidance on information requirements and chemical safety assessments on its website: (http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm?time=1302695653, Accessed 13.4.2011). It includes a number of guidance documents on the collection and assessment of the available information on the intrinsic properties of the substances to be registered, on the requirements specified by REACH, on the identification of data gaps and on the generation of the additional information required to comply with the Regulation.

Data sharing and avoidance of unnecessary testing (Title III)

This title establishes the data-sharing procedures for phase-in and non-phase-in substances. For both categories of substances, data collected through vertebrate animal testing must be shared, in exchange for payment.

For phase-in substances, the registrant was required to pre-register these within the transitional time period, starting 1 June 2008 and ending 1 December 2008. Pre-registration allows industry to benefit from extended registration deadlines for phase-in substances to allow industry to adapt gradually to the new requirements. ECHA has published on its website a list of these phase-in substances with their first envisaged registration deadline. The main communication mechanism for phase-in substances is the establishment of the Substance Information Exchange Forum (SIEF). All potential registrants, downstream users and third parties who have submitted information to ECHA in accordance with the provisions on pre-registration of phase-in substances or whose information is held by ECHA in accordance with the provisions on substances regarded as being registered are required to be participants in SIEF. The aim of SIEF is to facilitate the exchange of the information between potential registrants and to agree on classification and labelling when differences emerge. Accordingly, the SIEF participants are required to share existing vertebrate animal test data as well as agree on the generation of new test data. Each SIEF is to be operational until 2018.

For non-phase-in substances and phase-in substances that have not been pre-registered, the registrant is required to inquire from ECHA whether a registration has already been submitted for the same substance. If the same substance has previously been registered less than 12 years earlier, ECHA has to inform the potential registrant of this as well as the previous registrant. An agreement has to be made between the new and previous registrant on the costs for sharing the information of the previous registrant, who is required to make available to the new registrant the agreed information and give the new registrant the permission to refer to the previous registrant's full study report. If there is failure to reach an agreement, the potential registrant is to inform ECHA and the previous registrant thereof at the earliest one month after receipt of the name and address of the previous registrant.

In September 2007, ECHA published a guidance document[7] on data sharing. It describes data-sharing mechanisms for phase-in and non-phase-in substances under REACH.

Information in the supply chain (Title IV)

REACH requires that not only manufacturers and importers but also their customers, that are downstream users and distributors, have the information they need to use chemicals safely. Therefore, the supplier of a substance or a preparation is required to provide the recipient with a safety data sheet compiled in accordance with Annex II, when one of the following circumstances is met:

- a substance or preparation meets the criteria for classification as dangerous in accordance with Directives 67/548/EEC or 1999/45/EC;
- a substance is a PBT of a vPvB; or is bioaccumulative in accordance with the criteria set out in Annex XIII; or
- a substance is included in the candidate list (see Title VII) for reasons other than those referred in the above bullet points.

An actor in the supply chain who is required to carry out a chemical safety assessment for a substance has to ensure that the information in the safety data sheet is consistent with the information in this assessment. If the safety data sheet is developed for a preparation, it is sufficient for the information in the safety data sheet to be consistent with the chemical safety report for the preparation instead of with the chemical safety report for each substance in the preparation.

The safety data sheet need not be supplied where dangerous substances or preparations are offered or sold to the general public, as long as they are provided with sufficient information to enable users to take the necessary measures as regards the protection of human health, safety and the environment, unless requested by a downstream user or distributor.

Any actor in the supply chain who is required to prepare a chemical safety report has to place the relevant exposure scenarios (including use and exposure categories where appropriate) in an annex to the safety data sheet, covering identified uses and including specific conditions. The downstream user shall include relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for identified uses. The distributor shall pass on relevant exposure scenarios, and use other relevant information, from the safety data sheet supplied to him when compiling his own safety data sheet for uses for which he has passed on information.

Downstream users (Title V)

Downstream users are any industrial users of chemicals or users of chemicals in other industrial processes or producers of manufactured articles. They are required to consider the safety of their use of substances and to apply appropriate risk management measures. Hence, a downstream user has the right to make a use known to the supplier with the aim of making this an identified use. In making a use known, sufficient information is to be provided to allow the manufacturer, importer or downstream user to prepare an exposure scenario, for use in the chemical safety assessment. Distributors shall pass on such information to the next actor or distributor up the supply chain. Downstream users in receipt of such information may

prepare an exposure scenario for the identified use, or pass the information to the next actor up the supply chain.

Where the manufacturer, importer or downstream user, having assessed the use in accordance with the chemical safety report is unable to include it as an identified use for reasons of protection of human health or the environment, he/she is required to provide ECHA and the downstream user with the reasons for that Decision without delay and not supply the downstream user with the substance.

