REACH

THE EU's NEW CHEMICALS REGULATION

KEMK

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MINISTRY OF SOCIAL AFFAIRS AND HEALTH
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Contents

WHAT DOES REACH MEAN? 3

REGISTRATION 5

EVALUATION 6

AUTHORIZATION PROCEDURE 8

BANS AND RESTRICTIONS 8

COMMUNICATING INFORMATION IN THE SUPPLY CHAIN 9

GHS – HARMONISED CLASSIFICATION AND LABELLING SYSTEM 11

ENTRY INTO FORCE 11

EFFECTS IN FINLAND 11

FURTHER INFORMATION 13

WHAT DOES REACH MEAN?

REACH is a new chemicals regulation, (EC) No 1907/2006, which is binding on the Member States of the European Union. The REACH Regulation came into force on 1 June 2007. REACH applies primarily to European manufacturers of chemical substances and importers who are importing substances into the EU region. The regulation also places new obligations on downstream users of chemicals[1].

Operators must show how chemicals can be used safely. Sharing information up and down the supply chain of substances and mixtures will increase with the REACH Regulation.

If you are a manufacturer, importer or downstream user as referred to in the REACH Regulation, check the position of your company in the REACH system and find out what your company's obligations are.

It is important for implementing the REACH system to clarify the concepts and definitions used in the Regulation, for example the definitions of a substance and mixture (preparation). These are given in Article 3 of the Regulation and can also be read for example at www.reachinfo.fi and from June 2007 on the website of the Finnish National Helpdesk at www.reach-neuvonta.fi.

The duties of the authorities in the sector will also change. Supervision will emphasize supervision of the implementation of registrations and supervision at the workplace of the risk management measures mentioned in the safety data sheets revised to comply with the Regulation.

REACH is an abbreviation for the **R**egistration, **E**valuation and **A**uthorization of **Ch**emicals. The aim of the REACH Regulation is ensure a high level of health and environmental protection in the entire EU and at the same time to increase the competitiveness of the EU's chemical industry through stringent safety requirements and the promotion of product development. This will be achieved by registering substances in a central database, evaluating certain substances,

[1] Downstream users are companies that use chemicals in their operations. A distributor, on the other hand, is a company that only stores and forwards chemicals in the EU region. Distributors and consumers are not downstream users.

an authorization procedure for the most hazardous substances, and a 'protective net' of bans and restrictions on chemicals. The new system is based on the risk management of **substances** contained in chemical mixtures and, in certain cases, contained in articles.

All substances manufactured in or imported into the EU in a quantity of at least one tonne per manufacturer or importer per year will be registered in a chemicals database maintained by the European Chemicals Agency. The purpose of registering is to document the safety assessment concerning a substance and the information used in it. In order to avoid unnecessary testing, the Agency will evaluate the necessity of registrants' testing proposals. The Agency and authorities in the EU Member States will also evaluate the risks in certain substances annually. The use of substances causing very high concern will be subject to a permit.

