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How can Small and Medium-Sized Enterprises Manage the Challenges Imposed by REACH?

by

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1 Abstract

How can Small and Medium-Sized Enterprises Manage the Challenges Imposed by REACH?

The European regulation “Registration, Authorisation, Evaluation and Restriction of Chemicals” (REACH) has entered into force on June 1st, 2007. It sets a new legal benchmark for the whole European Union (EU) and is unprecedented worldwide: REACH now applies the principle “no market access without data” to the entire chemical industry within the EU, resulting in a shift of the burden of evidence to producers and importers who must now prove and document that their chemicals can be applied safely. The aim of REACH is to better understand and document the risks associated with the uses of chemicals. Producers and importers of chemicals will be forced to register their products formally at a new European Chemicals Agency (ECHA) in Helsinki, Finland, before they are allowed to (further) sell them in the EU.

In this work, difficulties for Small and Medium-sized Companies (SMEs) imposed by REACH are assessed, appropriate responses to manage these challenges are discussed and recommendations for companies in different roles (especially for producers, importers and downstream users of chemicals) are given.

Primary data was gathered in an exploratory interview study. The interviewees were selected from the chemical industry, from the authorities and from consultancies. Additional interviewees from the pharmaceutical industry shared their experiences under a highly regulated working environment and provided a benchmark for advanced product portfolio management techniques.

Two case studies exemplify the REACH implementation approaches of:
- a manufacturing company (producer) and
- a commercial house (trading company) for chemicals
  (importer and downstream user).

According to the findings of this study REACH is only one factor of the turbulent and globalised environment in which SMEs in the chemical industry must operate. In general, SMEs will be able to cope with the challenges imposed by REACH if they prepare themselves carefully and carry out their compliance projects in a disciplined manner, but some SMEs face serious risks:

- producers and importers of chemicals may not recover the costs associated with their registrations.
- if their business depends on chemical substances of very high concern (i.e. carcinogenic chemicals) subject to authorisation under REACH they may be forced to substitute the respective chemical or to withdraw it from the market starting in the year 2009. Consequently they must use the remaining time to develop strategic options.
- the most serious threat for downstream users is that their suppliers stop to deliver key chemicals for their special applications.

But REACH may provide new options as well, since more competitive SMEs have the chance to develop servicing areas and to improve their customer-orientation.

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2 Introduction

The European Union (EU) regulation “Registration, Evaluation, Authorisation and Restriction of Chemicals” (REACH, 1907/2006/EC) has come into force on June 1st, 2007. Central aim of this backbone of the new legislation for hazardous chemicals is to better understand and document the risks associated with the application of chemicals. Producers and importers of chemicals will be forced to formally register their products at a newly founded European Chemicals Agency (ECHA) in Helsinki, Finland before they are allowed to (further) sell them in the EU. Hazardous substances must undergo expensive toxicological tests, with the costs to be borne by producers and importers.

The new legislation will have a huge impact on producers, importers and applicants of chemicals and preparations made from them.

In particular, producers and importers must invest a lot of money to have their chemicals registered. The focus of this work is to analyse the effects of REACH on Small and Medium-sized Enterprises (SMEs), which, in contrast to large chemical companies, may not have structures in place, which would allow them to develop compliance procedures in an expedient and efficient manner.

For the purposes of this work not only SMEs are reviewed within the ambit of the EU (2003) recommendation (companies with less than 250 employees and less than 50 million EURO annual turnover). The industrial landscape especially in Germany suggests to subsume most of the so-called German “Mittelstand” by the term SMEs. These companies are often family-owned and (at least partially) managed by the owners. Common legal forms are limited or general partnerships (“Kommanditgesellschaft” or “Offene Handelsgesellschaft”) and limited liability companies [“Gesellschaft mit beschränkter Haftung” (GmbH)]. The resources of such companies are often limited.

Weigand (2006) describes the case of CHT R. Beitlich GmbH, Tuebingen, Germany, a manufacturer and distributor of auxiliaries for the textile industry, for whom registration costs for its 296 chemical substances, 47 out of own production

(in the 1 – 1,000 tons/year annual turnover range), will amount to at least € 20 million. Weigand sees no way to pass the 40 to 100 % sales price increases (depending on volume; calculated under cost allocation over 5 years) to the customers. Although the headcount of the company is 600 in Germany and 1,500 worldwide, the author describes the company as an SME. This example illustrates that for such companies the new legislation is a considerable burden, which might threaten their existence. Some other case studies are described in Wolfgardt *et al.* (2004, p. 29-52).

Because so many companies are affected, it is worthwhile to develop strategies, showing how SMEs can manage these challenges.

This study aims to describe and evaluate different strategic options based on discussions with experts in the field. It aims to find answers how SMEs can cope with the challenges imposed by REACH. Related tasks under investigation are:

- Information management
- Effective (product) portfolio management
- Change management and the provision of appropriate organisational structures and resources
- The financial implications thereof and their consequences.

Still most SMEs did not assign significant resources to manage these new challenges. To comply with the new regulations SMEs must:

- develop appropriate corporate strategies to stay profitable,
- define registration and documentation targets as well as their future product portfolio,
- find ways to cooperate with others while protecting their core intellectual property (Norman, 2001).

The following literature review will report publications in the field and recommendations for REACH-compliance activities given therein. A paragraph about the history of the new EU chemicals legislation shall provide some insight into the context of REACH and related legal initiatives. The next paragraphs

explain, which activities are required by REACH and, which costs will be incurred. Further paragraphs discuss related management issues, which must be addressed in order to plan and implement REACH compliance efforts effectively.

3 Literature review

3.1 The new European chemicals legislation

The EU Regulation No. 1907/2006 REACH (concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals) is the backbone of the new European chemicals legislation. It is based on the United Nations (UN) Globally Harmonised System (GHS), which provides the basis for the worldwide harmonisation of systems for the classification and labelling of hazardous chemicals (UNECE, 2007). Among many other prescriptions given therein REACH is implementing the GHS part concerning Material Safety Data Sheets (MSDS).

According to REACH producers and importers of chemicals will be forced to register their substances within the next years (in steps depending on market volume and associated hazards) starting from 2008. In Germany an amendment of the Chemicals Act (Chemikaliengesetz - ChemG, 1980) will define in detail how REACH will be implemented (BMU, 2007). It shall enter into force on June 1st, 2008. The addresses of national authorities, which are responsible for REACH activities are given in BMU (2007a) e.g. in Bavaria industrial inspection boards will enforce REACH on the regional level (Zeitler, 2006).

In 2008 REACH will be complemented by an EU regulation named Classification, Labelling and Packaging (CLAP), implementing the remaining parts of the GHS (UNECE, 2003, 2005, 2007). Since some classifications for certain chemicals will change, CLAP will influence the execution of REACH too – but to a small extend.

3.2 History of the new EC chemicals legislation

When the German Chemicals Act (ChemG, 1980) came into force in 1981 it introduced general restrictions for selling chemicals. At that time 100204 chemicals

were already marketed and not subject to any market barriers. These “existing chemicals” were documented in the European Inventory of Existing Commercial Chemical Substances (EINECS) database. From there on “new chemicals” had to be registered and information about the substance properties had to be submitted to the national authorities [in Germany the “Anmeldestelle Chemikaliengesetz” at the Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA) in Dortmund], before manufacturers or importers were allowed to sell them. Having passed this bureaucratic hurdle these “new chemicals” were included in the European List of Notified Chemical Substances (ELINCS) database. “Existing chemicals” were therefore treated differently. In many cases little information was available about the potential hazards associated with their use.

Motivated by a wide-spread dissatisfaction with this unequal treatment and other shortcomings of the chemicals legislation of that time, the European Commission (2001) laid down its “Strategy for a future Chemicals Policy”, which is implemented through REACH.

Heitmann and Tschochohei (2007) state that “REACH introduces the principle of precaution into the European chemicals legislation”. They see REACH as an international benchmark and expect improvements in respect to Environment, Safety and Health (ES&H) through this process.

Hey, Jakob and Volkery (2007) explain how “REACH fits into a transition phase from environmental policy-making by law (i.e. restriction and punishment) towards other governance approaches based upon networking, voluntary commitments, benchmarking and other forms of “soft law” within the EU aiming at motivating companies to take more responsibility for their actions”.

3.2.1 Similar legal initiatives

Although general restrictions for market access are new for the chemical industry the regulations under REACH are not unprecedented. In areas of special concern similar regulations entered into force earlier.

3.2.1.1 Biocides

The market entry of biocides is regulated by 98/8/EC (BAUA, 2007), which entered into force in Germany by an amendment of the ChemG in 1982. Marketing of biocide products is only allowed if all active compounds are listed in a positive list in Annex I and IA of 98/8/EC. Each active compound not listed must undergo an authorisation process: Applicants have to carry out a safety assessment and submit a safety report, which is the basis for a comprehensive evaluation by the BAuA. The BAuA can grant an authorisation and appropriate limitations for the use. According to 1896/2000/EC "old" biocides marketed before May 14th, 2000 had to be "notified" to the BAuA to remain in the market after December 14th, 2003. Applicants must provide appropriate information for the evaluation of the notified biocide product. 2032/2003/EC lists all notified biocides and defines transitional time intervals for the submission of active compound dossiers. Until May 13th, 2010 all safety reports must be submitted. Test results have to be submitted by using the International Uniform Chemical Information Database (IUCLID) software.

3.2.1.2 Agro-pesticides

Agro-pesticides are regulated by EU directive 91/414/EEC (1991). The current regulatory framework is described by Streloke (2007). He identifies the following scientific issues, which currently cause the biggest problems in the regulatory process: "Implementation of probabilistic risk assessments, endocrine disruption, persistent compounds in soil, refined risk assessment for birds and mammals, mesocosm studies, monitoring data or risk mitigation measures" (p. 403). These issues are relevant for REACH as well. Authorisations of active compounds can be granted in case that the respective compound is listed in the positive list of Annex I of 91/414/EEC after an evaluation by the European Commission. Specific regulations for "old" compounds exist. Moreover, guidance documents [paralleling REACH Implementation Projects (RIPs)] were prepared (European Commission, 2007). Predicted Environmental Concentrations (PEC, also referred to by REACH) are calculated by FORUM (Forum for the co-ordination of pesticide fate models

and their use) models (FOCUS, 2001). A revision of 91/414/EEC is under way.

3.2.1.3 Medical products

Requirements similar to the registration of chemicals under REACH were first introduced into the pharmaceutical industry by 65/65/EEC (1965). Over time the duties for pharmaceutical companies became more restrictive according to the German Pharmaceutical Products Act (*Arzneimittelgesetz* - AMG, 1976), 2309/93/EC (1993), 297/95/EC and 2004/726/EC. On a global scale the standards for drug development and market access have been harmonised by the United States Federal Drug Administration (FDA) and by the expert working group of the International Conference on Harmonization of the Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). In general the pharmaceutical industry has to meet higher regulatory standards (i.e. additional clinical trials) compared to the chemical industry. Nevertheless the legislation for medical drug substances exhibits striking similarities with the requirements under REACH [e.g. toxicological studies, authorisation, foundation of the European Medicines Agency (EMEA), waiving (EMEA, 2007)].

3.3 Potential effects of REACH

The European Commission (2003) studied the potential effects of the new legislation while REACH was in an early stage of the negotiations. Getzner (2006) published an economic study for Austria. He concludes that the overall effect of REACH will be an improved efficiency of the Austrian economy. Nevertheless Getzner himself states that the most critical parameter is the “economic value” of a statistical death of a person. Had he not taken the monetary approach of the European Commission, which sets the value of a statistic death as € 3,72 million, but a value approximately 80 % less, then the sum of all economic impacts of REACH would be negative.

In general the companies using chemicals will have to meet higher safety

documentation requirements. These requirements will increase the costs, which have to be covered by the respective product. Tomschik (2006) assumes that SMEs producing or importing substances in excess of 1000 t/y will be deeply affected and some will stop their production, because the products cannot cover the registration costs. But the same might apply for substances in excess of 10 t/y [starting from this annual turnover a Chemical Safety Report (CSR) must be submitted].

