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REACH – Overview

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REACH- Overview

1 Introduction

On 1st June 2007, a totally revised legislation for chemicals will become effective in the European Union. Known by its abbreviation REACH the "Regulation of the European parliament and of the council concerning the ***R***egistration, ***E***valuation, ***A***uthorisation and Restriction of ***Ch***emicals" will fundamentally change the current European Union's chemical control legislation, which presently consists if the Dangerous Substances Directive (DSD), the Dangerous Preparations Directive (DPD), the Existing Substances Regulation and the Marketing and Use Directive.
The text of the REACH regulation was published in the Official Journal of the European Union on 30 December 2006 (Regulation (EC)1907/2006).

This brochure gives a general overview of REACH. Further brochures are available on request from Ciba® Expert Services, dealing with industry-specific issues and recommended actions for:

- importers
- downstream users
- small/medium chemical producers in the EU

2 Registration

At the core of REACH is a scheme for the registration of commercialized substances. Upon entry into force of REACH, all substances will need a technical dossier and be registered, before being manufactured or imported in quantities of 1 t/a or more. There are increasing regulatory demands depending on the respective volume. Transitional provisions apply for substances that already have been on the market. For these so-called phase-in substances, different deadlines apply over an eleven years period. Higher tonnage substances require the most data, and have to be registered first. Lower tonnage substances require less data and can be registered later. Additionally, phase-in substances need to be pre-registered, to enable manufacturers and importers of the same substance to share data. Registration requirements apply equally to either the EU-manufacturer of the substance or to the importer, who brings the substance into the EU.

The pre-registration of phase-in substances will start 12 months after the introduction of REACH and will end 6 months later (1 June 2008-1 December 2008).

For registration of phase-in substances, the following deadlines apply:

- 3.5 years: for substances in quantities of 1000 t/a or more and all known CMR (carcinogenic, mutagenic, toxic to the reproduction) class 1 or 2 substances (> 1 t/a) and substances classified as very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment (R50/53) (>100 t/a)
- 6 years: for substances in quantities of 100 t/a or more,
- 11 years: for substances in quantities of 1 t/a or more.

Substances needing registration:

- Substances imported or manufactured at > 1 ton per annum, either produced or marketed as such or in preparation, have to be registered, unless exempt.
- Substances in articles are subject to registration (at > 1 ton per annum of substance) if they are dangerous, released during normal and reasonably foreseeable use and disposal, or if they could be released unintentionally and adversely affect human health or the environment (for details see below).

- ***Notified New Substances***

Substances already notified as new substances under the Dangerous Substance Directive[1] and listed in ELINCS are considered as having been registered. A registration update is however required if the respective volume threshold is exceeded or if new information is available.

- ***New Substances***

During the first year after REACH will have become effective, new substances must be notified still according to the present new substance legislation 92/32/EEC. After this first year new substances must be registered according to REACH before they can be marketed.

- ***Exemptions***

- Non-isolated intermediates
- The specific substances listed in Annex IV of the Regulation
- Substances covered by Annex V
- Radioactive substances
- Products resulting from use
- Products resulting from reactions with additives
- By-products
- Hydrates, providing the anhydrous form is registered
- Non-dangerous natural substances
- Natural gas, crude oil and coal
- Substances used exclusively in applications covered by the Plant Protection Products Directive or the Biocidal Products Directive are also exempt.
- Polymers (for details see below)

- ***Research Chemicals***

Substances < 1000 kg are generally exempt from registration, thereby also covering products used in research and development. Above this quantity, a product- and process-orientated research and development (PPORD) exemption can be granted for 5 years - extendable for further 5 years depending on use. The basis is the submission of a dossier to the European Chemical Agency containing the research program and a list of the customers, substance identity, labeling, quantity and information on the quality. A substance used under the PPORD exemption cannot be supplied to the public.

- ***Preparations, semi-finished goods, articles***

As mentioned above, REACH applies to substances either being produced or marketed as such or in mixtures or preparations.

Substances in articles must be registered if the substance is present in quantities over 1 ton per producer or importer per year and the substance is intended to be released under normal or reasonably foreseeable conditions of use.

[1] Directive 92/32/EEC of 30 April 1992 amending for the seventh time Directive 67/548/EEC.