A downstream user can also keep his/her use confidential or decide to use a substance outside the conditions described in the exposure scenario communicated to him in a safety data sheet. In this case the downstream user is required to do a chemical safety report with exposure scenarios for his intended uses and, if necessary, make changes to the supplier's hazard assessment.

In January 2008, ECHA published a guidance document[8] for downstream users. It describes the roles and obligations of downstream users, and advises them on how to prepare for the implementation of REACH.

Evaluation (Title VI)

ECHA is responsible for the evaluation of the dossiers and the evaluation of the substances. The substance evaluation process aims to clarify any grounds for considering if a substance constitutes a risk to human health or the environment. The evaluation of dossiers consists of checking registration dossiers and checking testing proposals. The purpose of checking a registration dossier for compliance is to ensure that the legal requirements of REACH are fulfilled and that the quality of the submitted dossiers is sufficient. At least 5 per cent of dossiers are required to be checked by ECHA. It will also assess if the explanation to opt out from a joint submission of data has an objective basis. The main objective of the examination of testing proposals is to check that reliable and adequate data are produced and to prevent unnecessary animal testing.

The testing proposal set out in a registration or a downstream user report is examined by ECHA. Priority is given to registrations of substances which have or may have PBT, vPvB, sensitizing and/or carcinogenic, mutagenic or toxic for reproduction (CMR) properties, or substances classified as dangerous according to Directive 67/548/EEC above 100 tonnes/year with uses resulting in widespread and diffuse exposure. Information relating to testing proposals involving tests on vertebrate animals is published on ECHA website. ECHA will make its Decision on the testing proposal based on the procedure laid down in Articles 50 and 51.

For substance evaluation ECHA, in cooperation with the Member States, will develop criteria for prioritizing substances with a view to evaluating these further. This prioritization is risk-based and covers the following criteria:

- hazard information, for instance structural similarity of the substance with known substances of concern or with substances which are persistent and liable to bio-accumulate, suggesting that the substance or one or more of its transformation products has properties of concern or is persistent and liable to bio-accumulate;
- exposure information; and

- tonnage, including aggregated tonnage from the registrations submitted by several registrants.

Based on these criteria ECHA will compile a draft Community rolling action plan, which covers a period of three years and specifies the substances to be evaluated each year. Substances are included if there are grounds for considering (either on the basis of a dossier evaluation carried out by ECHA or on the basis of any other appropriate source, including information in the registration dossier) that a given substance constitutes a risk to human health or the environment. ECHA will submit the first draft rolling action plan to the Member States by 1 December 2011 and submit draft annual updates to the rolling action plan to the Member States by 28 February each year. ECHA will then adopt the final Community rolling action plan on the basis of an opinion from the Member State Committee (responsible for resolving potential divergences of opinions on draft decisions proposed by ECHA or the Member States) and publish the plan on its website, identifying the Member States who will carry out the evaluation of the substances listed therein.

ECHA is also responsible for coordinating the substance evaluation process and ensuring that substances on the Community rolling action plan are evaluated. In doing so, ECHA relies on the competent authorities of Member States. In carrying out an evaluation of a substance, the competent authorities may appoint another body to act on their behalf. Member States may choose a substance or substances from the draft Community rolling action plan with the aim of becoming the competent authority for that/those substances. In cases where two or more Member States have expressed an interest to evaluate the same substance, ECHA will refer the matter to the Member State Committee. If the Member State Committee fails to reach a unanimous agreement, ECHA shall submit the conflicting opinions to the Commission, which will then make the final decision.

A Member State may notify ECHA at any time of a substance not on the Community rolling action plan, whenever it is in possession of information which suggests that the substance is a priority for evaluation. ECHA will then decide whether to add this substance to the Community rolling action plan on the basis of the opinion of the Member State Committee.

In June 2007, ECHA published a guidance document[9] on dossier and substance evaluation. It describes the evaluation tasks to be performed by the authorities in evaluating testing proposals, by ECHA in performing compliance checking and by the Member States Competent Authorities in carrying out substance evaluations.

Authorisation (Title VII)

Substances of very high concern are subject to authorisation by the Commission with regard to particular uses. The aim of the authorisation procedure is to ensure the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled and that these substances are progressively replaced by suitable alternative substances or technologies where these are economically and technically viable. To this end, all manufacturers, importers and downstream users applying for authorisations are required to analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution. Chemicals do not have to be registered in order to enter the authorisation procedure. Also note that while incorporation of the substance in articles is a substance use that requires an authorisation, the use of articles is not subject to authorisation.