Especially authorisation (see respective paragraph below) is a serious threat for companies who use Substances of Very High Concern (SVHCs, hazardous chemicals with e.g. carcinogenic properties). These companies will face pressure to substitute the respective substances by more environmentally friendly compounds. Where companies find no appropriate response to this challenge they might have to stop their operations.

3.4 Technical issues associated with REACH

Details of the REACH procedures were tested in pilot projects (SPORT, 2005). But only large companies like BASF AG (now BASF SE), Ludwigshafen, Germany took part. Guidance documents based on these results are currently under development in REACH Implementation Projects (RIPs):

Table 1. Completion dates for RIPs (last update: February 23rd, 2008)

RIP	Name	Completion date
1	Process description	
2	REACH-IT (IUCLID)	6/2007
3	Guidelines for the industry	
3.1	Registration	June 2007, updated February 2008
3.2	Chemical Safety Report	Early 2008 (expected)
3.3	Information requirements for intrinsic properties	Autumn of 2007 (expected)
3.4	Data sharing	Sept., 27th., 2007
3.5	Requirements for downstream users (DUs)	January 2008
3.6	GHS-classification and -labelling (CLAP)	2008 (expected)
3.7	Authorisation application	End of 2007 (expected)
3.8	Compliance with requirements for substances in articles	Autumn of 2007
3.9	Socioeconomic analysis	Preliminary report 2/2006 2008 (expected)
3.10	Identification and naming of substances	June 2007
	Intermediates	June 2007, updated February 2008
	Scientific Research and Development (SR&D) and Product and Process Oriented Research and Development (PPORD)	June 2007, updated February 2008
	Monomers and Polymers	June 2007
4	Guidelines for the authorities	
4.1	Dossier evaluation	June 2007
4.2	Substance evaluation	
4.3.	Process for identification of Annex XIV substances	Autumn of 2007
4.4	Preparation of Annex XV dossiers: - Substances of Very High Concern (SVHCs) - Harmonise Classification & Labelling - Restrictions	June 2007
4.5	Guidance priority setting for evaluation	Autumn of 2007 (expected)
5	Pre-ECHA	
6	Setting up the ECHA	

The practicability of REACH for Donwstream Users (DUs) was tested in the PRODUCE (Piloting REACH on Downstream Use and Communication in Europe)

project (2006), which revealed a need for further clarification and simplification.

To manage the REACH processes a new European Chemicals Agency (ECHA) was founded in Helsinki, Finland in June 2007.

3.5 Legal issues associated with REACH

Ashford (2007) points out that it is often difficult to decide how to name the chemical, which is going to be registered (compare RIP 3.10) – especially in the case of complex mixtures as they normally occur in the polymer sector. But this name will be the key criterion for the assignment of companies to a certain Substance Information Exchange Forum (SIEF), wherein they are expected to cooperate with other registrants. Ashford argues that, “because there is little time to build trust within cooperations aiming to share registration efforts and costs, many companies have expressed concern over participating in such cooperations for fear of falling foul of EU competition law”. RIP 3.4 (2007) provides guidance on the relationship between REACH and EU competition law and how potential risks can be overcome (note that RIPs have no legal status in contrast to REACH). One way to comply with both sets of legislation is the engagement of an "independent" third party or trustee. According to Ashford this concept has been tested in similar initiatives such as the U.S. Environmental Protection Agency (EPA) High Production Volume (HPV) Challenge Program started 1998 and the OECD "Screening Information Data Set" (SIDS) program started 1989.

3.6 The chemical industry in the EU

The turnover of the EU chemical industry was € 718,688 billion in 2005 and € 764,938 in 2006 [VCI (2007, p. 98)]. Germany is the largest European producing country, accounting for 21.3 % of the EU turnover in 2005, followed by France (13.3 %), Italy (10.7 %) and the United Kingdom (10.4 %).

Products of the chemical industry are: basic chemicals, pesticides, polymers, paints and varnishes, cosmetics and detergents etc. This industry is a key supplier

of all sectors of the economy – at least indirectly. About 30 % of the amount of the chemical products is further processed within the chemical industry itself through complex value chains.

The activities of the companies within the European chemical industry as well as their sizes vary considerably. SMEs are often suppliers or customers of the larger companies. According to European Commission (2003) SMEs represented more than 95 % of the firms by number in 2000, accounting for 30 % of the production value and 36 % of the employment [1,887 million employees in 2000 and 1,748 million in 2005 according to VCI (2007, p. 110)].

VCI (2007, p. 48) reports that the German chemical industry comprised 3,485 companies in the year 2005. 3,192 or 91.6 % of them being SMEs. They accounted for 23.6 % of the total employment of 451,589 employees and for 18.7 % of the overall turnover of 154,428 billion € (162,196 billion € in 2006).

3.7 Duties imposed by REACH

3.7.1 Communication up and down the supply chain

One of the main targets of REACH is to improve the communication concerning chemical hazards up and down the supply chains. Since June 1st, 2007 MSDSs for chemical substances and preparations have to comply with REACH and are no longer written according to the commission directive 91/155/EWG, which had been amended by the commission directives 93/112/EC and 2001/58/EC. The author knows from his own experience as a scientific service provider that companies regard this first requirement just as a routine duty, which can be fulfilled easily.

In practice, REACH imposes the following new requirements:

DUs must inform their suppliers about their applications of chemicals in order to make sure that these uses will be included in the registration.

In case that a Substance of Very High Concern (SVHC) is contained in a preparation in excess of 0.1 % by weight suppliers must at least identify the respective chemical to their customers.

3.7.2 Pre-Registration

Between June 1st and November 30th, 2008 producers and importers must pre-register their EINECS substances. By pre-registering, producers or importers declare to the ECHA:

- they produce or import the chemical (not a preparation: only substances can be registered!). As a consequence this chemical becomes a “Phase-in” substance.
- when they are going to register the substance by making use of the transitional time intervals specified in Article 23 of REACH (until 2010, 2013 or 2018 respectively).

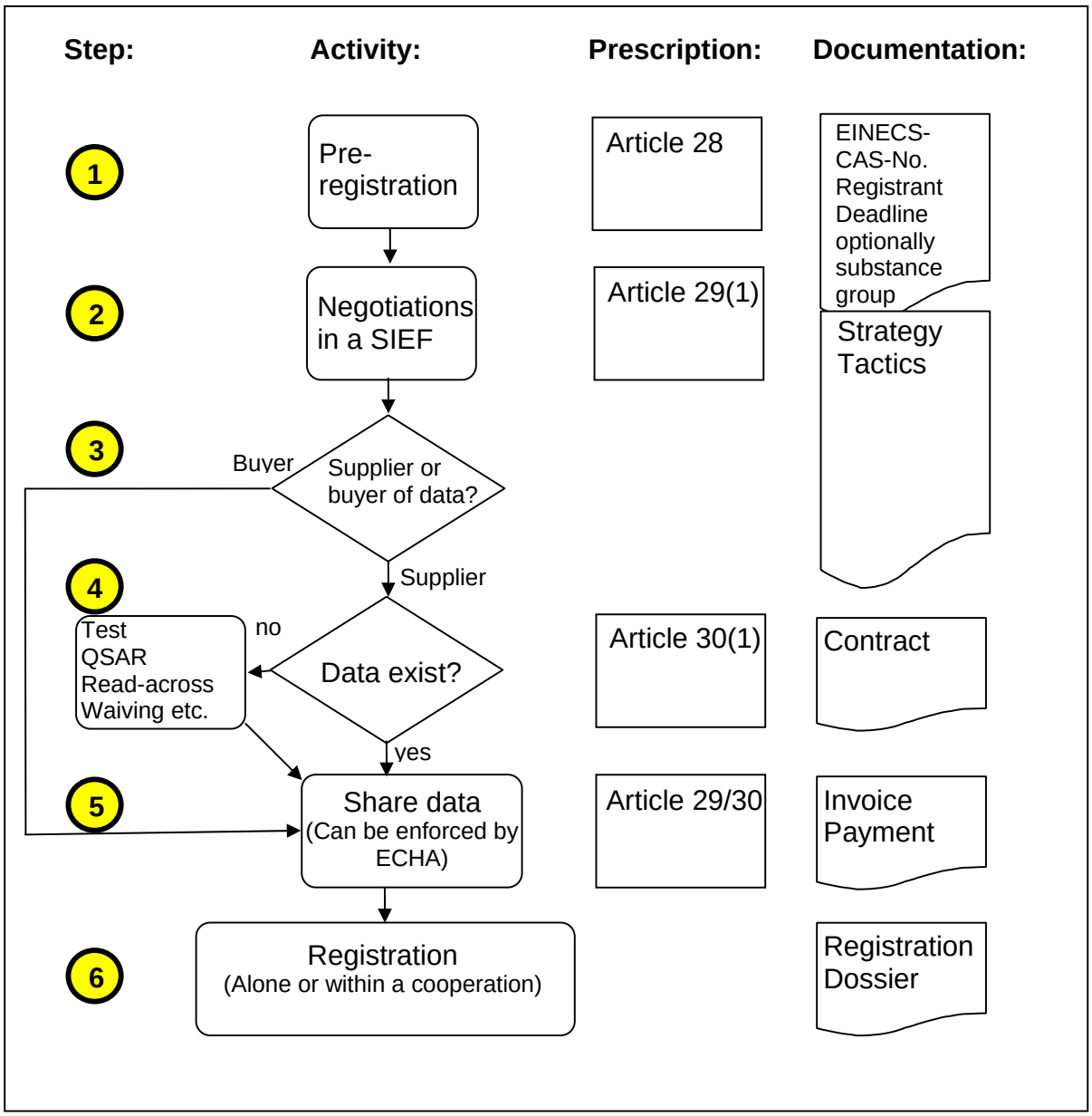
Through the pre-registration companies automatically become participant of a Substance Information Exchange Forum (SIEF) provided by the European Commission. Using this electronic contact platform producers and importers shall find other companies who strive to register the same chemical. All these companies manufacturing or importing the same chemical shall collaborate in order to exchange data, close data gaps and file a mutual registration dossier. Each chemical shall be registered only once (OSOR-principle: one substance one registration). How SIEFs will be formed was explained in detail by Kowalski (2007).

No further “new substances” will be included in ELINCS from June 1st, 2008 on. Then new chemicals will be subject to immediate registration under REACH.

3.7.3 Registration

Each existing (EINECS) chemical of which more than one ton per year is produced or marketed by one company in the EU must be registered by the respective producer(s) or importer(s). This process comprises the following steps:

Figure 1: Flowchart for the registration process



3.7.3.1 Exemptions from the obligation to register

To the extend that substances are already subject to other EU market entry regulations, no further registration is necessary. This applies especially for ELINCS chemicals, as well as for agro-pesticides and biocides. Furthermore, REACH is not applicable to pharmaceutically active compounds (APIs), nutrition additives and animal food. Moreover, Annexes IV and V of REACH list various substances,

which are exempted from registration e.g. many minerals. Also polymers, fulfilling defined criteria are exempted. REACH does not apply to the fields of waste, transportation, not isolated intermediate products (within production processes) and radioactive substances.

Substances can also be temporarily exempted to allow for research [Product and Process Orientated Research and Development (PPORD)].

3.7.3.2 Transitional time intervals after pre-registration

Companies can make use of the transitional time intervals (Article 23 of REACH) by pre-registering existing chemicals. Those companies not making use thereof for any reason must register their chemicals immediately.