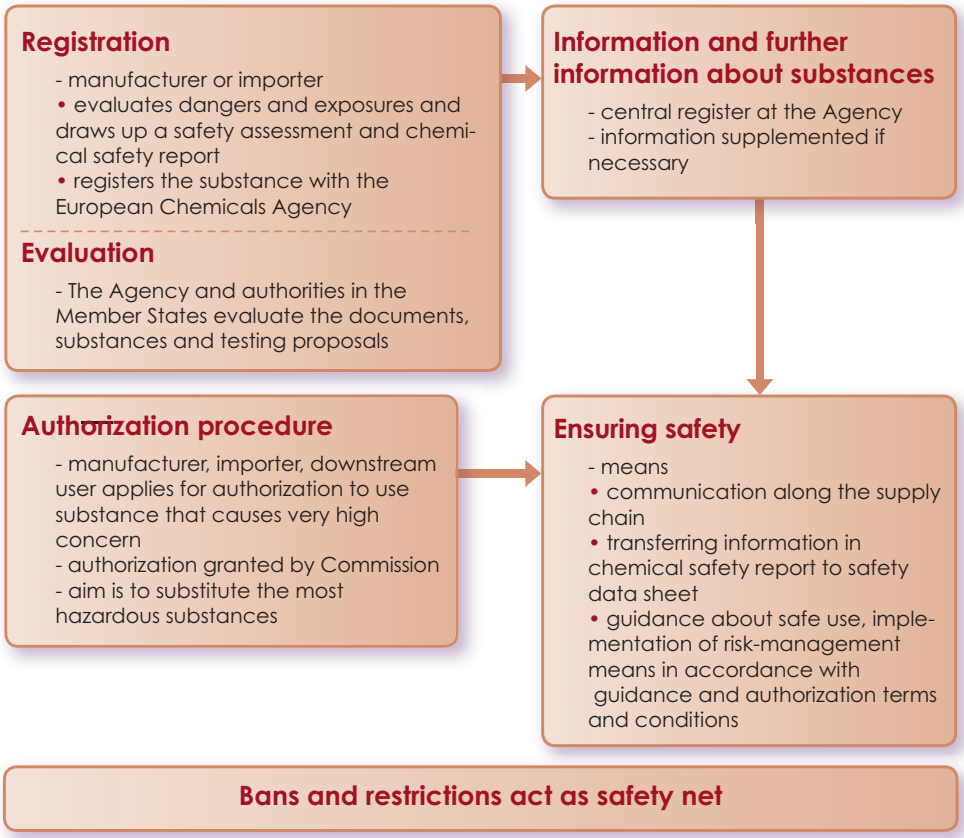
Substances that cause very high concern are those that are carcinogenic, mutagenic and toxic for reproduction, those that are persistent, bioaccumulative and toxic, and those for which there is scientific evidence that they cause equivalent concern.

A manufacturer or importer of a substance must make a safety assessment of the manufacture and use of their substance, taking into account the various uses of the substance in question. For this reason, users of a substance will supply information about their own use to the manufacturer or importer of the substance in question. The manufacturer or importer will take into consideration the results of the safety assessment in their safety data sheets.

The new European Chemicals Agency is situated in Helsinki (Annankatu 18, see the cover picture). The Agency will administer the REACH system and support national authorities in technical and scientific matters associated with the implementation of the REACH Regulation. The tasks of the Agency will include the acceptance of registrations and authorization applications, the maintenance of various databases, and publicity. The Agency started operating on 1 June 2007. Agency employees will come from all the Member States.

The National Product Control Agency for Welfare and Health (STTV) and the Finnish Environment Institute (SYKE) has been appointed as the Competent Authorities for the REACH Regulation. These authorities have also set up a helpdesk for REACH matters.

Figure 1: Simplified diagram of REACH system



REGISTRATION

A substance that falls within the registering procedure (as is, in a compound or in an article) cannot be manufactured or placed on the market in the European Union without being registered. The aim is to gather information about the properties of a substance and ensure that a safety report on the substance has been made.

What does registration mean and who performs it?

Registration means the acquiring of information about a **substance**, evaluating the risks associated with the handling of a **substance** and forwarding this information to the European Chemicals Agency. The requirement applies to a manufacturer or importer (import into the EU), if the manufacture or import quantity is at least 1 tonne/year per manufacturer or importer. Generally, the manufacturer or importer of a **substance** will prepare registration in cooperation with other manufacturers or importers of the same substance.

The amount and extent of information required in connection with registration depend primarily on the tonnage of the substance. The REACH Regulation defines precisely what information must be submitted. For some substances, however, there are exceptions to the registration requirements. Phase-in substances will be registered over a period of eleven years from the entering into force of the Regulation. The most dangerous substances and those being produced in large amounts are being registered first.

A substance in an article must also be registered if there is more than one tonne of it annually in the articles per manufacturer or importer, or when the substance is intended to be released from the article. In this case, a pre-determined schedule is followed for registering the substances. Furthermore, even if the substance is not intended to be released from the article, the Agency must be notified about the substance if the following conditions are met: the substance is one that causes very high concern, the substance is contained in the articles in question in the quantity of more than one tonne per year per manufacturer or importer, and there is more than 0.1 per cent by weight of the substance in the articles.

Before registration, manufacturers and importers will pre-register their substances so that manufacturers and importers of the same substance can contact each other in order to make the actual registration. This pre-registering must be done between 1 June 2008 and 1 December 2008. Pre-registering is important so that the transitional times given for the actual registration in the Regulation can be applied.

