

Ciba Specialty Chemicals

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Ciba[®] Expert Services

Marketing your chemicals in the European Union under REACH

Actions for manufacturers outside the EU



Our Knowledge – Your Advantage

Value beyond chemistry

Marketing your chemicals in the European Union under REACH

1	INTRODUCTION	3
2	THE SITUATION OF NON-EU MANUFACTURERS OF CHEMICALS	4
3	PREPARATION FOR REACH	8
4	CONCLUSION	11
5	SERVICES FOR REACH BY CIBA® EXPERT SERVICES.....	12
6	CONTACT AT CIBA® EXPERT SERVICES.....	13

1 Introduction

On 1st June 2007 REACH entered into force. REACH is the “Regulation of the European parliament and of the council concerning the **R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **C**hemicals”. REACH will fundamentally change the current European Union’s chemical control legislation, which presently consists of the Dangerous Substances Directive (DSD), the Dangerous Preparations Directive (DPD), the Existing Substances Regulation and the Marketing and Use Directive.

Importers and manufacturers have similar responsibilities under REACH. However, the situation for manufacturers located outside the EU may be difficult as they need to support substances in a possibly unfamiliar jurisdiction. This brochure is targeted to help companies located outside the EU, summarizes the specific implications and suggests actions to be taken in preparation for REACH.

This brochure describes the likely consequences for non-EU importers. The text of the REACH regulation has been published in the Official Journal of the European Union on 30th December 2006 (Regulation (EC)1907/2006, corrigendum on 29th May 2007).

A general introduction into the subject is given on a separate brochure available on request from Ciba[®] Expert Services.

2 The situation of non-EU manufacturers of chemicals

For non-EU manufacturers, REACH represents a jurisdiction with unique chemical control principles which may differ strongly from their domestic regulations. Moreover, REACH is unprecedented in its demand for information and administrative requirements especially for high volume chemicals. It is likely that many companies supplying chemicals into the European Union have limited experience with comparable schemes - unless they participated in any HPV (High Production Volume) initiatives or have notified New substances to the European Competent Authorities according to directive 92/32/EEC.

REACH obligations apply to every importer of a substance and multiple imports lead to multiple registrations. Registration remains proprietary. A non-EU manufacturer is not automatically an importer in the sense of REACH unless he has a registered company base in the European Union. An importer can only be a company which is legally established in the EU. The importer role can be taken by an affiliate company, a dealer, an agent, or a customer.

In addition to REACH, the European Commission will publish very soon its proposal for a Regulation to introduce in Europe the Globally Harmonized System for classification and labelling (GHS), replacing over a period of several years the Dangerous Substances and Dangerous Preparations Directives. The GHS is the United Nations' Globally Harmonised System of Classification and Labelling 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 introduction of GHS may well present a challenge equivalent to the implementation of REACH, in terms of administrative efforts. All actors in the supply chain are required to update their SDS according to GHS.

- **Only representative of a non-Community manufacturer**

The legislation allows non-EU manufacturers to appoint a legally recognised body in the EU to act as his *"Only" representative* in fulfilling the importer's obligations. Comparable to the "sole" representative scheme of new substance notifications, the main difference is that the only representative must have a sufficient background in the practical handling of chemical substances. He needs to keep available and up-to-date information on quantities imported and customers sold to, as well as the latest updates of the Safety Data Sheet (SDS) and the registration dossier.

- **Re-Export of substances**

Substances on their own, in a preparation or in an article, which are subject to customs supervision, or in a free zone or free warehouse with a view to re-exportation, or in transit, are excluded from the obligations defined by REACH. Substances which are manufactured and registered in the European Union, exported to a non-EU company, by which it is used in a formulation, and then imported back into the European Union, need not be registered again.