Table 2. Transitional time intervals for the registration of "Phase-in" chemicals

Deadline	**Tonnage band**
December 1st, 2010	Registration completed of substances, which are marketed by at least one producer or importer in quantities exceeding 1,000 t annually within the EU. The same applies for SVHCs such as Carcinogenic, Mutagenic or toxic for Reproduction (CMR) substances over 1 t/year. Applies as well for substances classified as very toxic for aquatic organisms over 100 t/year
June 1st, 2013	Registration completed of substances over 100 t/year, which are classified as toxic for aquatic organisms
June 1st, 2018	Registration completed of all other substances over 1 t/year

3.7.3.3 Information submission requirements

Annexes VII, VIII, IX and X of REACH contain standard information requirements for substances manufactured or imported in quantities exceeding 1, 10, 100 and 1000 tons per year. These annexes are committed to the priority to explore alternative sources of information [e.g. *in vitro* data, *in vivo* data, historical human data, data from Qualitative or Quantitative Structure-Activity Relationship (QSARs) and data from structurally related substances (read-across approach)] before new (especially *in vivo*) tests are carried out.

3.7.4 Chemical Safety Assessments and Chemical Safety Reports

For all substances subject to registration of which more than 10 tons per year are produced or marketed by one company a Chemical Safety Assessment (CSA) shall be performed and a CSR must be established. Although the exact requirements for CSRs are not defined yet (compare RIP 3.2 in table 1) it is already foreseeable that such assessments will require a considerable effort. Therefore the registration costs increase significantly when the annual turnover of a chemical exceeds 10 tons. Fahrbach's findings (2007) confirm that problems for SMEs will be related to the registration of substances above 10 tons per year.

Annex I of REACH includes provisions for preparing CSRs.

Annex XII contains provisions for DUs to prepare CSRs for their individual uses.

To protect Confidential Business Information (CBI) CSRs containing specific information about uses and expositions can be submitted separately even in joint registrations [Article 11 (1)].

3.7.5 Authorisation

Authorisation is a serious threat for companies, because this process puts pressure on them to substitute the respective chemical.

According to Article 58(3) of REACH the ECHA will publish its first recommendation of priority substances to be included in Annex XIV (list of substances subject to authorisation) on June 1st, 2009. SVHCs listed in the Annex XIV e.g. Carcinogenic, Mutagenic or toxic for Reproduction (CMR) chemicals or very Persistent, very Bioaccumulative (vPvB) substances must undergo authorisation in order to continue their use for a time interval specified by the authorities. Together with the listing a "sunset date" will be defined until which an authorisation must be granted latest to continue the use. This does not mean that the respective substance is prohibited. But the registrant must explain in his application for authorisation why he cannot substitute the substance with reasonable effort and how he is going to counter the risks involved in the use of this chemical. If risks

remain, he must submit a socio-economic study in which he lays down why an important economic advantage by this use outweights the risks involved.

Heitmann & Reihlen (2007) studied the implications and the likely effects of a substance being published on a candidate list for Annex XIV. They conclude that:

- It will be mainly the task of formulators (companies who blend chemicals for special applications) to substitute substances in their preparations. They will often react to a strong demand by their customers.
- In many branches lists of substances, which shall not be contained in products, already exist [e.g. the Oslo and Paris Commissions (OSPAR)]. There might be a transfer of substances from these lists to the candidate list. But individual companies will often wait until they are forced to react, because they rank the risk of ineffective substitution efforts higher than loss of business due to delayed activity.
- Customers will prefer products without SVHCs ("announcement effect"). But as enforcement of limit values is difficult, retailers without sensitive brands might continue their business without additional efforts and this will often remain undetected.

Ahrens *et al.* (2006) present case studies about substitution projects and answer the question: why and under which circumstances are companies able and willing to substitute hazardous substances? The authors propose to introduce the concept of precaution into the product development and into the chemicals portfolio management of firms.

3.7.6 How far are downstream users concerned?

Most of the burdens of the new obligations have to be carried by Manufacturers and Importers (M/Is). DUs will try to avoid registrations as Tomschik (2006) recommends by:

- Sourcing raw materials from EU suppliers
- Making sure that the own uses of substances comply with those described in

the respective MSDS of the supplier

- Otherwise to inform the supplier about the own application so that he includes this use in his registration
- Searching for alternative substances

In certain cases the burden can remain with the DU [e.g. when he decides to write a CSR, because the supplier of the respective chemical refuses to include a special use in his registration or when suppliers increase their sales prices].

3.8 Direct costs of the duties imposed by REACH

The European Chemicals Bureau (ECB) has estimated the testing costs per substance in each of the tonnage bands (Pedersen et. al., 2003).

Table 3. Estimated average testing costs per substance (in EUROs)

Scenario	1 – 10 tonnes/year	10 – 100 tonnes/year	100 – 1,000 tonnes/year	> 1,000 tonnes/year
Minimum test needs	8,600	40,500	128,000	185,000
Average test needs	12,100	73,100	163,000	208,000
Maximum test needs	16,400	152,000	244,000	278,000

The testing costs per tonne of an average substance were estimated assuming the production of 3, 30, 300 and 3000 tonnes/year, respectively, and that the costs are distributed equally over 10 years (van der Jagt et al., 2004):

Table 4. Estimated testing costs per tonne of an average substance (in EUROs)

Scenario	1 – 10 tonnes/year	10 – 100 tonnes/year	100 – 1,000 tonnes/year	> 1,000 tonnes/year
Minimum test needs	285	135	43	6
Average test needs	404	244	54	7
Maximum test needs	548	506	81	9

Risk & Politics Analysts, Ltd. (RPA, 2003) argues that SMEs will tend to produce a lower number of substances than large companies and will produce these at a lower tonnage. Table 4 highlights the potential difficulties that SMEs are likely to

have in recovering their costs. There is an order of magnitude difference in costs per tonne of substance between each adjacent tonnage band!

Table 5 reports estimated costs per ton of registered substance for different kinds of chemicals subject to REACH.

Table 5. Costs per ton of registered substance (Minimum Tonnage)(in EUROs)

tonnes/year	1 – 10	10 – 100	100 – 1000	> 1000
Phase-in Full Registration	41470	6206	2872	471
Less Onerous Registration Phase-in	0	0	506	72
Phase-in polymers	26046	3474	682	95
Intermediates Isolated On site or Transported	11218	1122	115	11
Intermediates Transported	0	0	0	46

Having analysed contribution margins for chemical products within the portfolio of several companies Fahrbach (2007) concludes that producers of specialities – which are likely to be SMEs – will face high business risks in the tonnage band between 10 and 1000 tons/year. Especially SVHCs constitute high business risks.

While this paper is written the registration fees are still under negotiation:

Table 6. ECHA fees* (in EUROs)

Turnover in t/a	Basic registration fee	Participant of a joint submission**	SME	SME participant of a joint submission **
≥ 1 - 10	1,600	1,200	160 – 1,120**	120 – 1,120**
≥ 10 - 100	4,300	3,225	430 – 3,010**	323 – 2,258**
≥ 100 – 1,000	11,500	8,625	1,150 – 8,050**	863 – 6,038**
≥ 1,000	31,000	23,250	3,100 – 21,700**	2,325 – 16,275**
Other fees				
Authorisation	50,000	37,500	7,500 – 40,000**	5,625 – 30,000**
PPORD	50 - 500**	(1st applications) equally		
	100 – 1,000**	(extension) equally		
Appeals	2,000 – 6,000	Equally		
Confidentiality	1,500 – 4,500	1,125 – 3,375	150 -3,150***	113 – 2,363**

* according to the draft of the cost regulation (European Commission, 2007a)

****** Depending on the size of the company

*** In case of a joint registration, the ECHA will invoice the reduced free from each of the cooperating registrants

The draft prescribes fees for applications to keep information confidential depending on the kind of information and the size of the respective company as well (compare last row of table 5). The final version of this cost regulation will be issued in 2008.

Note that there is no pre-registration fee (Article 28 referring to the pre-registration is not cited in article 74 of REACH).

Furthermore, no fee is due for the registration of a substance in quantities of between 1 and 10 tonnes/year where the dossier submitted contains the full information in Annex VII [Article 74 (2)].

3.9 Related challenges for companies

To manage their compliance efforts effectively, companies must develop additional capabilities as set out below.

3.9.1 Strategy development

Business strategy is a central issue in the context of this study and many different definitions exist. But none of these definitions has been universally accepted. The author of this paper proposes an own operational definition of what it means to develop a strategy:

Building and implementing a strategy means to select diligently from several options how to act to reach objectives while making effective and efficient use of limited resources.

This definition is similar to the ones given by Hammonds (2001) and by Grant (2002) but it may be more complete and appropriate for SMEs.

Diverse approaches to strategy building exist (Mintzberg and Lampel, 1999).

Johnson and Scholes (1989) identified three main aspects of strategic management:

- Strategic analysis (or appraisal)
- Strategic choices and
- Strategic implementation

To define future product portfolios and related registration obligations requires what Hamel and Prahalad (1994) call “foresight”.

3.9.2 Strategic chemicals portfolio management

SMEs must carefully evaluate their product portfolios to stay profitable while deciding about investments for REACH compliance. If SMEs are importers and resellers with a large portfolio of different chemicals and preparations from several non-EU suppliers, they are in a particularly difficult position (Thoms, 2007).

3.9.2.1 Chemicals portfolio analysis

Each company must review the substances it produces, imports or uses in quantities exceeding 1 tonne/year to find out the role REACH assigns to the firm in relation to the product. Related duties and costs depend on this role and on:

- The annual turnover of the chemical (tonnage band)
- Whether the chemical is at risk to become subject to authorisation
- Whether the data required are available free of charge or not
- Whether the registrant is an SME and/or a participant in a joint registration
- The timing of payments
- Whether access to the market may be provided or limited by cooperations or restricted through schedules (e.g. for negotiations).

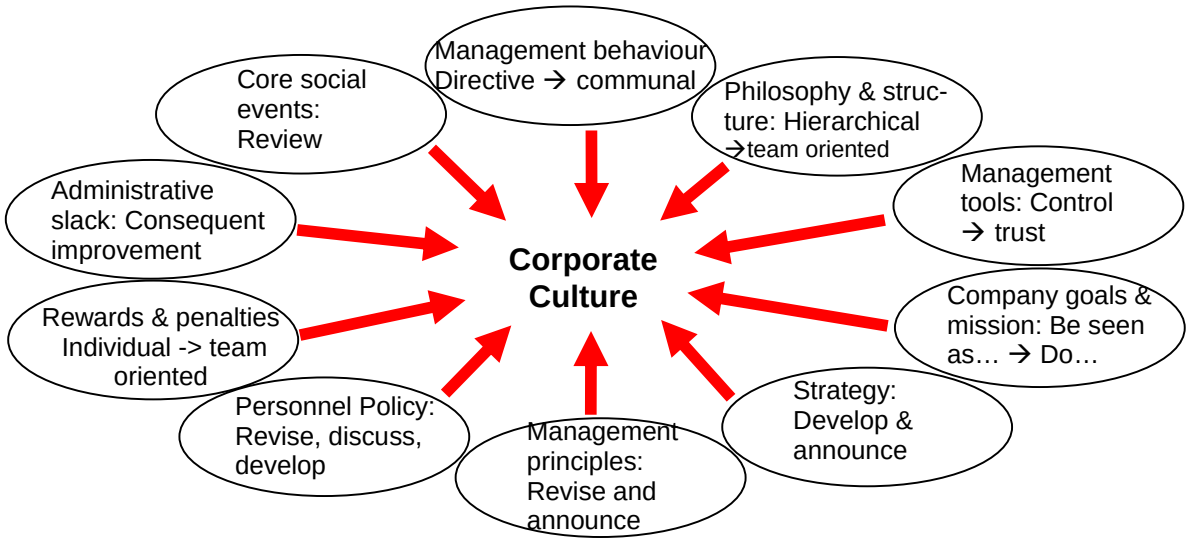
How to carry out the financial assessment of strategic options was explained by Mills (1995). Because of inflation and uncertainties in the prediction of the future, payments that are due earlier are more valuable for companies compared with later payments. To adjust for these effects the Discounted-Cash-Flow (DCF) method shall be applied. This should be complemented by sensitivity analyses. Taxation should be considered too (Schraft, 2005). Such evaluations are complex and should therefore be carried out by strategic controllers as well as taxation

specialists to provide in-depth insights into the cost and earnings implications of alternative options.