The Agency will carry out a pre-check on the registrations and request additional information if necessary. The manufacture and import of a substance may continue if the Agency does not indicate otherwise within three weeks or three months of the submission of the registration. The Agency will give registered substances a registration number. Registration is subject to a fee.

The Agency will maintain an online public database, which will have information about the name, classification and labelling of the registered substances, results of toxicity tests, the no-effect concentrations determined for a substance, and the instructions required for safe handling. The Regulation stipulates what information can be considered to be trade secrets or professional secrets and thus can be excluded from a public database.

EVALUATION

The purpose of evaluation is to prevent unnecessary testing, to guarantee the quality of testing and to create confidence that industry is complying with the set requirements. Decisions on what further information is needed are taken on the basis of evaluation.

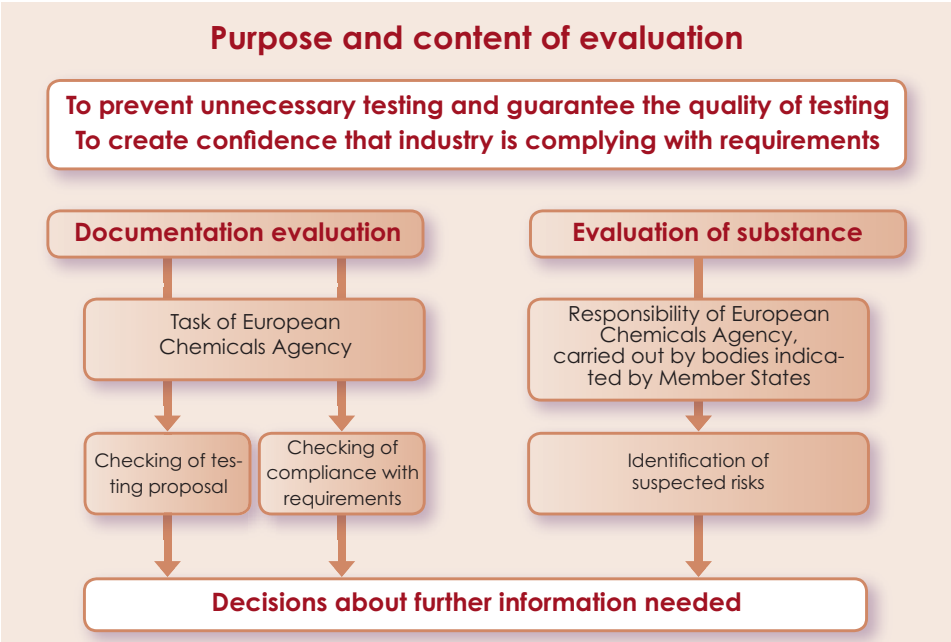
Who evaluates and what?

Evaluation in connection with the REACH Regulation means two things:

- Evaluation of documents means an evaluation carried out by the European Chemicals Agency of the compliance of registration and other documents with requirements and the necessity for a proposal for testing presented by an operator. The Agency will be able to ask the registrant to supply information needed about a substance.

- In addition to evaluating documentation, authorities will evaluate substances in accordance with an annual work list. Authorities and the Agency will together select for evaluation substances that are suspected of causing a particular risk. The Agency will draw up a proposal for the first evaluation list four years after the Regulation comes into force. The aim of evaluation is to find substances about which **additional information** is needed in order to secure risk management. The further information must be sent within the deadline decided upon by the Agency.

Figure 2: Evaluation procedure in the REACH system



AUTHORIZATION PROCEDURE

The aim of the authorization procedure is to guarantee adequate management of risks in the handling of substances causing very high concern and to promote the substitution of these substances with safer substances or methods. The procedure will be staggered starting on 1 June 2008.

Who applies for authorization and for what substances?

Substances recognised as causing very high concern come within the sphere of the authorization procedure. An authorization applies to the **use** of a substance. Substances requiring an authorization will be listed in an Annex in the Reach Regulation; these substances cannot be placed on the market or used without an authorization. Substances will be added to the Annex gradually, a few dozen at a time. An application for authorization will not need to be submitted until a substance has been added to the Annex. It is not necessary to apply for authorization to manufacture a substance or to use an article.

The authorization application will be submitted to the European Chemicals Agency, and a decision on it will be taken by the European Commission. An application for authorization for the use of a substance will be made by the manufacturer, importer or downstream user of the substance or all of them together. A downstream user will not need to apply for authorization for the use of a substance if its use is already covered by the authorization obtained by the manufacturer or importer.