The substances in Annex XIV require an authorisation. A manufacturer, importer or downstream user cannot place a substance on the market if that substance is included in Annex XIV, unless it is authorised. The categories of substances to be included in Annex XIV are listed in Article 57 and include:

- Substances meeting the criteria for classification as carcinogenic category 1 or 2 in accordance with Directive 67/548/EEC;
- Substances meeting the criteria for classification as mutagenic category 1 or 2 in accordance with Directive 67/548/EEC;
- Substances meeting the criteria for classification as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EEC;
- Substances which are persistent, bioaccumulative and toxic in accordance with the criteria set out in Annex XIII;
- Substances which are very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII;
- Substances – such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) or (e) – for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an equivalent level of concern to those of other substances listed in points (a)–(e) and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59.

Article 59 sets out the procedure that applies for identifying substances meeting the criteria for inclusion in Annex XIV and establishing a candidate list for eventual inclusion into Annex XIV. The Commission may ask ECHA to prepare a dossier in accordance with relevant sections of Annex XV for substances which in its opinion meet the criteria for Annex XIV inclusion. In a similar vein, a Member State may prepare a dossier in accordance with Annex XV for Annex XIV inclusion.

ECHA is required to publish on its website a notice that an Annex XV dossier has been prepared for a substance and invite all interested parties to submit comments within a specified deadline to ECHA. Within 60 days of circulation, the other Member States or ECHA may comment on the identification of the substances in the dossier to ECHA. If ECHA does not receive or make any comments, it shall include the substance into the candidate list. When comments are made or received, ECHA will refer the dossier to the Member State Committee within 15 days of the end of the 60-day period. If, within, 30 days of the referral, the Member State Committee reaches a unanimous agreement, ECHA will include the substance in the candidate list.

Prior to a Decision to include substances in Annex XIV, ECHA will, taking into account the opinion of the Member State Committee, recommend priority substances, selected from the candidate list. Priority is normally given to substances which have PBT or vPvB properties, have a wide dispersive use or are of high volumes. The number of substances included in Annex XIV and the dates specified in transitional arrangements and review periods need also to take into account ECHA's capacity to handle applications in the time provided for. ECHA made its first recommendation of priority substances to be included in Annex XIV by 1 June 2009 and will make further recommendations at least every second year. Before ECHA sends its recommendations to the Commission, it has to make them publicly available on its website. ECHA is required to invite all interested parties to submit comments within three

months of the date of publication, in particular on uses which should be exempt from the authorisation requirement, and take these comments into consideration in its recommendations. Once a substance has been included into Annex XIV, it cannot be subjected to new restrictions under the procedure outlined in Title VIII with the exception of substances in articles, which may be subjected to new restrictions under this procedure, even if listed in Annex XIV.

Any Decision to include a substance in Annex XIV will be done through the comitology procedure. The Decision will specify for each substance its identity, intrinsic properties, transitional arrangements, review periods for certain uses and uses or categories of uses exempted from the authorisation requirement, if any, and conditions for such exemptions, if any. Uses or categories of uses may be exempted from the authorisation requirement provided that the risk is properly controlled on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance.

Once a substance is included in the system, those using or making available such a substance will need to apply for an authorisation for each use of the substance with the Commission being responsible for granting such authorisations. An authorisation is granted if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIV is considered to be *adequately controlled* in accordance with section 6.4 of Annex I and as documented in the applicant's chemical safety report, taking into account the opinion of the Committee for Risk Assessment. When granting the authorisation, the Commission will take into account all discharges, emissions and losses, including risks arising from diffuse or dispersive uses, known at the time of the decision. However, the adequate control route does not apply to:

- CMR substances and Article 57(f) substances, for which it is not possible to determine a threshold in accordance with section 6.4 of Annex I;
- Substances that have PBT properties and substances that have vPvB properties identified under Article 57(f); and
- PBT or vPvB substances, identified through the criteria in Annex XIII.

Six years after the entry into force of REACH, the Commission is to review whether endocrine disrupters should also be excluded from the adequate control route.

If an authorisation cannot be granted under the adequate control route or for substances listed above, an authorisation may still be granted if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies. This Decision will be taken after consideration of the following elements:

- the risk posed by the uses of the substance, including the appropriateness and effectiveness of the risk management measures proposed;
- the socio-economic benefits arising from its use and the socio-economic implications of a refusal to authorise as demonstrated by the applicant or other interested parties;
- the analysis of the alternatives submitted by the applicant or any substitution plan submitted by the applicant, and any third-party contributions submitted; and
- available information on the risks to human health or the environment of any alternative substances or technologies.

In addition, the opinions of the Committee for Risk Assessment and the Committee for Socio-economic Analysis have to be taken into account. In January 2011 ECHA published a guidance document[10], which describes the socio-economic analysis under the REACH procedure on applications for authorisation.