3.9.3 Change management

If SMEs find themselves not prepared to overcome the challenges given the current shape of their organisations, then appropriate changes must be planned and implemented. Doppler and Lauterburg (2000) describe change management as processes in which many different issues have to be addressed. They recommend new structures based on network models and process chains and on a teamwork-based and customer-focussed culture. Apart from difficult to change culture-shaping factors (personnel structure, means of production, products & services, age & history of the company) there is a variety of important parameters, which shape the culture of each company and can be easily influenced:

Figure 2: Culture-shaping parameters, which can be influenced



(adapted from: Doppler and Lauterburg (2000), p. 298)

The management has to analyse each of these parameters carefully and derive adequate measures to influence them.

3.9.4 SIEF-processes, collaboration and joint registration management

Pedersen (2004) analysed the motivations of companies for entering into an alliance. He found that strategic alliances are seen as a tool to attenuate uncertainty and risks. Hutt *et al.* (2000) carried out a case study with focus on personal relationships within alliances and state that good personal relationships between managers can cross organisational boundaries effectively so that such alliances become successful.

In most cases SMEs will not hold a dominant position in their markets and become lead registrants within a SIEF. Therefore strategies recommended for large companies (like excluding others from proprietary information about substances in order to further strengthen a de-facto monopoly) will only be feasible in extraordinary cases. In general SMEs will enter into cooperations. According to Ihme (2007) strong arguments support joint registrations:

- a unified position of the registrants
- synergies in intellectual and financial resources
- cost reductions for data generation and dossier preparation
- reduced registration fees.

However, much effort must be invested in the “consideration of potential pitfalls and the organisation of daily cooperation”. Each company has to decide whether to take part, on the timing and its contribution.

3.9.4.1 Cost scenarios for alliances

Ihme (2007) reports cost scenarios for cooperations with payments from up to 15 parties, the time of entry, the quality of data owned or provided, and the type of use granted. Results indicate that “data-owning parties founding the cooperation can expect re-imbursements during the entire project to be 20 times higher if 5 late registrants pay 50 % of study costs for data access only, compared to becoming full members contributing on a proportional basis. Non-data owners joining earlier also profit, but to a much lesser degree. Costs for parties not joining but accessing

data at a late stage were about 4-fold higher than costs for full data access under proportional conditions".

Based on DCF evaluations (interest rate 6 % per year) small tonnage companies might reduce their financial burden by 30 % if they register in the end of the 11-year window and postpone payments accordingly.

Under REACH, sharing of all costs among SIEF participants can be freely negotiated (compare RIP 3.4 on data sharing, 2007). If no agreement can be achieved, REACH requires equal cost sharing between owner and buyer.

3.9.4.2 Formalities within cooperations

Often cooperations start with a letter of intent. They can meet different legal forms. According to Ihme (2007) contract elements comprise:

- the purpose
- the process of founding (e.g. individual interests and contributions)
- admission, late entrance conditions and withdrawal of members and termination
- the rights and duties of representatives and management,
- the decision making process,
- measures to be taken in case of non-performance of members
- procedures for the settlement of disputes
- rights in data (ownership of intellectual property), and
- the confidential supply of sensitive data e.g. via trustee services.

3.9.4.3 Opting out

In spite of the "One Substance One Registration" (OSOR)-prescription companies might prefer to register alone and not to cooperate with others. Article 11 (3) of REACH lists valid reasons for "opting out". The ECHA can check the obligatory explanation given by the registrant [Article 41, 1(d)].

3.9.5 Data retrieval, testing and alternative methods

For many chemicals information required by REACH is already available in the literature and in databases [e.g. the REGISTRY database of the Chemical Abstracts Services (CAS) provider, which can be accessed in Germany via the Scientific Technical Network (STN) in Karlsruhe]. Nevertheless effective and cost efficient searches can only be carried out by experienced information retrieval experts, because background knowledge about valid information sources and their limitations is required.

In case information gaps remain after a comprehensive search tests can be carried out by specialised laboratories.

Alternatively Annex XI lists circumstances under which new testing does not appear scientifically necessary e.g. when a Qualitative or Quantitative Structure-Activity Relationship (QSAR) can be applied. QSARs are methods to detect preferably linear relationships in series of similar compounds, which allow to deduce the unknown properties of compounds with known structure. They relate properties of different chemical compounds to certain structural features of the respective molecules.

Apart from that, so-called “in-silico” methods can be applied to “calculate” toxicological properties of substances by computational modeling (Ekins, 2007).

3.9.5.1 Naming, grouping of substances and exemptions

RIP 3.10 provides guidance on the correct naming of substances of well-defined composition and substances of poorly defined or variable composition. This defines the breadth of compositions covered by a single substance registration (potential grouping of similar compositions) and – consequently – which participant belongs to which SIEF. RIP 3.10 is therefore very important for registrants. Companies will have to consult their naming approaches with the authorities before pre-registering (Ashford, 2007). Potential exemptions from registration obligations must be unequivocally identified. Haas (2007) describes the naming of substances and for which mixtures of substances separate pre-registrations are required.

3.9.6 Information management – REACH-IT

Zack (1999) proposes a 14 step framework on how to develop a corporate knowledge strategy. He points out that the knowledge strategy must be linked to the corporate strategy, which in turn is defined based on a Strengths, Weaknesses, Opportunities & Threats (SWOT) analysis. Wong (2005) presents a set of Critical Success Factors (CSFs) that can act as a list of items for SMEs to address when adopting Knowledge Management (KM). They are:

- Management and leadership support
- Culture
- Information Technology (IT)
- Strategy and purpose
- Measurement
- Organisational infrastructure
- Processes and activities
- Motivational aids
- Resources
- Training and education, and
- Human Resource Management (HRM).

These CSFs are similar to those for large companies given in earlier publications tabulated by Wong (2005). Wong added “training and education” as well as HRM. But culture, motivational aids, training and education can be regarded as aspects of HRM as well. To customise a set of CSFs for SMEs the author of this paper proposes to reduce the number of CSFs, because SMEs have limited resources to monitor CSFs. Presumably IT, organisational infrastructure and measurement are less important for SMEs compared to large companies.

3.9.6.1 Software

Data must be submitted electronically using the IUCLID software, which is provided free of charge by the ECB (2007).

Enterprise Resource Planning (ERP) systems and databases may constitute the underlying software solutions in appropriate ISs. In some cases the system architecture will have to be re-designed e.g. by purchasing a new Environmental Safety and Health (ES&H) software module for an existing ERP system.

3.9.6.2 Collection and validation of information

Internal procedures for information processing must be validated (DeSpautz, 1998). Moreover chemical experts should assure the quality of this information.

3.9.6.3 IT-security

Unauthorised access to and/or manipulation of information must be prevented and the integrity of the data must be preserved. Many SMEs will find this difficult, because it is not part of their current working habits [Chapter: Security consciousness in the “Mittelstand” (SMEs), chapter 6 in Gora and Krampert (2003), p. 97-112]. Another issue is potential attacks from the Internet e.g. hacking inside the computer network of a company.

An appropriate IT-security concept must be formulated and accepted by all employees with access to sensitive information [Chapter: Modern Security Management, chapter 10 in Gora and Krampert (2003), p. 197-208].

Differentiated access rights with user authentication by password entry, fingerprint, etc. provide means to prevent unauthorised access (Vacca, 2007).

3.9.6.4 Competitor intelligence

How to analyse competitors and to define appropriate strategies was described by Porter (1980). According to Porter, a firm that is “stuck in the middle” between the three generic strategic approaches to outperform other firms (overall cost leadership, differentiation and focus) is in an extremely poor strategic situation. This will often be the case for SMEs, because their resources are limited.

Companies should search to find out the strategic moves of their competitors. Potential moves of competitors should be taken into consideration (Hussey and Jenster, 1998) while laying out the own approaches.

3.9.6.5 Ways to assure confidentiality in SIEF-processes

Recommendations to keep Confidential Business Information (CBI) secret are given in RIP 3.4 (2007, p. 105).

According to Article 4 of REACH a company can appoint a Third Party Representative for all communications with other SIEF-participants. In such cases the identity of this company will normally not be disclosed by the ECHA.

During preparation of registration dossiers support from an independent party as a trustee can safeguard non-disclosure of sensitive information to the other cooperation partners. Additionally an independent trustee can be a means to avoid conflicts with competition law (Ihme, 2007).

In case registrants apply for this and pay a certain fee according to European Commission (2007a) the authorities will keep the information specified in this application confidential.

3.9.7 Effective management of projects and resources

REACH will make it necessary to apply project management techniques.

Burghardt (2006) as well as Cleland (2005) provide comprehensive guides for project management. The “GPM Deutsche Gesellschaft für Projektmanagement e.V.” (2007, German Society for Project Management) offers up-to-date information about all facets of project management.

3.10 Conclusion from the literature review

This literature review explains, which duties REACH imposes and highlights several areas where appropriate responses from SMEs will be required.

To develop and execute such responses will stretch the resources of many SMEs. Therefore diligent analysis, planning and project management is key.

The insights gained in this literature review will be complemented by and tested against the findings of the field research presented below.

4 Aims and objectives of the primary research

This study aims to find answers how Small and Medium-Sized Enterprises (SME's) can manage the challenges imposed by REACH. Related problems are:

- How to decide whether the registration of a substance will be profitable or whether the substance shall be withdrawn from the market
- How SMEs can protect their know-how while registering chemicals
- Change Management (if necessary):
  - Which organisational structures and resources are needed?
  - How can they be provided?
- How can SMEs minimise the risk that their suppliers withdraw chemicals, which are key for their processes?
- What are the financial implications of all this and how important are they in decision making?

4.1 Scope of this research

This research is to identify, and focus on, the immediate and most threatening problems SMEs face through REACH. Related issues shall be discussed and evaluated based both on the above literature review and on fieldwork. The negotiations on REACH preceding the final decision of the European Parliament in the end of 2006 have polarised the participants. This polarisation between environmental activists and environmental authorities on the one side and representatives of the industry as well as authorities dealing with commerce on the other side has remained. Therefore the author of this study collects and contrasts different views to derive "inter-subjective" conclusions about the relevance of what is currently happening and possible opportunities or threats through REACH.

According to the author's judgement authorisation is covered by earlier work (see paragraph "Authorisation") as comprehensively as possible, because still national law and guiding documents are under negotiation (compare table 1 above).

Usually SMEs in Germany are not listed at the stock market. Therefore potential influences of the registration/authorisation of substances on a share prize as discussed by Sturm (2007) for pharmaceutical companies will not be treated here.

Unsolved legal issues like the impact of REACH on recycled materials (Klett, 2007) are outside the scope of this dissertation too.

This study faces the difficulty that many of the effects under consideration cannot yet be quantified, because many relevant prescriptions e.g. some of the RIPs, are still not finalised (compare paragraph "Technical issues associated with REACH"). Therefore already existing similar legislative initiatives (see respective paragraph) for biocides, agro-pesticides and medical products may provide insights. The aim of this study will be to find analogies, to search for conclusions and for lessons learnt, which can help to manage the REACH processes SMEs have to go through.

The immediate challenge for SMEs will be to develop a strategy until the pre-registration starts on June 1st, 2008 to make the optimum decisions. This requires an understanding of the different strategic options the respective SME has. *The target of this study is to clarify the underlying mechanisms.* The exploratory research design described below was chosen to rank the areas where appropriate responses by SMEs are required.

5 Research methodology

Howard and Sharp (1995) describe how to manage a research project.

Accordingly a literature search in the Internet, in libraries and commercial databases was carried out and reviewed in the introductory part of this study. The findings of this search will later be combined with those of the fieldwork to further refine the conclusions.

5.1 The interview study

Hair *et al.* (2007, p. 124) recommend small samples of personal interviews or case studies for the collection of qualitative data in exploratory studies like this one. Since the issues imposed by REACH are new and vague (i.e. currently emerging) exploratory research is a must (Cooper and Schindler, 2001, p. 139). According to them (p. 134) face-to-face and telephone interviews are particularly helpful when dealing with complex or sensitive issues – which is the case here. Semi-structured interviews, where the interviewer asks related, unanticipated questions may result in insightful information (p. 135). The core part of this research was therefore constituted by an “interview study” (Henley Management College, 2005) in a semi-structured manner. Issues (especially costs, profitability, knowledge management, the protection of intellectual property and project evaluation) were discussed in one-to-one meetings and telephone interviews.