Authorization for the use of a substance will be granted if the applicant shows that the risks caused by the use of the substance are at an acceptable level. Authorization can also be granted when the socio-economic risks outweigh the risks caused by use or if there are no suitable alternative substances or technologies available.

An authorization granted will be given an identity number that must be mentioned on the label of the substance or of any preparation containing it. An authorization granted will always apply to a specific use. Conditions may be set for the authorization, and the authorization will be granted to a named person (persons, company, companies). The preconditions for granting authorization will be subject to a time-limited review on a case-by-case basis.

BANS AND RESTRICTIONS

According to the REACH Regulation, the manufacture, placing on the market and use of a substance in the EU can be banned for a justified reason or it can be restricted. A proposal for a ban or restriction can be made either by the European

Chemicals Agency or an authority in a Member State. The decision about a ban or restriction will be made by the European Commission, and the decision will be added to the Annex in the Regulation. Existing bans and restrictions concerning substances have been transferred as such to the Regulation Annex on bans and restrictions. National restrictions will be replaced by the REACH Regulation Annex from 1 June 2009.

COMMUNICATING INFORMATION IN THE SUPPLY CHAIN

Chemical safety assessment and chemical safety report

A downstream user of a chemical, e.g. an industrial plant using a substance or mixture in a process, will notify the manufacturer or importer of the substance in question (or substance included in a mixture) about its own use and the exposure of human beings or the environment to the substance in connection with the use. The manufacturer or importer, for their part, will take into account the method of application and the exposure associated with it in the chemical safety assessment that they make. The safety assessment will deal with the safety perspectives associated with the manufacture and use of a substance throughout the entire life cycle of the substance. There is an Annex in the REACH Regulation describing how to draw up an assessment and chemical safety report.

A manufacturer or importer will send a chemical safety report written on the basis of the safety assessment to the European Chemicals Agency in connection with the registration. In the report, the manufacturer or importer will give notice of all the known uses of the substance reported on.

Information for safety data sheet

A manufacturer, importer or downstream user (in the capacity of formulator of substances) will append a description of the risk management procedure, arising as a result of the downstream user's use and the safety assessment (also known as an exposure scenario), to the safety data sheet supplied with the chemical. An exposure scenario is a description of the measures needed in order to ensure that no risk is caused to health or to the environment by the use of that particular substance.

A downstream user will check that his own use[2] is included in the safety data sheet and that instructions for safe use are given in an appendix to the sheet. If the downstream user's use is not indicated in the safety data sheet, the downstream user must notify the manufacturer, importer, other downstream user or

[2] In the REACH Regulation, 'use' means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilization.

distributor so that this use can be taken into account in the manufacturer's or importer's safety assessment. If a downstream user so desires, for example because of a business secret relating to the use of a substance, he may himself also perform a safety assessment in accordance with the Regulation. A downstream user does not, however, need to perform his own safety assessment if the amount of own use is less than one tonne per year.

A downstream user must observe the safety guidelines applying to the use of a substance or preparation.