Any producer or importer of articles should notify the Agency if a substance is of very high concern, is present in those articles in a concentration above 0.1% and in quantities over 1 ton per producer or importer per year. This is not necessary if the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal.

The Agency can take decisions requiring producers or importers of articles to submit a registration for any substance in those articles, if the substance is present in those articles in quantities over 1 ton per producer or importer per year, the substance is released from the articles, and the release of the substance from the articles presents a risk to human health or the environment.

- ***Intermediates***

Non-isolated intermediates are exempted from REACH. A distinction is made between isolated intermediates which remain on site, and those which are transported to other sites under controlled conditions. For the latter type of intermediate, where more than 1000 tons per manufacturer per year are transported, more data is required.

On-site isolated intermediates at 1 ton per annum are registered with information on the identity of the manufacturer and substance, classification and available test data. Transported intermediates, manufactured and used with strictly controlled release are registered with the same information as on site isolated intermediates at > 1 ton and with Annex VII test (see below) data at > 1,000 ton per annum. If a strict control can not be shown, requirements apply as for normal substances.

- ***SIEF and consortia formation***

In order to avoid repetition of work, and above all to avoid duplication of vertebrate testing, pre-registrants of phase-in substances will enter a SIEF (Substance Information Exchange Forum) in order to help registrants to find other registrants of the same substance. Membership of the SIEF is mandatory for all pre-registrants of a substance. In certain cases the SIEF might evolve into a voluntary legal entity, a consortium or task force, set up to jointly submit registration dossiers.

The establishment of consortia/task forces will probably be one of the biggest challenges created by the future legislation. A number of problems must be solved, in forming consortia:

- legal (antitrust laws),
- financial (fair burden sharing),
- organizational (collaboration of various departments within the company and between the different companies),
- psychological (different mindsets, national and company cultures),
- protection of trade secrets.

- ***Polymers***

REACH does not apply to polymers meeting the respective OECD polymer definition. Non-registered monomers or other starting substances, at 2% (w/w) in a chemically-bound form in the polymer at 1 ton per annum have to be registered. The polymer exemption is intended to be reviewed, but no deadline is provided in the regulation.
The alleviations for intermediates (see above) can not be applied to monomers.

- ***Chemical Safety Report (CSR)***

The registrant must perform a chemical safety assessment and prepare a chemical safety report for all substances if he manufactures or imports the substance in quantities of 10 tons or more per year. The chemical safety report documents, the chemical safety assessment which should be conducted for either each substance on its own or in a preparation or a group of substances. A chemical safety assessment needs not be performed for a substance which is present in a preparation if the concentration of the substance in the preparation is less than certain limits. A chemical safety assessment includes a human health hazard assessment, a physicochemical hazard assessment, an environmental hazard assessment and a PBT and vPvB assessment.

If, as a result of carrying out the hazard assessments, the manufacturer or importer concludes that the substance meets the criteria for classification as dangerous or is assessed to be a PBT or vPvB, the chemical safety assessment shall include an exposure assessment including the generation of exposure scenarios.

CSR is part of the technical submission dossier.

- ***Safety Data Sheets (SDS)***

The primary tool for information transfer is the well-established safety data sheet (SDS) for all dangerous substances. The provisions of the current Safety Data Sheet Directive (91/155/EEC as amended) are carried over into the REACH. The SDS contains all current 16 chapters with specific expansions (e.g. registration numbers, identified uses and uses advised against, information on substances requiring authorization, exposure scenarios in Annex etc.). Where chemical safety assessments are performed, relevant exposure scenarios shall be annexed to the SDS and shall thus be passed down the supply chain.

- ***Globally Harmonised System (GHS)***

The GHS is the United Nations Globally Harmonised System of Classification and Labeling of Chemicals. It was agreed at the 2002 UN World Summit on Sustainable Development in Johannesburg that the GHS should be implemented worldwide, with a target date of 2008.
The GHS will provide harmonised health and safety information for chemical substances and mixtures. The European Commission has stated that the GHS implementing legislation would be adopted at the same time as the final REACH legislation. A draft proposal for a Regulation to implement the GHS into Community law is currently under preparation by the Commission services. A public stakeholder consultation is foreseen during 2006. The new legislation will replace, after a transitional period, the currently existing provisions on classification and labeling of chemicals, as set out in Council Directive 67/548/EEC and Directive 1999/45/EC as amended. The introduction of GHS may well present a challenge equivalent to the implementation of REACH, in terms of administrative efforts.