The flexibility of this method is an important advantage compared to a questionnaire study, where additional questions for later clarification are not possible. Insights might emerge only after the first interviews have already been conducted. Then, this explorative research allows to investigate the respective aspect in detail.

5.1.1 Sampling

Potential interview partners were identified and asked to discuss issues related to REACH. Only in two cases an interview was denied. In one of these two cases at least a short statement about the own approach was added. Interviewees were selected from:

- Personal and professional contacts of the author of this study
- Professionals identified in the course of the literature search
- The Henley Alumni network
- Recommendations from interviewees

An emergent “judgement sampling” approach (Hair et al., 2003, p. 217) was applied to collect views from different perspectives. Within this study 13 interviews were carried out.

5.1.2 Interview procedures

Interviewees received material about REACH some days in advance to the actual interview to prepare themselves (see Appendices: “REACH - New EU chemicals legislation”, “Proposed steps to REACH-registration” and Figure 1). The interviews started from a questionnaire, which was sent to the interviewees in advance too. The initial questionnaire was pre-tested by discussing it with the first interviewee before the actual interview. This pre-test was carried out to verify that the questions were clear and addressing key issues while giving enough room for further comments hopefully given by the interviewees. While the research proceeded, further interviewees were identified. Questions were adjusted keeping in mind earlier findings and the special background of the respective interviewee. Where interviewees had published a paper about REACH the questionnaires contained at least one question referring to their work. All but three interviewees had read the questions in advance and had thought about appropriate answers (two of these three were consultants who entered directly into the interview when they were contacted).

The semi-structured interviews were digitally recorded except where interviewees disagreed (only one interviewee disagreed). After each interview the author of this study prepared a written protocol and e-mailed it to the interviewee for amendments and additional statements. This procedure often yielded further information. The interviewees cooperated well.

If necessary or desirable further issues were clarified via e-mail or telephone. Applied deductive research as explained by Gummesson (2000) was carried out.

Moreover some of the interviewees provided additional literature for the study.

The author is aware that his interview partners can only spend a limited amount of time supporting his research. He therefore focused on core issues where the respective interviewee is especially competent. Moreover the author tried to provide a calm and undisturbed atmosphere during the interview. Although the author had only limited control of the circumstances of the interviews, most of the interviews were carried out without significant disturbances.

5.1.3 Analysis of the qualitative results

Each statement within an answer was treated separately. In case it fitted under a heading of the findings, this paragraph was amended accordingly. If the statement constituted a new aspect, an additional section was added to the findings.

In contrast to other studies the answers were not analysed in terms of percentages of interviewees sharing a certain opinion. This kind of analysis cannot be applied here, because the questions asked differed from interviewee to interviewee (except for the first 3 interviews, which were based almost on the same set of questions). As explained in the preceding sub-paragraph this procedure was chosen to exploit the special expertise of each interviewee in an optimum manner. To give at least some quantitative measures, the interviewee's professional positions were specified. It was emphasised when more than one interviewee expressed the same view.

Due to the nature of this exploratory research only qualitative information was

obtained. Since many issues are still in the process of development “hard” data are often not yet available. In some cases contrasting opinions or expectations among the different groups of interviewees were found and reported. To solve these discrepancies is beyond the scope of this exploratory research.

Based on the results of the interviews the appropriateness of certain approaches for the implementation of REACH projects and their implications for SMEs were discussed and strategies for companies in different positions or roles (e.g. importer) were given (compare chapter discussion).

5.1.4 Case studies

A case study is proposed as the preferred approach, when “how” or “why” questions are to be answered (Ghauri and Grønhaug, 2005, p. 115). Accordingly two case studies exemplify the approaches chosen by:

- A chemical manufacturing company as well as by an
- Importer, commercial house and formulator.

These case studies are based on information given by interviewees as well as on published information i.e. newspaper articles and company websites. Both case studies were reviewed and accepted by the respective interviewee.

6 Findings

6.1 Impact of REACH on the chemical industry

The pre-registration deadline is still three quarters of a year ahead. Therefore companies must prepare themselves. But they do not need to make immediate decisions yet.

All interviewees were confident that SMEs in general will be able to cope with the new requirements introduced by REACH if they address these tasks early and work consequently to solve the related problems. Nevertheless, they expected that at least some companies will run into difficulties, which will threaten their existence.

The new requirements will force manufacturers and importers of chemicals to manage their product portfolios more deliberately. In the long run companies must cope with higher costs for providing the basic requirements of market participation. Managers must plan for appropriate capacity, funds to cover test and registration costs as well as other resources. The interviewees from the chemical industry (among them two general managers) and a consultant (employed by a chartered accounting company) identified cost problems for medium sized companies especially in the range between 10 and several 100 tonnes/year.

All but one interviewee (employee of the Ministry of Environment) agreed that shutdowns and acquisitions of companies as well as relocations (i.e. the transfer of products to countries outside the EU) of chemical products and/or the production of articles from chemicals can be expected.

Interviewees No. 7, No. 9 (compare appendix) and a consultant (consultancy in the field of environmental protection) expressed their view that the new standards will make the European chemical industry more competitive. Moreover one interviewee (No. 13) argued that all stakeholders including consumers will profit if chemical hazards associated with products are better understood and

documented. Another interviewee (a general manager) regards REACH as over-complex and a burden.

Interviewees from the industry as well as the interviewees No. 7 and No. 9 fear market distortions between Europe and non-EU countries as well as between different countries and regions within the EU. Such distortions can result from different behaviours of authorities in different countries or regions. To minimise such distortions a forum for the exchange of control measures was created on EU level in order to consult and teach each other how to proceed.

6.1.1.1 Many chemicals will disappear from the market

All interviewees agreed that many substances will disappear from the market. One consultant from the pharmaceutical industry (former director of R&D) reported a case where a certain chemical – although it had favourable properties and was obviously not hazardous - could not be used as an ingredient for tablets, because neither the producer nor the potential customers (pharmaceutical companies) wanted to pay for the registration. The interviewees No. 7 and No. 9 as well as the interviewees from the industry expressed fears that DUs will run into difficulties if their suppliers stop delivering key substances.

But the streamlining of product portfolios can yield efficiency effects as well: In many cases suppliers know that different substances in their portfolio are used for identical purposes. Here REACH can trigger the switching to the “best in class” product and the drop of superfluous parallel chemicals from product portfolios. Consequently the turnover of the “best in class” product will increase and extra efforts for providing parallel products can be saved.

6.1.2 Increasing chemicals safety standards worldwide?

The interviewees No. 7 and No. 9 as well as those from the industry and two consultants argued that market participants in other parts of the world will monitor the developments initiated by REACH and define appropriate responses. Therefore these interviewees expect increasing environmental and chemicals safety

standards worldwide. Nevertheless, interviewee No. 11 (general manager) and two consultants (former director of R&D and former manager in the fine chemicals industry) doubt that REACH will yield such positive effects.

6.2 Registration costs

Interviewees from the industry criticised the cost structure for registrations:

One interviewee (general manager) complained about the fees for joint registrations, which he regards as being unfair: According to him the ECHA has almost the same amount of work whether a registrant submits his dossier alone or in cooperation with others. But in the latter case the ECHA will invoice 75 % of the single-registration fee from each company taking part in the joint registration (European Commission, 2007a). He argued that the ECHA will enrich itself excessively in case that e.g. 8 companies submit a joint registration.

Apart from the fees registrants have to invest additional effort for:

- Internal activities to support the REACH compliance processes
- External costs for tests, consultants, lawyers, SIEF administration, training of employees, etc.

A consultant (employed by a chartered accountant firm) pointed out that in most cases only the expenses resulting from the registration or authorisation of a certain substance are calculated. Further impacts on resources and problems like authorisation risks or difficulties to source certain chemicals are often neglected.

An interviewee (from the Ministry of Environment) reported that before REACH entered into force Chemical Safety Reports (CSRs) were prepared by authorities as well. This task will be completely shifted to the industry. The requirement to provide a CSR for the tonnage band > 10 tons/year is still under negotiation. CSRs might be required for lower tonnages as well when REACH is amended at a later stage.

6.3 Pre-registrations

Pre-registrations are free of charge. But companies should keep in mind that each pre-registration introduces them automatically into one SIEF where they are obliged to cooperate. At least they will have to answer questions asked by other participants. Companies should therefore pre-register diligently.

6.4 Authorisation risks

Authorisation risks can threaten the existence of companies. Unfortunately companies cannot predict whether a chemical will become subject to authorisation.

A consultant (from a consultancy in the field of environmental protection) pointed out that to have a chemical authorised requires a considerable investment and that this will motivate companies to explore alternative options.

The requirement to have substances authorised will become effective in 2010. According to the director of the ECHA this time frame was chosen to give companies enough time to carry out appropriate measures to solve related problems.

Manufacturers of potential candidate chemicals for authorisation must be aware that their suppliers might face similar problems. This is often neglected. The interviewees from the chemical industry and the consultants underlined that whole product groups will disappear from the market. Until this happens these products can be used as “cash cows” (maximum return – minimum investment strategy).

Theoretically chemicals subject to authorisation can be relocated to countries outside the EU. But since the markets there will observe the regulations in the EU and customers might become reluctant to buy, a sustainable market success in non-EU countries is questionable.

Interviewees from the industry, from consultancies and from the authorities agreed that to subject a chemical to authorisation will be a political decision (made preferably on the national level): The CSR will be weighed against the conclusions from the economical study by politicians – not by scientists.

6.4.1 Substitution of chemicals

The authorisation puts pressure on companies to substitute the respective chemical by one with less hazardous properties. To develop a substitute product line requires extensive investments as well as time. In most cases, SMEs cannot easily afford both. An interviewee (R&D chemist) reported that his company produces and markets a chemical for which authorisation risks exist. Therefore, a substitute product line was launched in parallel, which is currently much more expensive and yields a small sales volume compared to the original product.

6.5 Relocations

Two general managers commented that relocation of production sites to countries outside the EU is simple for companies. Especially relocation to Asian countries like China and India is already a major trend, which might be further nurtured by additional costs imposed by REACH, because these costs can be avoided by such moves. Nevertheless the advantages, costs and further implications of these moves must be carefully analysed in advance.

Three issues support relocation trends:

- There will be no inspections of production facilities outside the EU
- Many DUs in the EU will find it difficult to source certain chemicals for low-turnover uses, which are not registered by the manufacturer/importer
- Importing articles into the EU, which contain substances subject to REACH is not restricted.

6.6 Impact of REACH on downstream users

DUs must communicate up and down the supply chain to make sure that:

- Important substances for their processes stay available. Because most portfolio decisions have not been made yet, suppliers are currently not prepared to state clearly how they will proceed. Since DUs are suppliers

for various industries themselves, the effects of substances being withdrawn from the supply chains is an unpredictable risk.

- Together with registering chemicals their uses must be specified. In case that the producer/importer does not include a certain use in his registration, DUs can notify their use to the ECHA.

In case that doubts remain whether suppliers will register an important chemical or a certain use, DUs are allowed to register the respective chemical themselves. It is not necessary to pre-register prophylactically. According to interviewee No. 9 (director of the ECHA), there will be an additional time frame for DUs after November 30th, 2008.

In general the business strategy of DUs is not affected by REACH as long as they do not face the abovementioned problems and no significant additional costs are incurred. Nevertheless, DUs must define their information strategy as well.

6.7 Substance Information Exchange Fora and cooperation

Joint registrations will lower the registration costs for each individual registrant and can lead to a better quality of the submitted material. But these advantages are only brought about if standard procedures (i.e. standard contracts) are applied. The evaluation of data and negotiations (especially about cost-sharing) can become complicated (compare: RIP 3.4, 2007), time consuming and expensive.