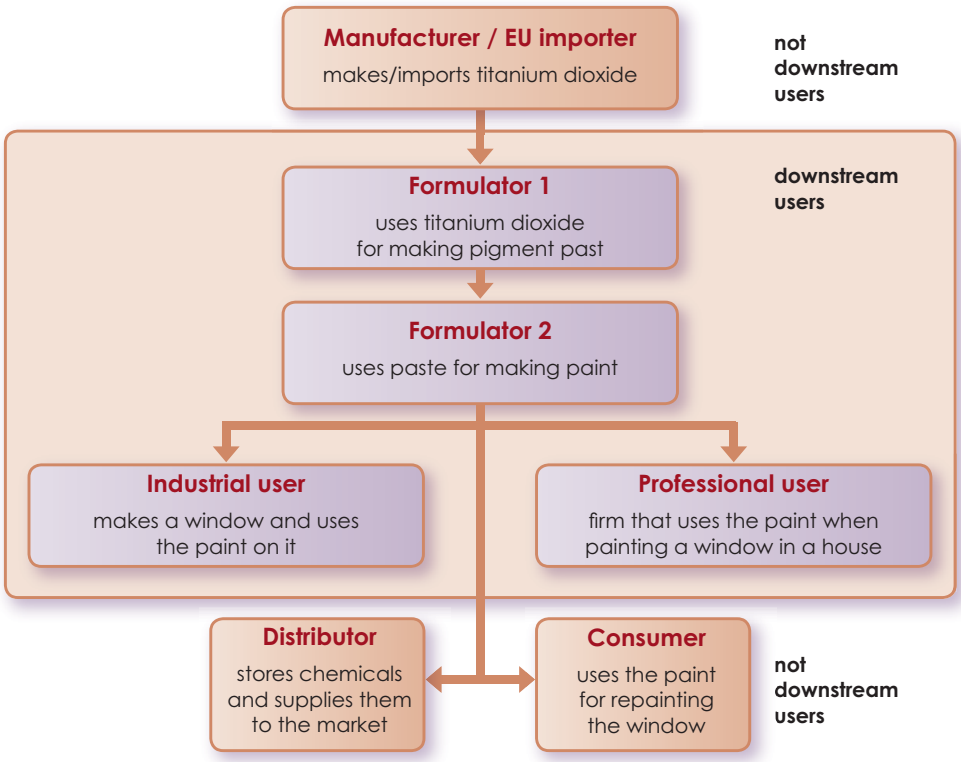
If a company using a chemical (such as a formulator of substances) supplies that chemical to another user, the use by the next party in the chain must also be taken into account in the registration, safety assessment and safety data sheet of the chemical.

Distributors of a chemical, such as companies importing substances and preparations into Finland from within the EU and other chemical suppliers, are obliged to communicate information both up and down a substance's supply chain.

The safety data sheet will in the future include more information than before (e.g. safety assessment information), but its structure will remain almost unchanged.

It will not be necessary to update safety data sheets immediately on 1 June 2007 to comply with Annex II of the REACH Regulation. In practice, the need to update a safety data sheet will arise as the implementation of the REACH Reg-

Figure 3: Example of downstream users in REACH system



ulation progresses, for instance when the first registration stage for substances comes to an end and when the classification and labelling inventory of all the substances on the market has been completed by 1 December 2010.

GHS – HARMONISED CLASSIFICATION AND LABELLING SYSTEM

The European Union is preparing a new EC regulation on the classification and labelling of chemicals. This regulation will implement the globally harmonized system (GHS) in the EU region, an internationally approved system for determining and classifying the dangers caused by chemicals and for supplying information on the dangers. The Commission's proposal for the GHS Regulation was presented on 27 June 2007.

ENTRY INTO FORCE

The Reach Regulation entered into force on 1 June 2007. It prescribes transitional times of varying length for the procedures in the Regulation (cf. Figure 4). Many of the obligations will be applied from 1 June 2008, at which time the registration of new substances and pre-registration of 'existing' substances (phase-in substances), which must be done by 1 December 2008, will begin.

EFFECTS IN FINLAND

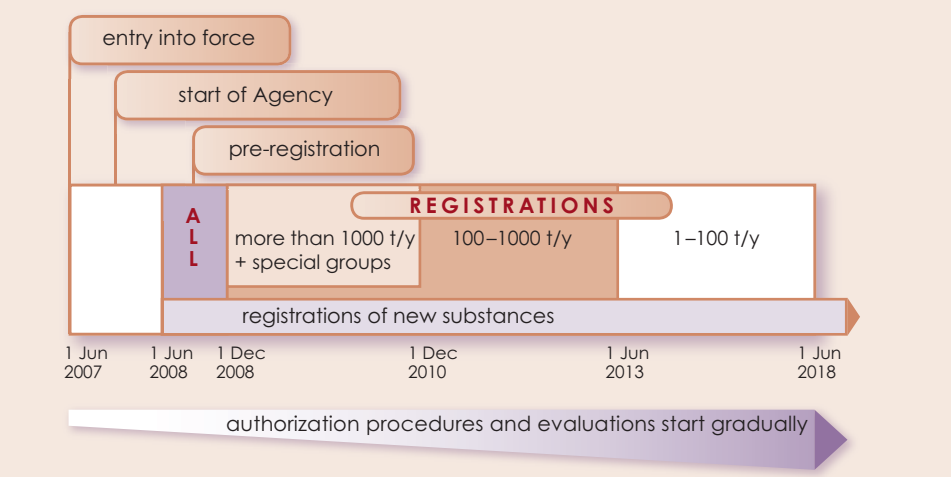
The REACH and GHS Regulations are EC Regulations and will apply in Finland as they stand.[3] Versions of REACH in Finnish and Swedish were published in the European Union's Official Journal on 30 December 2006 (EUOJ No. L396) and later as a corrigendum on 29 May 2007 (EUOJ No. L136).