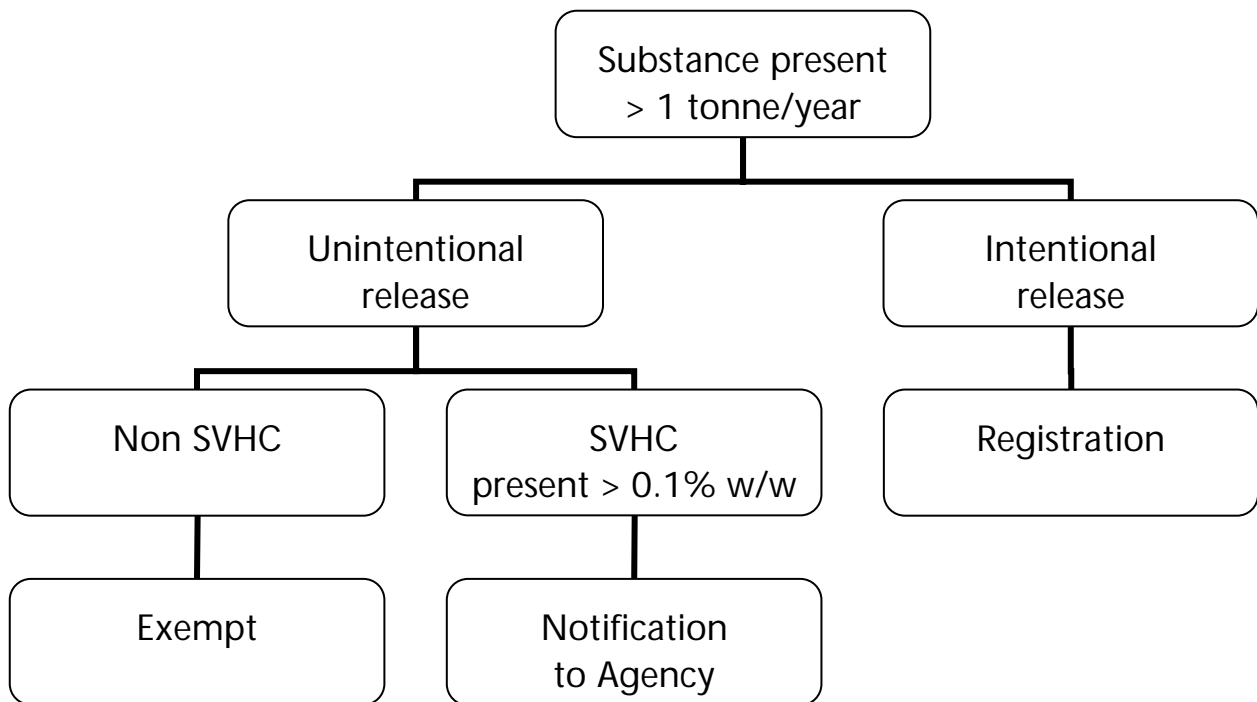
- **Import of preparations**

Substances in preparations are not exempt and must be registered individually.

- **Import of semi-finished goods and end-use articles**

Substances could be affected under the legislation and also semi-finished goods and components contained in articles. The REACH regulation defines an article as “*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*” This definition differs slightly from the one retained by the OECD.

For a substance in an article, the following applies¹:



¹ SVHC Substances of very high concern: Carcinogenic, mutagenic, or toxic to reproduction (CMRs) categories 1&2, persistent organic pollutants (POPs), persistent, bio-accumulative and toxic pollutants (PBTs), very persistent and very bio-accumulative substances (vPvBs), and on a case-by-case basis endocrine disrupters and substances of an equivalent level of concern

Obligations for substances imported²

• Registration

Registration requirements apply to every importer, with regulatory demands increasing by volume. From 1 year after the entry into force of REACH, all new substances will need to be registered before they are imported in quantities of 1t/y or more. During the 1 year transitional period, substances marketed in the European Union >10 kg/y will need to be notified according to the Dangerous Substance Directive³. Transitional provisions also apply to substances currently on the market known as “phase-in substances”. These have to be brought into the system over an 11 year period with deadlines for registration based on volumes.

Manufacturers and importers are required to “pre-register” phase-in substances which they plan to register, to enable manufacturers and importers of the same substance to find partners for data sharing of vertebrate testing (mandatory) and reach agreement on classification and labelling. The forum to allow data sharing is the SIEF (Substance Information Exchange Forum), which will be initiated by the Agency after the pre-registration.