Only one interviewee (general manager) was reluctant regarding the potential benefits of cooperations with competitors. He rated confidentiality issues as being very important.

One consultant (from a consultancy in the field of environmental protection) reported that larger companies have already founded alliances. Another consultant (scientific service provider) confirmed that this will bring these companies into a strong position when it comes to negotiating cost sharing within a SIEF.

It is the exclusive task of the participants of each SIEF to clarify whether all of the substances they want to register are identical (compare Haas, 2007 and RIP 3.10).

6.7.1 Data trading within SIEFs

The exchange of data within SIEFs is a central element of the REACH process. Often parts of the costs of providing information are hidden, because they are incurred through internal efforts. But even such costs can be shared due to the private nature of the agreements negotiated within SIEFs. Those who offer data are in a strong position, because the exact conditions of the agreements with other SIEF participants will in most cases stay confidential (a consultant employed by a scientific service provider referred to his experience from biocide dossiers). Buyers will therefore not know whether they contribute an equal share of the testing costs or whether their payment means actually a profit for the supplier of the data. The interviewee further commented that if buyers of data are dissatisfied later, they must accept that they have negotiated a disadvantageous agreement.

A new manufacturer/importer can only pre-register until one year before the transitional time for registrations for his respective tonnage band ends. For a smaller tonnage band this may even happen after other SIEF participants have registered. Then the new registrant and the existing group of registrants can negotiate whether the new registrant joins or whether he will register separately while certain data are shared. Three consultants pointed out that under such conditions the members of the existing cooperation will be in a strong negotiation position: The new manufacturer/importer will not be interested to lose time and money by suing his counterparts. He might therefore accept demands, which he regards as unfair.

Two consultants expect that companies can even make profits by selling test results or other know-how. But no interviewee thought that earning money by selling data is a realistic strategy for SME registrants.

6.8 Opting out

A joint registration can become disproportionately expensive from the point of view of companies with lower data submission requirements in case that the other

SIEF participants go for a registration in a bigger annual tonnage band, so that high administration costs are incurred. Then, opting out (compare paragraph 3.9.4 “SIEF processes”) is an option.

Opting out is an option too when information about a hazardous but highly profitable application shall be protected.

One consultant (from a consultancy in the field of environmental protection) pointed out that dossiers, which are submitted separately will preferably be selected for evaluation.

6.9 Additional business opportunities through REACH

6.9.1 Learning through REACH

Companies must acquire knowledge to carry out the REACH processes successfully. Many managers from the chemical industry have not yet understood the implications of the upcoming regulations. But one consultant emphasized that SMEs who use chemicals only in smaller tonnage bands have the chance to learn from the experiences of other companies who registered earlier.

One consultant (from a consultancy in the field of environmental protection), one interviewee from the chemical industry (EH&S professional) and the interviewees from the authorities expressed their expectation that investing in better understanding the risks associated with the use of hazardous chemicals will be worthwhile for companies and make them more competitive.

Although SMEs employing in-house specialists for Environment, Health & Safety (EH&S) are in a favourable position no interviewee thought that companies must change their internal structures as a response to REACH.

6.10 Confidentiality issues

SMEs fear that valuable know-how might be disclosed within the REACH process e.g. through MSDSs. All interviewees agreed that this is an issue.

6.10.1 Information strategy

All companies are well advised to formulate an information strategy, before starting to communicate. This strategy must define, which know-how shall be treated as Confidential Business Information (CBI). An interviewee (ECHA director) referred to RIP 3.4 (2007), which names examples of CBI.

REACH offers several ways how companies can have CBI protected.

Companies should be aware that the authorities must publish certain information to achieve environmental protection as well as workers' and/or customers' health protection [Preamble of REACH (117)].

Therefore companies can aim for their individual registration (compare: "opting out") when they want to keep their know-how secret under any circumstances.

6.10.2 Identity of a registrant

Disclosure of the identity of a registrant might make potential competitors aware of attractive markets, which were overlooked earlier. Companies can solve this problem by hiding their identity. To use the services of a third party representative is a valid option. But one consultant (scientific service provider) warned that this approach can make the negotiations within the SIEF difficult, because the other participants might not trust their anonymous counterpart. Another consultant (in the field of environmental protection) doubted that companies can hide their identity through the entire cooperation process.

6.10.3 Tonnage bands

Companies cannot keep it secret when they aim for an early registration deadline in SIEF negotiations. Therefore market expectations for certain chemicals will become transparent for competitors.

6.10.4 Uses

Downstream users have the right to inform producers/importers about their uses to have their special use included in the registration of the respective chemical. This motivation conflicts with the reluctance of DUs in attractive markets to disclose their use of a certain chemical to their suppliers: The exact use is an indicator for the value the DU generates through this chemical. Suppliers could therefore charge higher prices for products, which allow for high-value applications (“value pricing” as opposed to “cost-based pricing”).

One interviewee (general manager) and one consultant reported that information on use can effectively disclose recipes of preparations.

6.10.5 Potential information leaks

All interviewees agreed that the authorities will keep secret information confidential – as far as this is intended by REACH.

But information leaks might exist in the SMEs themselves e.g. through insecure information systems (ISs), an unclear information strategy or incautiousness.

6.10.6 Information notaries

Only in cases where registrants do not trust each other, an information notary will manage the process of buying data. Two consultants (from a consultancy in the field of environmental protection and from a scientific service provider) commented that this approach does not make much sense under normal circumstances since often not the data themselves are required but a “letter of access”, which allows its owner to use data from external sources for his own registration.

6.10.7 Trustees

Trustees can be helpful in SIEF negotiations e.g. by:

- Evaluating studies without disclosing the content to other parties
- Compiling information so that each cooperation partner can access his data exclusively.

6.10.8 Conflicts with competition law

When companies negotiate within the SIEF process it is likely that they talk about prices as well. Therefore conflicts with the competition law will arise. The ECHA director and the employee of the Ministry of Environment confirmed Ashford’s (2007) statement that companies might face conflicts with competition law while negotiating with competitors in SIEFs. A consultant (former manager in the fine chemical industry) commented that there is no solution for this conflict. The interviewee from the Ministry of Environment recommended that companies should seek help from lawyers to avoid such problems. Additionally, a consultant (scientific service provider) recommended comprehensive written agendas and a protocol for each meeting

6.11 Information systems

Surprisingly the interviewees unequivocally expressed the conviction that SMEs will not need additional ISs. Current state-of-the-art practices were regarded as appropriate to cope with the additional Knowledge Management (KM) requirements.

The following items were mentioned as supporting confidentiality of information:

- secure servers and firewalls
- change of passwords in regular intervals
- secure data transfers
- motivating employees to keep secrecy.

6.12 Learning from the pharmaceutical industry

Since the pharmaceutical industry went through a legislative process similar to REACH earlier, this industry has already built up experience, which can be helpful to the chemical industry. Such capabilities or experiences are:

- Preparation of documentations
- Management of cross-functional teams starting early in development processes
- Product portfolio management systems.

The chemical industry can acquire these capabilities e.g. by hiring experts from the pharmaceutical industry.

6.13 Lobbying for SME's on EU-level

SMEs often show a lonesome-warrior attitude. Moreover, they are organised – if at all – in small lobby organisations with almost no representation on EU-level. This situation automatically puts them into an underprivileged position when the conditions for their operations are negotiated there. SMEs must therefore learn to organise effective lobbying for their requirements on EU level. One way to do so is to found joint-venture representations of several national lobby organisations.

This is important for SMEs, because the interests of large companies, which are mainly considered in discussions about operation conditions, differ considerably from those of SMEs.

6.14 Risks of REACH

No interviewee was able to predict the effects REACH will exert on the chemical industry. All interviewees from the industry agreed that REACH is only one aspect of the Political, Economic, Social, Technological, Legal and Environmental (PESTLE) environment companies have to cope with. Two interviewees (ECHA director and the employee of the Ministry of Environment) even speculated that REACH might mean almost nothing for the chemical industry.

6.15 Case studies

To illustrate how competent firms like a producer and an importer of chemicals prepare themselves the following short examples are given.

6.15.1 Zschimmer & Schwarz GmbH & Co. KG

Zschimmer & Schwarz GmbH & Co. KG Chemical Factories (Z&S) in Lahnstein, Germany is a medium-sized producer of chemicals and a formulator of preparations. The company has approximately 500 employees in Germany. It concentrates on producing auxiliaries for the fibre, ceramic, leather and fur industry and on manufacturing surfactants for the cosmetics and cleaning agent industry. Furthermore, Z&S trades in chemicals and provides a customer and application-oriented service through a worldwide network of affiliate companies and representatives.

The company uses approximately 900 substances subject to REACH of which 300 are manufactured in its own facilities. These substances range from 1 to 6,000 tonnes/year. The annual turnover in Germany is approximately 150 million €.

Without external help the company built up an inventory of all these substances,

compiled basic data and clarified the roles it has in relation to each respective chemical.

Pre-registrations will be carried out for all substances of interest to make sure that the company can make use of the respective transitional periods until 2010, 2013 or 2018, respectively.

When it will become clear that certain chemicals must be substituted, appropriate portfolio management decisions will be made. Presumably the portfolio will be slimmed down drastically starting 2010.

Calculations based on the assumption that registrations will be carried out in cooperation with other registrants resulted in estimated costs of 50 million €.

In most cases customers will not be able to pay e.g. 35 % more for chemical products. Therefore the company expects many customers to relocate their production to countries outside of the EU.

The company expects no authorisation risks.

Nevertheless the management sees a considerable risk that suppliers of important chemicals will stop delivering, because they are not interested to pay for the registration of niche applications. The company faces the problem that many suppliers are not prepared to state clearly whether certain products will be available in the future.

The company currently struggles to cope with other trends as well e.g.:

- Increase of the prices for raw materials
- Weakness of the US$ in relation to the EURO: This lowers the margins for products made in the EU, which will be paid in US$ after being exported e.g. to North American Free-Trade Agreement (NAFTA) countries
- Relocation of the production of chemicals, preparations and articles to other countries. The company itself will relocate the production of chemicals for the Chinese market to China.

6.15.2 Lehmann & Voss & Co. KG

Lehmann & Voss & Co. KG (LuV) in Hamburg, Germany, is a medium-sized family enterprise, which was founded over 110 years ago. The company is a commercial house for chemicals and a formulator of chemical and mineral specialities. Many of these products are customised by LuV to optimise the individual products of customers or their manufacturing processes.

The company employs a staff of 268 people in Germany. With own warehouses and extensive handling facilities, the company offers a wide range of different packaging forms. Customer-specific modifications and problem solutions are developed in an own laboratory and a pilot plant.

LuV sells its products directly in Germany and the neighbouring countries. Subsidiaries in the United Kingdom, France, Italy, Switzerland and Romania serve the markets there. This organisation provides expert service throughout Europe.

LuV uses substances mainly in the range from 1 to 100 tonnes/year each. Its annual turnover was 156 million € in Germany and 192 million € for the whole group in 2006.

LuV started its REACH-related activities four years ago. Since then, several REACH workshops for customers were carried out. The company wants to become known as a problem-solver for its customers concerning REACH issues. With its own legal and environmental department the company had already appropriate structures in place to address issues related to hazardous chemicals effectively.

LuV decided to run the REACH process with its own resources in order to keep it under control. After having built up an inventory of all relevant substances, the company compiled basic data and clarified the roles it has in relation to each respective chemical. Moreover, the company tries to clarify its market position for each product. The market position (in most cases: small niche supplier) indicates how LuV can behave in the SIEF process. As a niche supplier LuV will cooperate actively in SIEFs.

The business units of LuV will decide about their respective pre-registrations

bearing in mind the individual market potentials of their individual products. Only minor changes of the product portfolio are expected. Depending on the acceptable breadth of use definitions according to RIP 3-2 certain special uses of imported chemicals might not be registered by LuV.

Currently, the company expects no authorisation risks although classifications can change when the EU regulation Classification, Labelling and Packaging (CLAP) will enter into force in 2008.

LuV has asked its EU suppliers whether their products will further be available. This was confirmed in most cases, because the respective chemicals are often main products.