When assessing whether suitable substances or technologies are available, the Commission needs to consider whether the transfer to alternatives would result in a reduced overall risk and the technical and economic feasibility of alternatives for the applicant.

Authorisations are subject to a time-limited review and will normally be subject to conditions, including monitoring. Authorisations may be reviewed at any time if the circumstances of the original authorisation have changed (risks or socio-economic impact) or if new information on possible substitutes becomes available. In its review, the Commission may amend or withdraw the authorisation. In cases where there is a serious and immediate risk for human health or the environment, the Commission may suspend the authorisation.

All applications for an authorisation have to be made to ECHA. The information to be included into an authorisation application is listed in Article 62.

In June 2007, ECHA published a guidance document[11] for the preparation of Annex XV dossiers on the identification of substances of very high concern. It describes how the authorities (Member States Competent Authorities or ECHA) can prepare an Annex XV dossier with a view to identifying a substance of very high concern.

In August 2008, ECHA published its guidance document[12] on inclusion of substances in Annex XIV. The guidance provides an overview of the authorisation procedure from the identification of the substances subject to authorisation until their inclusion in Annex XIV.

In January 2011, ECHA published a guidance document[13] on the preparation of an application for authorisation.

Restrictions on the manufacturing, placing on the market and use of certain dangerous substances preparations and articles (Title VIII)

The restrictions procedure is a safety net to address unacceptable risks to human health or the environment, arising from the manufacture, use or placing on the market of substances. Any substance on its own, in a preparation or in an article may be subject, where justified, to restrictions. They do not have to be registered to be restricted. Also note that the restriction procedure can be used for the import or use of articles containing an Annex XIV substance, not covered by the authorisation procedure.

Annex XVII sets the conditions for the manufacture, placing on the market or use of certain substances where there is an unacceptable risk to health or the environment. Until 1 June 2013, a Member State may maintain any existing and more stringent restrictions in relation to Annex XVII, provided that those restrictions have been notified according to the Treaty.

If the Commission considers that the manufacture, placing on the market or use of a substance on its own, in a preparation or in an article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed, it shall ask ECHA to prepare a dossier which conforms to the requirements of Annex XV. After the sunset date for

a substance listed in Annex XIV, ECHA needs to consider whether the use of that substance in articles poses a risk to human health or the environment, which is not adequately controlled. If ECHA considers that the risk is not adequately controlled, it will prepare a dossier which conforms to the requirements of Annex XV. Within 12 months of the receipt of the request from the Commission ECHA will suggest restrictions, if the dossier so demonstrates, in order to initiate the restrictions process. Similarly, if a Member State considers that the risks to human health or the environment are not adequately controlled it has to notify ECHA and propose to prepare a dossier which conforms to the requirements of the relevant sections of Annex XV. If the substance is not on ECHA's list of substances, for which an Annex XV dossier is planned or underway, the Member State has to prepare a dossier which conforms to the requirements of Annex XV within 12 months of the notification to ECHA. If this dossier demonstrates that action on a Community-wide basis is necessary, the Member State has to submit it to ECHA in the format outlined in Annex XV, in order to initiate the restrictions process.

The Committee for Risk Assessment and the Committee for Socio-economic Analysis have to check whether the dossier submitted conforms to the requirements of Annex XV. ECHA is required to make all dossiers conforming to Annex XV, including the restrictions suggested, publicly available on its website and invite interested parties to comment within six months of the date of publication. Within nine months of the date of publication, the Committee for Risk Assessment is required to formulate an opinion as to whether the suggested restrictions are appropriate in reducing the risk to human health and/or the environment, based on its consideration of the relevant parts of the dossier. Within 12 months of the date of publication, the Committee for Socio-economic Analysis has to prepare a draft opinion on the suggested restrictions and on the related socio-economic impact. ECHA will then publish the draft opinion on its website and invite interested parties to give their comments on the draft opinion. Then ECHA will submit the opinions of the Committees for Risk Assessment and Socio-economic Analysis to the Commission. Then the Commission is to prepare a draft amendment to Annex XVII. Where the draft amendment diverges from the original proposal or if it does not take the opinions from ECHA into account, the Commission has to annex a detailed explanation of the reasons for the differences. A final Decision will be made in accordance with the comitology procedure.

ECHA has published guidance[14] on the socio-economic analysis undertaken as part of restrictions. ECHA has also published a guidance document[15] for the preparation of Annex XV dossiers on restrictions. It describes how the authorities (Member States Competent Authorities or ECHA on request from the Commission) can prepare an Annex XV dossier to propose a restriction under REACH.

Fees and charges (Title IX)

This title provides for fees and charges to be paid by the registrants. The structure and amount of the fees will take account of the work to be carried out by ECHA and the competent authority and will be fixed at such a level as to ensure that the revenue derived from them when combined with other sources of revenue is sufficient to cover the cost of the services delivered. In all cases, a reduced fee shall be set for SMEs.