The pre-registration of phase-in substances is between 1st June 2008 and 1st December 2008.

Registration of phase-in substances after entry into force of the legislation:

- 3.5 years: for substances produced/imported in quantities of 1000 t/y or more per manufacturer or importer, R50/53 substances produced/imported in quantities of >100 t/y and all known CMR substances (deadline 1st December 2010)
- 6 years: for substances produced/imported in quantities of 100t/y or more per manufacturer or importer (deadline (1st June 2013)
- 11 years: for substances produced/imported in quantities of 1t/y or more per manufacturer or importer (deadline 1st June 2018).

Substances notified under the Dangerous Substance Directive (listed in ELINCS) are considered as having been registered.

• Authorisation

Substances of very high concern (SVHC) have to be authorized. The applicant, the importer or manufacturer must show that:

- the risks involved in a specific use of the substance are adequately controlled and
- feasibility of alternative substances was investigated, or
- the social and economic benefits outweigh the risks.

The authorization may be subject to conditions, restrictions, and time limitation. Substitution of these substances is explicitly encouraged.

Obviously, there is no guarantee that an authorization would be granted even if the importer is himself convinced that the above mentioned conditions are fulfilled. The necessity of an authorization might lead to a partial or total substitution of substances supplied by an importer.

² the same as for manufactured within the EU

³ Directive 92/32/EEC of 30 April 1992 amending for the seventh time Directive 67/548/EEC.

- **Information required for registration**

Various experimental data are required for the technical dossier such as analytical data, physico-chemical data, ecotoxicological and toxicological data. The higher the volumes the more data are required. Table 1 gives an overview on the maximum test requirements. The vertebrate test data and the related costs *must* be shared. The other data and their costs *can* be shared between the registrants of a substance.

Table 1. Maximum test requirements under REACH for different volume ranges.

Import volume \ Number of Studies*	Phys-chem. Tests	Toxicity tests	Ecotoxicity tests
1-10	14	5	3
10-100	14	14	7
100-1000	17	19	23
>1000	17	24	29

* The numbers of tests displayed here corresponds to the total amount of tests listed in the corresponding annexes. A real test program can consist of fewer tests, if certain tests will be waived due to reasons specified in the text of the regulation.

- **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),
- the protection of trade secrets.

3 Preparation for REACH

First of all, non-EU chemical companies must take the threat seriously if they have business in Europe. One of the immediate effects of the introduction of REACH is an enhanced competitive pressure. If this has not been done yet, create the necessary awareness within your company.

Companies need to be aware that missing deadlines can mean taking the product off the market and that a lengthy preparation is required. Companies should also be aware about business opportunities which may arise.

3.1 Actions to be taken

3.1.1. Assess your product portfolio

a) Identify products

Identify all products (substances, preparations, semi-finished goods, articles) imported into the European Economic Area and therefore potentially falling under REACH.

- Identify all uses of these products you are aware of. Collaboration with customers is indicated but not mandatory at this point in time.
- Exclude product groups not falling under the scope of REACH (e.g. articles not expected to release substances in significant amounts under any foreseeable conditions, other products being exempt). Include all remaining products into the further assessment.

b) Create an inventory of individual chemical substances.

Break down products to substance level (under REACH, substances are regulated even if contained in preparations). Identify CAS numbers and, if possible, the EINECS or ELINCS numbers.

Check whether any of the substances are likely to be exempt under REACH or could be filtered out for later consideration. Examples are:

- Substances in Annexes IV and V (certain commodity chemicals, specific types of reaction products, coal, crude oil, etc.)
- Substances already notified under Directive 92/32/EEC (7th amendment of Directive 67/548/EEC)⁴ by your company.
- Any substances that meet the OECD polymer definition but include respective monomers.

c) Confirm the total annual volumes of these substances.

Define the volume bands they fall under (>1 tpa, >10 tpa, >100 tpa, >1000 tpa,) for export into the European Economic Area.

d) Collect all available data on these substances

- intrinsic properties (in-house, data publicly available).
- assess quality of test data.
- classification & labelling information.
- Safety Data Sheet compliant with existing legislation. The SDS as such is part of the registration dossier, but it is the key tool for communication in the supply chain.