Being an importer LuV contacted its non-EU suppliers as well. The reactions indicate that in general the new requirements are often not yet understood. Nevertheless e.g. Asian suppliers are interested to learn more about REACH. But LuV assumes that it has to register its imported chemicals without significant help from non-EU suppliers.

7 Discussion

7.1 Building a REACH compliance strategy

Since the resources of SMEs are limited, managers must define trade-offs while formulating their REACH compliance approach. Orsato (2006) proposed a framework for defining and prioritising areas of organisational action, optimising the return on environmental investments, and transforming these investments into sources of competitive advantage.

Figure 3: Generic Competitive Environmental Strategies

Competitive Advantage	**Lower Costs**	Eco-Efficiency	Environmental Cost Leadership
	Differentiation	Beyond Compliance Leadership	Eco-Branding
		Organisational Processes	**Products and Services**
		Competitive Focus	

Depending on the types of markets a company serves and its capabilities managers should select the appropriate competitive focus (organisational processes or products/services) and the potential source of competitive advantage (cost or differentiation) for their firm. These choices will lead them to one of the four strategies described below:

Eco-Efficiency

A company focusing on this strategy will continuously improve the productivity of its processes while decreasing the environmental impact and the costs associated with them. Such practices yield their rewards in themselves. When this strategy is

applied in its pure form, there is no motivation to invest in related Public Relations (PR) activities.

Zschimmer & Schwarz GmbH & Co. KG (first case study) applies this strategy.

Beyond Compliance Leadership

This is the strategy of choice for companies who strive not only to increase the efficiency of their organisational processes, but to have their efforts acknowledged by customers and the general public. An example of this approach was given in the second case study of Lehmann & Voss & Co. KG. This strategy requires that appropriate resources are provided to develop the capabilities needed.

Eco-Branding

Here the marketing is based on differentiation through environmental attributes of products. There are three basic pre-requisites for the success of this strategy:

- consumers must be willing to pay for the costs of ecological differentiation;
- reliable information about the product's environmental performance must be available to the customer and
- the differentiation should be difficult to be imitated by competitors.

If the company is not operating in a price-sensitive market, it can obtain a price premium. But the vast majority of the SMEs is not in this comfortable situation.

Environmental Cost Leadership

If a company must compete on price and environmental performance this is the strategy of choice. For firms operating in such markets, focusing on radical product innovation, such as material substitution and dematerialisation, makes more business sense than improving processes only incrementally. In the context of REACH this strategy might be beneficial for SMEs – especially for start-up companies and when suppliers are under pressure to withdraw certain SVHCs from the market.

7.2 Impact of REACH on SMEs in the chemical industry

According to the findings, companies in general will be able to cope with REACH. But compared to bigger companies SMEs will find it more difficult to comply with the new requirements. Among the SMEs the following groups are likely to be threatened the most:

- Importers of chemicals
- Producers or chemicals, especially if they have authorisation risks in their product portfolio
- DUs whose suppliers stop delivering key substances for their operations.

In the long run, the standards and basic costs of market participation will rise. Stronger and more competent companies will profit from this trend. Weaker and less competent companies will have to document at least a basic understanding of the risks they take while using chemicals and how to keep applications under control.

Shutdowns and acquisitions of companies as well as relocations were observed before REACH entered into force as well. The new regulations are only one of several PESTLE factors. Nevertheless, it cannot be ruled out that REACH will trigger such decisions.

Since variety has a stabilising effect in complex systems as supply chains, negative outcomes cannot be ruled out when substances are withdrawn from the markets.

7.3 Registration costs

Apart from the ECHA fees registrants must invest additional efforts as specified in paragraph 6.3 “registration costs”. In many cases these additional costs will exceed the fees by far.

Appropriate resources must be provided. SMEs should therefore plan diligently.

7.4 Pre-registrations

As explained in the findings companies should pre-register selectively.

7.5 Authorisation risks

Authorisation risks bear the most severe threats for companies under REACH.

The behaviour of the authorities and political decisions cannot be predicted. Companies should therefore identify substances at risk and develop appropriate measures especially if they tend to substitute chemicals. Substitution is regularly expensive, time consuming and goes along with development risks.

If companies identify high-value products in their portfolio at risk to become subject to authorisation, they must apply additional measures. Procedures originally developed for the pharmaceutical industry can help:

- Net present value (NPV) calculations applying the DCF method for each product should be carried out. A strategic controlling must be installed where it is not in place yet.
- Risk analyses (Bieber *et al*., 2006) estimate the resulting impacts, if products must be dropped. They are part of the standard portfolio management procedures in the pharmaceutical industry. Nevertheless they must be interpreted carefully: It is easy to calculate the potential consequences, when a substance is subject to authorisation. But nobody knows how likely it is that this really happens.

Geldsetzer (1998) studies product portfolio management methods for pharmaceutical companies. Some of those may be applied in the chemical industry as well. He concludes that simple models are in most cases not adequate to account for the complexity of the decision making task. But complicated approaches are often difficult to understand.

Blau *et al.* (2004) show how product portfolios can be optimized by Monte-Carlo-simulations taking into account interdependencies of the individual products.

Modeling can provide additional insights for decision makers. But this approach seems to be too sophisticated for the chemical industry, where product development times are considerably shorter compared to the pharmaceutical industry. In the chemical industry general managers of SMEs usually evaluate their product portfolios themselves and make appropriate decisions.

If an authorisation is too expensive Product and Process Orientated Research and Development (PPORD) might give a company additional time to work with a substance.

7.6 Relocation

Relocations should be based on an in depth analysis and planned carefully.

In cases where the sales volume of chemicals produced in Europe is low compared to the sales volume in other parts of the world, relocation of the respective products - i.e. the transfer of production sites and sales organisations to countries outside the EU – is a valid option.

7.7 Downstream Users

In most cases DUs will be affected by REACH indirectly:

- Suppliers might stop delivering key chemicals
- Problems can arise when special uses of chemicals are not registered by suppliers. But here the downstream users are free to register themselves.

These issues require active and effective communication up and down the supply chain.

7.8 Substance Information Exchange Fora and cooperation

SMEs will generally register substances in cooperation with other firms, because this is the easiest and most affordable tactic for them.

How well this will work depends on the individual behaviour of the SIEF-participants.

7.8.1 Data trading within SIEFs

The evaluation and negotiations regarding the conditions for the exchange of data or granting access to data can become complicated [compare RIP 3.4 (2007)]. External experts can help to carry out these tasks.

7.8.2 Conflicts with competition law

In cases where companies are aware of such conflicts they should seek the help of a lawyer. Compare the respective paragraph of the findings and RIP 3.4 (2007) for further measures.

7.9 Opting out

Opting out should be considered when cooperation costs become inadequately expensive (compare findings).

In case of high-value products with hazardous applications, which require special safety management know-how, opting out can be a way to keep sensitive information secret.

7.10 Confidentiality issues

While developing their information strategy companies must consider that there are several ways how information can be disclosed through REACH processes.

Regulation (EC) No 1049/2001 guarantees an easier public access to European Parliament, Council and Commission documents. Therefore a general trend can be expected that the access to information may become easier in the future for interested parties.

7.10.1 Separate submission of information within cooperations

To submit a CSR separately within a joint registration [Article 11 (1)] is a way to prevent disclosure of confidential know-how to other SIEF participants. This advantage should be weighed against the extra efforts required.

7.10.2 Uses

In general uses should be specified as broad as possible. Broad use specifications can help producers and importers to keep their niche customers. In most cases it will not be required that DUs disclose detailed information to their suppliers. Acceptable breadths of usage specifications will depend on decisions made by the ECHA and on RIP 3.2 (currently under development).

7.11 Information systems

Nicolaides (2007) reviews KM- and Decision Support Systems (DSS) for product development processes in the chemical industry. He concludes that the main values to be uncovered remain locked in other parts of development processes effectively hidden from software systems. According to him only wealthy organisations who invest in the associated aspects of such ISs generate good value from their use. Such associated aspects may be appropriate information and training of the employees. Nevertheless he sees the option for smaller organisations to generate extra value by purchasing improvements through KM systems and DSSs as services.

This conforms to the finding of this study that SMEs in general will not need extra ISs to effectively store, retrieve and distribute the information generated by their REACH compliance efforts. In this respect SMEs differ from big chemical companies, which have to register e.g. 1000 chemicals each and develop appropriate software tools as Clariant AG does (Passing, 2007).

Although the IUCLID software for the compilation and submission of data is

provided free of charge an appropriate training of the operators is required. One option for SMEs to fulfil this requirement is to purchase scientific services (i.e. the compilation and submission of data) from a specialised provider.

7.12 Case studies

The two companies described in the case studies are not included in the EU definition of SMEs, because their numbers of employees and their annual turnovers exceed the limit values, but they certainly fall within the SME definition used in this study. In any event they can be regarded as best practice examples how competent producers and importers of chemicals prepare themselves.

7.13 Cost modeling

Because financial considerations have a strong impact on profits the author of this study developed own simple cost models as table calculation sheets based on the cost information given in the introductory part and applying the DCF method. It soon turned out that the results of these calculations only provided lower cost limits: Due to the unpredictable negotiations in the SIEF- and in authorisation processes, higher costs than originally expected cannot be ruled out.

The same limitation applies for the findings reported by Ihme (2007)(compare section 3.9.4.1).

7.14 Lobbying for SMEs on EU level

That SMEs are not well represented on EU level is a major disadvantage.

Lobby organisations as the VCI have traditionally focused on the interests of large companies, because it is much more difficult for them to investigate and represent the highly differentiated needs of SMEs.

7.15 Bias between EU, national and regional level

Decisions about REACH were made by the European parliament. But the nations and local authorities are free to enact the detailed implementation rules. These rules can therefore – and will most probably – differ from state to state within Europe. Such differences might lead to competition distortions between companies in different countries. If national law defines trading in a not-registered chemical as a criminal act in Germany and only as contrary to order in e.g. Italy, German managers must fear imprisonment whereas Italian managers might pay a fine for the same offence. Therefore severe punishments should be harmonised on EU level. The constitution of an international harmonisation committee for mutual consultations is a first step.

Market distortions between different countries and regions within the EU as well as between Europe and external countries are likely. Although such distortions exist always they were taken as an argument against REACH. The forum for the exchange of control measures on EU level will have to be complemented by additional measures to reduce EU internal distortions. External distortions must be accepted, because they cannot be addressed directly by the authorities.

7.16 Risks of REACH

It cannot be ruled out that REACH might disturb potentially fragile equilibria within the chemical industry, because SMEs (who provide flexibility to the cumbersome structures) will be affected most. The question is: What will happen, when this flexibility diminishes? All parties involved in the process should therefore aim not to leave SMEs with burdens, which they cannot carry.

8 Conclusions

8.1 Business trends resulting from REACH

According to the literature review and the findings SMEs can expect the following external trends.

8.1.1 More transparency

REACH aims to improve transparency through different measures:

- Communication up and down the supply chain and exposure scenarios attached to MSDSs will provide more specific information to DUs.
- The requirement to declare substances subject to authorisation contained in preparations (article 33 of REACH) in concentrations higher than 0,1 % by mass (w/w) and to provide sufficient safety information on request will presumably deter customers from buying products containing such ingredients. Thus, the pressure on manufacturers and importers to substitute these chemicals will increase.
- ECHA will provide a database containing basic data about substances with which consumers might come into contact. This database will be open for public access [REACH-Preamble (117)].

Improved information access for customers and the public about the chemical hazards associated with the use of chemicals will force managers to ground the activities of their companies on a better understanding and to take responsibility.

8.1.2 Increasing chemicals safety standards worldwide?

Although the chemical industry in Asia grows rapidly, the European chemical industry still sets the benchmarks. This applies not only for REACH, but for the

progress in technology and regarding Environment, Health & Safety issues as well. Therefore, it can be expected that the chemicals safety standards will increase worldwide. But it is not possible to decide yet, whether this will be an effect of REACH. Presumably increasing safety standards are a general trend associated with technological and income progress. The income of the society who applies technologies is a key factor, because safety and environmental protection incur costs, which the society must be willing to pay. But REACH might be a supporting factor for this trend.