- ***Technical dossier***

The technical dossier for registration contains information on the properties, uses and on the classification of a substance and also guidance on safe use. Specific annexes of the Regulation specify the information required for registration. The general technical, commercial and administrative information needed for all registrations is stipulated in Annex VI.

The following information is required, which is very similar to the current new substance notification scheme:

- the identity of the manufacturer or importer;
- the identity of the substance;
- information on the manufacture and use of the substance;
- the classification and labeling of the substance;
- guidance on safe use of the substance;
- robust study summaries;
- a statement as to whether or not information has been generated by testing on vertebrate animals;
- proposal for testing where for substances with a volume above 100 t/a.

3 Authorization of high concern substances

Substances of very high concern will be listed in Annex XIV of the regulation and have then to be authorized before manufacture or use. Chemicals of very high concern will be those classified as categories 1 or 2 carcinogens, mutagens or reproductive toxicants (CMRs), persistent, bioaccumulative and toxic substances (PBTs), very persistent and very bioaccumulative substances (vPvBs), and on a case-by-case basis endocrine disrupters and substances of an equivalent level of concern. An authorization will only be granted upon specific application for which it can be shown that the risk is adequately controlled and there are no suitable alternatives. Authorizations are limited to certain uses or subject to specific restrictions.

3.1 Test data

The information on hazardous properties is linked to the manufacture/import level. In addition other information sources can be used under certain circumstances such as non-guideline or non-GLP tests, historical human data, a weight of evidence, structure activity relationships (SAR) or "read-across" from tested analogues. Directions on using such substitute data are given in Annex XI, including conditions for "substance tailored exposure-driven testing" to allow for reduced animal testing for low exposure substances.

The registrant is advised to gather and share existing information, consider the information needs, identify information gaps and only then generate the missing data for registration at 1 or 10 tons per annum or propose further testing at 100 or 1,000 tons per annum.

Data for substances at > 1 ton per annum (specified in Annex VII)

Physico-Chemical Properties	***Toxicological Data***	***Ecotoxicological Data***
• State of substance at 20°C • Melting/freezing point • Boiling point • Relative density • Vapour pressure • Surface tension • Water solubility • Partition coefficient n-octanol / water • Flash point or Flammability • Explosive properties • Self-ignition temperature • Oxidising properties • Granulometry	• Skin irritation or corrosivity evaluation or in vitro tests • Eye irritation evaluation or ***in vitro*** tests • Skin sensitization evaluation or local lymph node assay • Ames test • Acute oral toxicity	• Acute ***Daphnia*** toxicity • Algae growth inhibition • Ready Biodegradation

- ***Data for substances at ≥ 10 tons per annum (specified in Annex VIII)***

In addition to the data required for substances at > 1 ton per annum

Toxicological data	***Ecotoxicological data***
• In vivo skin irritation (unless classified from Annex VII data) • In vivo eye irritation (unless classified from Annex VII data) • In vitro gene mutation assay • In vitro chromosome aberration test • Acute inhalation or dermal toxicity • 28-day repeat-dose study (normally rat, oral exposure) • Reproductive/Developmental toxicity screening study • Toxicokinetic assessment	• Acute fish toxicity • Activated sludge respiration inhibition test • Further biodegradation • Hydrolysis test • Adsorption/desorption screening test

Data for substances at > 100 tons per annum (specified in Annex IX)

The registrant additionally proposes a testing program covering:

Phys-chem data	*Toxicological data*	*Ecotoxicological data*
• Stability in organic solvents and identification of degradation products • Dissociation constant • Viscosity	• ***In vivo*** mutagenicity studies • 28-day or 90-day repeat dose study in the rat • Pre-natal development toxicity study • Two-generation reproductive toxicity study	• Long-term Daphnia toxicity • Long-term fish toxicity • Simulation test on the ultimate degradation in surface water • Soil simulation test • Sediment simulation test • Identification of degradation products • Fish bioaccumulation study • Further adsorption/desorption study • Short term toxicity to invertebrates (earthworm) • Study of the effects on soil micro-organisms • Short-term toxicity to plants