⁴ ELINCS notification
Vers 6/07 11 October

e) Identify data gaps

Evaluate available data against the requirements detailed in Annex VII-XI of the regulation⁵ to identify missing data.

f) Identify substances of highest concern

Screen for PBT⁶ and vPvB⁷, endocrine disrupters, on the basis of available and predicted data.

Substances potentially falling under authorization requirements will require special attention for support under REACH. For such substances, substitution possibilities should be evaluated. If those should be further supported, information on application and use, respective risk management measures should already be known in detail (e.g. technical, personal, protective equipment, measures limiting emission to the environment).

3.1.2. Establish a REACH Master-plan taking into account the following points:

a) Define the role you would like to take under REACH

Decide for each substance how you will act:

- as importer via your EU affiliate company, or
- supporting your customers established in the EU and acting as importers, or
- represented by an Only Representative established in the EU.

b) Identify possibilities for consortia formation

Conduct a primary evaluation on whether other companies have an interest in the same substance, which quantities they currently manufacture and market, and what data they may have available. REACH will allow for consortia formation including sharing of data at a fair cost split.

c) Plan the implementation of REACH

- Start with a step-wise plan now, doing those things easily available as described above. Then do more detailed planning as more information becomes available.
- Define possible direct costs associated with the REACH process by determining quantities manufactured or imported, uses and potential exposures, likely information needed per substance, information and data already held and the possibility for consortia formation.
- Establish a time plan (what needs to be done by when and by whom).
- Estimate respective resource during REACH implementation.
- Possibilities for grouping, family formation, read-across to reduce costs.
- Define business opportunities.
- Define areas where confidentiality is critical.

⁵ For more info see Ciba[®] Expert Services General REACH brochure

⁶ Persistent, bioaccumulating and toxic substances

⁷ Very Persistent and very bioaccumulating substances

3.1.3. Further actions:

- Analyze commercial implications of REACH.
- Decide on products, potential substitution strategies, business opportunities.
- Initiate, if necessary, consortia formation.
- Establish which legal entity of your group of companies is involved as an importer for which substance/preparation or plan for the Only Representation.
- Assemble readily available information on uses and conditions of uses for the substance or preparation, i.e. exposure of the environment, your own workforce, at your customers' workplaces and eventually in end-uses.

Indicate for each substance or preparation a broad use category:

- industrial use
- professional use
- consumer use.

3.2 Classification and labelling

Before December 1, 2010, the Agency has to be notified on the classification and labelling of:

- substances subject to registration under REACH and
- substances within the scope of Article 1 of Directive 67/548/EEC, which meet the criteria for classification as dangerous in accordance with that Directive, and which are placed on the market either on their own, or in a preparation above the concentration limits specified in Directive 1999/45/EC.

The Agency will establish and maintain a Classification and Labelling Inventory in the form of a database containing the notified substances. The information in this database will be publicly accessible.

Review your classification & labelling and evaluate changes brought by the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). Compare and adjust, in agreement with other producers.

- In some cases your classification might not agree with that of the competitors.
- In some cases this will be easily rectified across producers.
- In other cases this may be difficult, especially where variations are due to impurities (marketing edge due to concept of safer product).
- The GHS requirements will change many classifications.

4 Conclusion

Now REACH is in force, all substances imported into the EU (which are not exempt) with a volume above 1 tonne per annum must be registered according a tonnage-triggered schedule from 1st June 2008 onwards. As registration is proprietary, the requirements will apply to all importers individually unless covered under an Only Representative Scheme. Substances newly brought on the market have to be registered immediately. For the others transitional provisions apply over an 11 years period.

The related procedures are complex. 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.

One of the immediate effects of the introduction of REACH will be higher competitive pressure. The way you prepare for REACH may be decisive in whether you can maintain and develop your business in Europe or not.

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

5 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 services*
We represent you in consortia, we provide you with technical advice. In addition, our experts consult consortia on technical matters.
- *Legal representation in the EU*
We act as your Third Party Representative or 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 labelling*
We have wide experience in applying EC criteria for classification and labelling 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.

6 Ciba® Expert Services

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