European Chemicals Agency (Title X)

ECHA has been established in Helsinki for the purposes of managing and in some cases carrying out the technical, scientific and administrative aspects of REACH and to ensure consistency at Community level in relation to these aspects. ECHA consists of:

- a Management Board, which is responsible for the tasks set out in Articles 78–80;
- an Executive Director, who is responsible for the day-to-day administration of ECHA. A detailed list of responsibilities is set out in Article 83;
- a Committee for Risk Assessment, which prepares the opinion of ECHA on evaluation, applications for authorisation, proposals for restrictions and proposals for classification and labelling under Title XI and any other questions that arise from the operations of REACH relating to risks to human health and the environment;
- a Committee for Socio-economic Analysis, which prepares the opinion on applications for authorisation, proposals for restrictions, and any other questions that arise from the operation of this Regulation relating to the socio-economic impact of possible legislative action on substances;
- a Member State Committee, which is responsible for resolving potential divergences of opinion on draft decisions proposed by ECHA or the Member States on evaluations (Title VI) and proposals for identification of substances of very high concern to be subjected to the authorisation procedure;
- a Forum for Exchange of Information on Enforcement, which coordinates a network of Member States authorities responsible for the enforcement of REACH. A detailed list of tasks can be found in Article 77 (4);
- a Secretariat, which works under the leadership of the Executive Director and provides technical, scientific and administrative support for the Committees and the Forum and ensures appropriate coordination between them. It also undertakes the work required of ECHA under the procedures for pre-registration, registration and evaluation as well as preparation of guidance, database maintenance and information provision. A detailed list of tasks can be found in Article 77 (2); and
- a Board of Appeal, which decides on appeals against decisions taken by ECHA.

The Management Board is composed of one representative from each Member State and a maximum of six representatives appointed by the Commission, including three persons from ‘interested parties’ (stakeholders) without voting rights and in addition two independent persons appointed by the European Parliament. The Management Board appoints the Executive Director.

The procedure for nominating candidates for the Committee for Risk Assessment and the Committee for Socio-economic Analysis is the same. Each Member State may nominate candidates to membership to these Committees and the Executive Director establishes a list of the nominees, which is published on ECHA's website. The Management Board appoints the members of these Committees from this list, including at least one member but not more than two from the nominees of each Member State that has nominated candidates. Each Member State appoints one member to the Forum. The Forum has to aim to have a broad range of relevant expertise among its members. To this end, the Forum may decide to appoint a maximum of five additional members. The Board of Appeal consists of a Chairman and two other members. The Chairman, the other members and alternates are appointed by the Management Board on the basis of a list of candidates proposed by the Commission, following a call for expressions of interest.

Classification and labelling inventory (Title XI)

This title has been repealed by Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (see section on Classification, Labelling and Packaging of Chemical Substances and Mixtures) with title XI of REACH being replaced by title V of this Regulation.

Information (Title XII)

The reporting requirements of the Regulation are for:

- Member States to submit a report to the Commission on the operation of the Regulation every five years, with the first report to be submitted by 1 June 2010;
- ECHA to submit a report to the Commission on the operation of the Regulation every five years, with the first report to be submitted by 1 June 2011;
- ECHA to submit a report to the Commission on the status of implementation and use of non-animal test methods and testing strategies every three years, with the first report to be submitted by 1 June 2011; and
- the Commission to publish a general report on the experience acquired and the distribution of funding made available by the Commission for the development and evaluation of alternative test methods, every five years, with the first report to be published on 1 June 2012.

Article 119 lists the information to be made publicly available, free of charge, over the Internet.

Competent authorities (Title XIII)

Member States have to appoint their competent authority or competent authorities. The competent authorities are responsible for the communication to the public of information on risks of substances. Competent authorities are also required to submit electronically to ECHA any available information that they hold on substances registered in accordance with Article 12(1), whose dossiers do not contain the full information referred to in Annex VII, in particular whether enforcement or monitoring activities have identified suspicions of risk. Member States are also required to establish national helpdesks to provide advice to manufacturers, importers, downstream users and any other interested parties on their respective responsibilities and obligations.

Enforcement (Title XIV)

Member States are required to lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and to take all measures necessary to ensure that they are implemented. The penalties must be effective, proportionate and dissuasive.