Data for substances at > 1,000 tons per annum (specified in Annex X)

The registrant additionally makes a testing program covering:

Phys-chem data	*Toxicological data*	*Ecotoxicological data*
	• Further mutagenicity studies • Long-term repeat-dose (> 12 months) study in the rat • Further toxicity study to investigate specific concerns • Two-generation reproductive toxicity study in the rat • Developmental toxicity (OECD 414) • Carcinogenicity study (often combined with the previous study, usually in the rat)	• Further biodegradation in water, sediment, soil-covering degradation rate and identification of relevant degradation products • Further environmental fate and behaviour studies • Long-term earthworm toxicity • Long-term toxicity to other soil invertebrates • Long-term plant toxicity • Long-term toxicity to sediment organisms • Long-term or reproductive bird toxicity

Options to reduce testing program

Annexes VII to X specify the standard data requirements and also the rules for waiving certain tests or additional studies.

Annex XI is dedicated to describing different opportunities for modification of the standard data requirements. These options are based on:

- grouping and "read across",
- data waivers, i.e. study technically impossible,
- substance-tailored exposure driven testing (above 100 tons only and for repeated dose and reproduction toxicity above 10 tons)
- weight of evidence approach,
- existing non-standard and/or non-GLP data,
- historical human data,
- (Quantitative) Structure Activity Relationships ((Q)SAR).

4 Getting ready for REACH

As the REACH regulation comes into force on 1st June 2007. companies subject to this legislation are advised to take action now to protect their interests in dealing with the new regulation, if they want to maintain their business in the coming years and to demonstrate to their clients that they are a reliable supplier.

Ciba® Expert Services has prepared action programs for different specific situations. Some are available on request as brochures, for instance for importers of chemicals, for downstream users, or for small and medium EU manufacturers of chemicals.

5 Conclusion

After the introduction of REACH, all existing substances manufactured within the EU or imported into the union (which are not exempt) with a volume above 1 ton per annum must be registered according a tonnage-triggered schedule. New Substances above 1 ton have to be registered immediately. (During the first year of REACH, new substances will still need to be notified according to the present new-substance directive 92/32/EEC.) Below one ton per annum there is no need to register the corresponding substance.

The procedure is complex: although testing costs can be reduced by sharing data, using replacement data or data waivers, additional testing may sometimes be necessary. It is thus important to have thorough regulatory guidance in devising the testing program and to ensure that the technical dossier and Chemical Safety Report, with the related risk assessment are of an adequate quality.

Ciba® Expert Services is the right partner for you to meet these challenges.

6 Services for REACH by Ciba® Expert Services

- ***Education and training***
  We visit you, help in training, organize seminars needed on the imminent changes in legislation and their implications.

- ***Strategic consulting***
  We help you make decisions how to shape your chemical business in the European Union after REACH. We review product and development portfolios to help define properties of your substances and to identify problematic substances in advance.

- ***Check if any of your substances may need authorization***
  Our experts in the fields of human and environmental safety help in classifying product ranges on the basis of PBT and other criteria.

- ***Consortia management and representation***
  We facilitate consortia formation, set up agreements and assist in task force management. In addition we can assist/represent you in consortia/task forces.

- ***Legal representation in the EU***
  We act as your Only Representative in the European Union.

- ***Test strategy***
  We tailor-make test strategies to minimize costs for the test program. We find the test houses with the best price/quality and monitor the contracted studies.

- ***Dossier preparation***
  We prepare Technical Dossiers for submission and Chemical Safety Reports.

- ***Reviewing test reports***
  We have extensive experience in reviewing test reports and check for adequacy and compliance with current test guidelines.

- ***Collecting other relevant test data***
  We find relevant data on your substance or close chemical analogues from the many available sources of information. We also use knowledge-based and computerized structure-activity analysis (SAR) to predict various properties.

- ***Reviewing and revising classification and labeling***
  We have wide experience in applying EC criteria for classification and labeling and preparing EU-format safety data sheets.

- ***Preparing/updating risk assessments***
  We prepare EU-format risk assessments on a regular basis and always ensure that possible future implications of risk assessment conclusions are addressed.

7 Ciba® Expert Services

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