The timetable for the GHS Regulation entering into force is still open at the moment because the Commission's proposal for the Regulation has not yet been adopted by the European Parliament and the Council.

National legislation overlapping the Regulations will be repealed. Also, national legislation will be enacted specifying the enforcement of the Regulations and the sanctions for infringing them. The chemicals enforcement carried out by the authorities will stress the implementation and observance of the means of risk management stated in the safety data sheets. An advisory service as specified in the REACH Regulation started up at the National Product Control Agency for Welfare and Health (STTV) and the Finnish Environment Institute (SYKE) on 1 June 2007.

[3] Directives are separately implemented in national legislation, but EC Regulations are legislation which is directly binding upon all Member States.

Figure 4: Timetable for REACH system



Practical guidelines

The European Chemicals Agency has issued implementation guidelines prepared in cooperation with industry, the authorities and the Commission, giving detailed instructions to the various players concerning the application of the Regulation (cf. link at www.reachinfo.fi).

The new legislation will place new obligations on the manufacturers, importers, downstream users and distributors of chemicals. The players (manufacturer, importer, downstream user) must find out what their role or roles are in observing the obligations of the REACH Regulation. It will also be necessary to draw up a list of the substances and mixtures (preparations) in the players' own use and check that up-to-date safety date sheets are available for all of them. The gathering of this information will facilitate the interaction and exchange of information between the downstream user and chemicals supplier. Later, once the GHS Regulation enters into force, the classifications that will change to conform to the GHS criteria must be transferred correspondingly to labelling warnings within the transitional times specified in the Regulation.

It is important for a user of a chemical to notify a chemicals supplier in good time of his own use and to ensure that his use is covered by the safety assessments performed by the manufacturer or importer. At the same time, it is worth ensuring that the chemicals supplier will continue supplying the substance in question for the purpose indicated.

REACH and GHS will not, however, change everything. For example, the general packaging requirements for chemicals and supervision of retail sales, the submitting of a safety data sheet, the forwarding of information about chemicals to the product register of the National Product Control Agency for Welfare and Health, and the rules and regulations applying to the industrial handling and storage of chemicals, will remain unchanged.

FURTHER INFORMATION

Information about the REACH and GHS Regulations is available on the REACH website of the Advisory Committee on Chemicals at www.reach-info.fi.

The REACH Regulation requires national authorities to set up a REACH Helpdesk, which in Finland is organized by the National Product Control Agency for Welfare and Health and the Finnish Environment Institute (www.reachneuvonta.fi).

The European Chemicals Agency will be maintaining various databases on chemicals, and some of these databases will be made publicly available on the Internet.

A great deal of information about the implementation guidelines for the REACH Regulation can be found on the European Chemicals Bureau's website at http://ecb.jrc.it/REACH/.

Information about the international GHS system can be found at www.unece.org/trans/danger/publi/ghs/ghs_rev01/01files_e.html.

The website of the Advisory Committee on Chemicals www.kemikaalineuvottelukunta.fi has information on topical matters concerning chemicals and links to sources of additional information.

The European Union has approved the new Chemicals Regulation, REACH, which entered into force on 1 June 2007 and is directly binding legislation also in Finland. The Regulation places obligations on chemicals manufacturers, importers and downstream users. Downstream users are companies that use chemicals in their operations. The REACH Regulation also applies in certain cases to articles from which chemicals are released intentionally, and thus manufacturers of machines and equipment, for example, may come within the compass of the obligations in the REACH Regulation.

This brochure by the Advisory Committee on Chemicals depicts the various procedures and timetables in the REACH Regulation and the effects of the Regulation in Finland. Further information on the Regulation is available on the REACH Helpdesk, which was set up on 1 June 2007 (www.reachneuvonta.fi), and on the website of the Advisory Committee on Chemicals www.reachinfo.fi

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