Annexes

The Regulation contains the following Annexes:

Annex I:	General provisions for assessing substances and preparing chemical safety reports
Annex II:	Guide to the compilation of safety data sheets
Annex III:	Criteria for substances registered in quantities between 1 and 10 tonnes
Annex IV:	Exemptions from the obligation to register in accordance with article 2(7)(a)
Annex V:	Exemptions from the obligation to register in accordance with article 2(7)(b)
Annex VI:	Information requirements referred to in article 10
Annex VII:	Standard information requirements for substances manufactured or imported in quantities of 1 tonne or more
Annex VIII:	Standard information requirements for substances manufactured or imported in quantities of 10 tonnes or more
Annex IX:	Standard information requirements for substances manufactured or imported in quantities of 100 tonnes or more
Annex X:	Standard information requirements for substances manufactured or imported in quantities of 1,000 tonnes or more
Annex XI:	General rules for adaptation of the standard testing regime set out in Annexes VII–X
Annex XII:	General provisions for downstream users to assess substances and prepare chemical safety reports
Annex XIII:	Criteria for the identification of persistent, bioaccumulative and toxic substances, and very persistent and very bioaccumulative substance
Annex XIV	List of substances subject to authorisation
Annex XV	Dossiers
Annex XVI	Socio-economic analysis
Annex XVII	Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles

Development of the Regulation

Before the first reading

Following a request from the European Council on 24–25 June 1999, the Commission published the White Paper on the Strategy for a Future Chemicals Policy (COM(2001)88) on 25 February 2001. The White Paper elicited numerous reactions, including from the Council and the European Parliament, including proposals to simplify the strategy or to reinforce the protection of the environment and health it would provide. The Commission met with stakeholders and established expert groups before publishing a draft proposal for a Regulation on 7 May 2003. This was strongly criticized by Governments of three Member States (Britain, Germany and France) as well as non-Member States (USA, Asia). A joint

letter written by President Chirac, Chancellor Schroeder and Prime Minister Blair was sent to Commission President Prodi before the Commission had even finalized the Proposal. This letter warned of the possible impacts REACH might have on the competitiveness of the European chemical industry. At the time of the letter, these three Member States together could constitute a blocking minority and hence it was a powerful expression of opinion. Consequently, the letter may have influenced the Decision that the proposal would be examined by both the Competitiveness Council and the Environmental Council.

The publication of draft legislation for consultation was unprecedented and emphasizes how contentious the Proposal was. Following the consultation and following further studies, discussions, position papers, lobbying and negotiations, the Commission formally proposed REACH on 29 October 2003. This Proposal was substantially modified from the earlier draft and overall these changes led to a reduced burden on industry and the weakening of environmental provisions.

In the European Parliament there was a conflict of competence between the Environment Committee and the Industry Committee as regards which should take the lead role on the proposal needed to be resolved. In the end, the Council of Presidents decided that the Environment Committee would be the lead committee on REACH.

In May 2004, the United Kingdom and Hungary released details of their 'one substance one registration' (OSOR) proposal, aimed at simplifying the registration procedure for chemicals under REACH. They were encouraged to develop the proposal by the Competitiveness Council, after a favourable response to the initial idea by a number of Member States.

At the Parliament's Environment Committee meeting on 30 November 2004, the rapporteur Guido Sacconi urged for caution amidst signs that Member States wanted to make significant changes to the REACH proposal. Instead of making major changes to the proposal he called for fine-tuning and consolidation of the balance struck between the industrial and environmental concerns. There were further concerns regarding changes to the proposal when the Industry Commissioner, Günter Verheugen, said in a 'better Regulation' speech in March 2005, that the Commission would screen existing proposals, which were with Parliament and Council, and withdraw them as necessary. This led to speculations that the new Commission would table a radically modified proposal on REACH. In the end the Environment Commissioner Stavros Dimas was forced to squash out these rumours, stating that the Commission had no plans to withdraw the REACH proposal, or to rewrite and resubmit it. Another distinctive feature of the REACH debate was the sheer number of Impact Assessments of varying quality with many of them being clear lobbying tools.

In the Competitiveness Council meeting on 6 June 2005 the ministers backed a proposal to establish a rolling plan for substances liable for evaluation, to be coordinated by ECHA. The rolling plan was based on a proposal by Malta and Slovenia, wherein a staged registration regime is established for the evaluation of substances according to prioritization criteria.

In August 2005, the European Commission initiated its REACH Implementation Projects (RIPs) with the intention of developing tools and guidance for industry on various aspects of REACH and a month later the UK Presidency compiled a compromise text based on the discussions to date.

A week before the first reading due on 18 November 2005, a compromise text on REACH had been agreed between the centre-right EPP party and the socialists covering substance registration procedures. The deal delayed the deadline for the registration of the most dangerous chemicals from three to six years. Firms would also be able to use a higher degree of generic exposure categories for risk assessments and some of the more expensive tests would not be required. When announcing the deal the rapporteur Guido Sacconi did not want to claim that the compromise provided the best possible balance but that it was the best politically available balance. It was rumoured that Guido Sacconi was pressured to accept EPP conditions to avoid a postponement of the vote.

First reading developments

On 18 November 2005, the MEPs reached their first reading position on REACH. The votes for adopting REACH were 398 votes in favour, 148 against and 36 abstentions. The MEPs supported the so-called Sacconi–Nassauer compromise, which weakened the registration requirements, which was quite similar to the UK Presidency's compromise proposal. The mechanism of OSOR was adopted by the Parliament, but with an opt-out clause, where firms would only have to refer to confidentiality problems to avoid OSOR. The MEPs also extended the time during which data would remain confidential from ten to fifteen years. The Socialists, Greens and Liberals joined forces to strengthen the authorisation procedure by defeating the centre-right EPP. Under the UK proposal it would have been possible to continue to use substances of very high concern if certain conditions were met, such as adequate control of risks. The Parliament however endorsed a stronger approach, where all substances of very high concern ought to be authorised *only* when suitable alternatives or technologies do not exist. In addition, the MEPs decided to set a five-year limit for all authorisations, compared to the case-by-case approach in the UK proposal. In addition several materials were exempted from the scope of REACH, such as cellulose pulp, minerals, ores and their concentrates, crude oil and several inorganic substances.

On 13 December 2005, the Competitiveness Council agreed a draft text, setting out the contents of its Common Position. As expected the main issue debated was the authorisation procedure and the obligations for substitution of substances of very high concern. As expected, the Council did not endorse the view of the European Parliament in its first reading. The Council decided that authorisations could be granted under the ‘adequate control’ route even if safer alternatives exist. However, the Council did move closer towards the view of the European Parliament by not granting an authorisation on the grounds of adequate control for substances that are persistent, bioaccumulative and toxic (PBT) or very persistent, very bioaccumulative (vPvB). It was now clear that reaching an agreement on authorisation would be one of the greatest challenges during the second reading.

Second reading developments

In June 2006, a group of 13 nations led by the United States issued a joint statement against REACH, with the aim to get it reviewed. The signatories were among the EU's biggest trading partners including Australia, Brazil, India, Japan, Korea, Malaysia, Mexico, Singapore, South Africa, Thailand and the United States. The coalition was put together by the United States, which has a history of being critical of REACH. A report[16] published in 2004 by the Special Investigations Division of the US House of Representatives provides an insight into the Bush administrations' hostile position towards REACH. According to the report, the Department of Commerce had planned, as early as 2003, a campaign to reach out

to countries planning to join the European Union, as well as countries outside of the European Union, in an effort to increase opposition to REACH.

During the opening debate in the Environment Committee, the Finnish minister for Trade and Industry and the chair for the second reading, Mauri Pekkarinen, supported the common position. He asked MEPs to 'seriously consider' what benefits might be achieved by retabling amendments, as this might lead to a 'snowball effect' where the number of amendments would be uncontrollable. Consequently, it was concluded that the Finnish Presidency was unlikely to support any changes to the authorisation procedure.

On 13 September 2006, the Environment Committee voted for a greener REACH in its second reading. The package was backed by 42 votes, with 12 votes against and 6 abstentions. On authorisation, the Environment Committee stuck to the European Parliament's stance in the first reading by requiring a mandatory substitution of substances of very high concern where alternatives exist. Before the vote in the European Parliament's plenary session in November, talks took place between the Parliament, Council and the Commission in trialogue meetings in accordance with the Interinstitutional Agreement in order to avoid the conciliation procedure. However, the negotiations between the European Parliament, Council and the Commission failed to achieve a deal in the meeting on 20 November. Then things took a turn for the worse during the scheduled final meeting on 27 November, when negotiations broke down after only an hour. At this point, the prospect of conciliation seemed increasingly likely with the substitution rules surrounding substances of very high concern being the main sticking point. An emergency meeting was scheduled for 30 November in which an informal deal was struck based on a compromise plan tabled by the Finnish Presidency. In the end, the European Parliament was unable to stick to its guns any longer and had to move from a requirement of mandatory substitution to mandatory substitution plans.

The European Parliament approved in its second reading on 13 December 2006 the compromise package agreed with the Council and the Commission with 529 in favour, 98 against and 24 abstentions. After the vote the Greens, the Nordic Green Left and the European United Left criticized the agreement on authorisations and questioned the transparency of the final negotiations between the European Parliament, the Council and the Commission.

Implementation of Regulation (EC) No 1907/2006

According to the accompanying document of the 26th annual report on monitoring the application of Community law (SEC(2009) 1684/2), ECHA has received about 2.7 millions pre-registration dossiers. If a company failed to pre-register by 1 December 2008, it can no longer place its phase-in substances on the market until it has completed registration.

The deadline for lead registrants responsible for coordinating the REACH registration process for producers and importers of the same substance was 30 November 2010. However, companies facing exceptional circumstances could be given more time to register if they were able to show that they could not meet the deadline because of circumstances beyond their control. ECHA listed in a press release[17] five specific instances where exceptional circumstances could apply. By the 30 November 2010 deadline 24675 registrations were submitted[18].

Within the process of authorisation ECHA has identified 73 substances (as of the end of December 2011) of very high concern (SVHC) for the candidate list subject to eventual authorisation. Out of these substances, seven were prioritized for authorisation. After a Commission Decision to make a substance subject to authorisation (inclusion in Annex XIV REACH) any manufacturer, importer or downstream user of that substance must apply for authorisation to use it. In September 2010 a committee of Member States voted to add the first six substances of very high concern (SVHCs) to the authorisation list and these six substances were moved from the candidate list to Annex XIV by Regulation (EU) No 143/2011. These six substances are 5-ter-butyl-2,4,6-trinito-m-xylene (musk xylene), 4,4′-diaminodiphenylmethane (MDA), hexabromocyclododecane (HBCDD), bis(2-ethylexyl) phthalate (DEHP), benzyl butyl phthalate (BBP) and dibutyl phthalate (DBP). A second batch of eight substances of very high concern was added to Annex XIV in February 2012. These were diisobutyl phthalate (DIBP), diarsenic trioxide, diarsenic pentaoxide, lead chromate, lead sulfochromate yellow, lead chromate molybdate sulphate red (2-chloroethyl) phosphate (TCEP) and 2,4-dinitrotoluene. These substances cannot be placed on the market or used in Europe without an authorisation. The substance specific deadlines for not being allowed to use the substances (sunset dates) ranges from 2014 to 2015. In addition Austria, Germany and the Netherlands have put forward proposals[19] to identify further eleven chemical substances as SVHC. The Member State Committee will review any comments on these when seeking agreement on the identification of the substances as SVHC before ECHA includes them in the candidate list.

On 29 August 2011 ECHA published a list of 20 substances of very high concern to be potentially included in the candidate list based on proposals from Member States and ECHA.[20] Nineteen of these substances are classified as carcinogenic and/or toxic for reproduction. In addition, one substance is proposed to be identified as a substance of ‘equivalent concern’ because of its endocrine disrupting properties and potential for serious effects on the environment. More detailed information about the reasons for inclusion of the substances to the candidate list as well as the proposed authority can be found on ECHA's consultation website.[21]

In February 2011 the ECHA published a report[22] of its experiences from its evaluation activities carried out in 2011. It found that a large part of the testing proposals had been adequately prepared. However, in the compliance checks only a small proportion of the dossiers were closed without further action. The report provides key messages for registrants and the ECHA hoped that the companies pay attention to these when preparing dossiers for the May 2013 deadline for substances produced or imported at a volume of 100-1000 tonnes per annum..

Enforcement and court cases

Member States were obliged to notify to the Commission their national provisions for penalties applicable for REACH infringements by 1 December 2008. According to the accompanying document of the 26th annual report on monitoring the application of Community law (SEC(2009)1684/2), the Commission drew Member States' attention to that obligation during the meetings of the REACH Competent Authorities and administrative letters before and after the notification deadline. A number of Member States did not fulfil these obligations and therefore by March 2009 legal enforcement action was launched against eight Member States. These have now been closed.

There has been a number of applications ((Case T-96/10, 17.2.2010), (Case T-1/10 4.1.2010) (Case T-94/10, 17.2.2010), (Case T-93/10, 17.2.2010), (Case T-268/10, 10.6.2010), (Case T-346/10, 18.8.2010) challenging the inclusion of specific substances into the candidate list . In these on-going cases the applicants are normally consortia of industries using these substances.

Further developments

The Commission has started the review of the scope of REACH mandated by Article 138(6), which calls on the Commission to assess by 1 June 2012 whether or not to amend the scope of REACH to avoid overlaps with other relevant provisions of EU law.

Related legislation

The following legislations interact with the REACH Regulation (EC) No 1907/2006:

- Regulation (EC) No 1272/2008 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 (CLP).
- Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (DSD).
- Directive 1999/45/EC on the approximation of the laws, Regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (DPD).
- Directive 2000/60/EC establishing a framework for Community action in the field of water policy (Water Framework Directive).
- Regulation (EC) No 689/2008 concerning the export and import of certain dangerous chemicals.
- Directive 2000/53/EC on end-of-life vehicles.
- Directive 2002/95/EC on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS Directive).
- Directive 2002/96/EC on waste electrical and electronic equipment (WEEE Directive).
- Directive 8/98/EC on placing of biocidal products on the market.
- Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.
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