8.1.3 Higher and further increasing costs for market access

Compared to pre-REACH times companies will be forced to accept higher costs for complying with the regulations for hazardous chemicals. As exemplified by Zschimmer & Schwarz GmbH & Co. KG (compare first case study), many companies will slim down their product portfolios. This may translate in a consolidation of the variety of chemicals marketed by companies. Therefore, competitive and wealthy companies will profit from reduced competition through REACH. The effect might even translate into higher margins. In contrast less competent and less wealthy SMEs will find it more difficult to compete. In general companies will need to become more professional and more customer-oriented in the future.

But European companies cannot expect that REACH will exclude competent companies from non-EU-countries from the EU markets.

8.1.4 Closures of manufacturing firms and acquisitions

Where SMEs already face difficulties or authorisation risks REACH may trigger acquisitions, shut downs or the relocation of production sites. But again: REACH is only one supporting factor of a general trend.

8.1.5 Many substances will disappear from the market

Decisions to keep or withdraw chemicals should be made on a reliable scientific and economic basis. Managers have the choice to invest in the registration of a chemical if they believe in the profitability of their product. But in many cases they will not see such prospects. Then they will slim down their product portfolio. Especially many chemicals subject to authorisation will be withdrawn from the market.

8.2 How should managers of SMEs proceed?

There may be many different individual ways, how SMEs can cope with the challenges imposed by REACH. To identify the best approach for their own company, managers of SMEs should:

1. Collect data about all chemicals the own company uses in quantities exceeding 1 ton/year
2. Analyse the role (manufacturer, importer or downstream user) the company has related to each respective chemical
3. Optimise the communication with stakeholders:
   - Downstream users of existing chemicals must make sure that these substances and their respective use will be registered and stay available
   - Uses of chemicals should be specified as broad as possible
   - Confidential business information (CBI) must be protected
   - SIEF negotiations should be carried out diligently
4. Assess the own position in the market
   (market leader, major or small supplier)
5. Evaluate potential implications of alternative approaches and define the strategy (eco-efficiency, beyond compliance leadership, environmental cost leadership, eco-branding, relocation or withdrawal) for each respective chemical. Before deciding about dropping chemicals from their product portfolio companies should try to understand the potential impact on their

remaining portfolio and on their customers

6. Estimate the future profits taking into account the REACH compliance costs, interest rates and the dates when both have to be paid (DCF-calculations)
7. Plan appropriate REACH compliance projects, provide the necessary resources and carry out these projects.

Note that in many cases strategy building, estimation of future profits and planning will be an iterative process. The evaluation of alternative scenarios will be helpful as well [compare (Schwartz, 1996)].

Management teams will apply what Mintzberg and Lampel (1999) call an “emergent strategy”, since many important aspects (e.g. RIPs) are not completely defined yet and will only become clear in the process. SMEs must therefore rely on their well-known strength: Flexibility.

8.3 Limitations of the research and need for future research

Gummesson (2000) points out that it is often difficult for business researchers to get access to what is actually happening within companies and that this access is in most cases limited by gatekeepers who have a direct interest in the outcome. He argues that the best opportunity for researchers/consultants to develop their pre-understanding is to operate as active participants in a process rather than as interviewers or detached observers. Access to relevant information limits this study too: Although competent interviewees provided insights in how SMEs can cope with the challenges incurred by REACH, the selection of interviewees depends on the personal possibilities of the author of this study. The findings of the study provide a variety of opinions resulting from the different positions and backgrounds of the interviewees. But for principle reasons these findings are not representative due to the judgement sampling approach (Hair *et al.*, 2003, p. 217) applied for selecting the limited sample of interviewees.

As long as REACH is new and developing fast, the exploratory research approach chosen is a must. Its further drawbacks were:

- The number of interviewees was small. Therefore it cannot be ruled out that relevant information has been overlooked or that aspects were rated as inadequately important. Especially the question how strong the impact of REACH on SMEs in the chemical industry will be cannot be answered yet.
- Only qualitative information was obtained.

8.3.1 Recommendations for further research into the subject

Since many processes are still under development, REACH provides a broad field for further analyses. The following aspects might be of special interest:

- Effects of the authorisation requirements after 2009
- Effects of the registrations of high tonnage band (> 1,000 t/a) chemicals and SVHCs after 2010
- Effects of the registrations of chemicals in the tonnage band > 10 t/a after 2013
- Relative importance of REACH as a driver for change in the chemical industry compared to other influences such as e.g. globalisation or currency valuation
- Retrospective evaluation of REACH in respect to economic and environmental effects as well as in respect to the competitiveness of the European chemical industry.

When the full effects of REACH will become visible in several years studies with more representative sampling can yield quantitative information.

9 Recommendations

As the aims of companies differ, so will their REACH compliance strategies. Nevertheless, there will often be similar interests among companies when they are in the same situation. Therefore some recommendations are given below how companies can proceed from certain starting points.

9.1 Tactics for manufacturers

Companies must estimate the market opportunities for their substances and plan carefully to stay profitable.

A tactic to limit the registration costs is to skip uses, which only contribute a minor part of the overall sales volume of a certain substance. But this can cause problems for DUs. Both producers and DUs should address such problems.

9.2 Tactics for importers

Importers should apply product portfolio management techniques: Assign appropriate resources (see paragraph “registration costs” in the preceding chapter) carefully.

Likewise they should motivate their non-EU suppliers to share the registration costs with them. If this is not feasible, sourcing from EU suppliers can be an alternative.

9.3 Tactics in case of authorisation risks

In case of authorisation risks advanced portfolio management techniques may be valuable tools.

The candidate lists of substances for Annex XIV of REACH and related political discussions should be carefully monitored. In case that the own products appear in

this discussion political lobbying might be helpful.

Companies should consult with their suppliers and customers prior to their withdrawal or substitution decisions.

9.3.1 Develop alternatives in case of authorisation risks

Potential substitute products and related processes should be identified. A company can reduce its risk by starting a new substitution product line in parallel if this is affordable.

9.4 Tactics for downstream users

When downstream users shift the registration tasks to their suppliers, they can limit their extra REACH efforts to a minimum.

They should provide only general information about their use for the registration.

DUs must make sure that key substances stay available and are registered including their special use. They should ask their suppliers to confirm this. In case a supplier does not register DUs should consider to register key substances themselves.

9.4.1 Protect confidential business information

Where dissemination of know-how or valuable market information must be protected, DUs should make use of the non-disclosure prescriptions within REACH.

In the case that disclosure of CBI cannot be tolerated, DUs must register the substance themselves by adopting the role of a manufacturer/importer.

9.5 Special recommendations for SMEs affected by REACH

9.5.1 Formulate an information strategy and act accordingly

An information strategy is a basic requirement before starting to communicate. This information strategy must be clearly communicated and understood within the whole company, so that each employee can act accordingly.

Companies must be aware that they can disclose know-how through external documentation like MSDSs. Such material must therefore be prepared and handled carefully.

9.5.2 Define responsibilities and tasks

Clear responsibilities must be defined.

Project management techniques may help to implement the selected strategy.

9.5.3 Get support from specialised consultants

In many cases, consultancies can deliver REACH processes more efficiently compared to producers/importers or DUs: Consultancies build up their REACH-know-how once and can use it several times, whereas registrants need considerable learning efforts, but apply their know-how only once.

9.5.4 Have data compiled and evaluated by scientific service providers

In many cases SMEs do not have the capacity and/or the competence to retrieve and evaluate relevant scientific material. If the risk of disclosure of CBI is low, scientific service providers can help effectively.

They can also submit data to the ECHA using the IUCLID software. Because at least two days of user training are recommended, having this capability in-house is only worthwhile if many submissions have to be made over a longer period of time.

9.5.5 Apply alternative approaches to avoid toxicological tests

To avoid expensive toxicological animal tests alternative approaches are explicitly recommended by REACH. Nevertheless they must yield plausible results and should be agreed with the authorities. Approaches as such described in the sub-paragraph "Data retrieval, testing and alternative methods" are discussed by Hammar (2007). The AnimAlt-ZEBET database provided by the "Deutsches Institut für Medizinische Dokumentation und Information" (German Institute for Medical Documentation and Information – a subsidiary of the German Ministry of Health) in Cologne contains evaluated methods.

9.5.6 Evaluate investments in additional information systems critically

According to the findings of this study, it is not worthwhile for SMEs to invest in additional ISs just for REACH compliance. Such investments should only be considered where additional reasons apply, e.g. if the company uses outdated information technology.

9.5.7 SIEF process and cooperation

Participants in the REACH process should use standard processes and contracts. Customised contracts will require high lawyer fees. Additional measures will be necessary in cases where conflicts with the competition law might arise.

9.6 Lobbying for SMEs on EU level

Lobbying on EU level becomes increasingly important for SMEs. Managers should therefore find ways to have their needs represented there as well. They should request that their lobby organisations delegate representatives on EU level. Where this is deemed to be too expensive, lobby organisations might cooperate or even merge. Another way is to form an organisation to handle a certain problem. In the case of REACH the "initiative for a better REACH" has been founded, which

developed proposals from the perspective of medium-sized chemical companies within the negotiations about REACH. Approximately 300 companies organised themselves in order to negotiate improvements.

10 Personal reflections and development

The author of this study is a chemist and was a self-employed scientific service provider with approximately 10 years of practical and managerial experience gained in different industrial branches during the course of this study. He started his MBA studies 3 years ago to complement his technological know-how with an additional competence in business. As a service provider he was already confronted with REACH requirements. He found out that the combination of chemical and managerial know-how provides an excellent basis for consulting in the field of hazardous chemicals. Therefore he selected REACH as the research-object of his dissertation in order to improve his know-how as a consultant for SMEs in the chemical industry.

It turned out that the approach of an extensive literature search combined with an explorative interview study yielded a good overview of the mechanisms behind REACH.

The different backgrounds of the interviewees provided views from several perspectives. Therefore it is no surprise that contrasting opinions were expressed sometimes. The interviewees cooperated very well. Because all interviewees are experts in their respective field, it was interesting to discuss the topic with them.

At the end of this work, the author has achieved his objective to understand the implications of REACH in more depth. Nevertheless, many questions can only be decided retrospectively in several years.

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12 Appendices

12.1 List of Interviewees

(in chronological order)

12.1.1 Interviewee No. 1

Interviewee No. 1 is a director of marketing of a medium-sized pharmaceutical company.

Earlier in his career he was in charge of regulatory affairs.

Apart from other academic degrees he holds an MBA from the Henley Management College.

12.1.2 Interviewee No. 2

Interviewee No. 2 is a consultant for the pharmaceutical industry.

Until recently he was a director of Research & Development in a medium-sized pharmaceutical company, which develops and markets proprietary medical products.

Earlier in his career he was in charge of regulatory compliance in this same company.

Apart from other academic degrees he holds an MBA from the Henley Management College.

12.1.3 Interviewee No. 3

Interviewee No. 3 is a chemist who works in a central research & development department of an affiliate company of a big multinational chemical company. Earlier in his career he worked for a medium-sized producer of speciality polymers.

Apart from other academic degrees he holds an MBA from the Henley Management College.

12.1.4 Interviewee No. 4

Interviewee No. 4 is a consultant who has developed consulting services related to REACH since 2005. He works for a well-known chartered accounting company.

12.1.5 Interviewee No. 5

Interviewee No. 5 is an Environment, Health & Safety specialist in an SME, which imports and uses chemical preparations for certain technical purposes.

12.1.6 Interviewee No. 6

Interviewee No. 6 is the general manager of a medium sized producer of chemicals for certain technical purposes. Until recently he was a leader of the lobby organisation of his industrial sector.

12.1.7 Interviewee No. 7

Interviewee No. 7 is an officer in a Ministry of Environment of a German Bundesland.

Since several years he is actively involved in the political discussions about REACH, holds lectures and has published several papers in this area.

12.1.8 Interviewee No. 8

Interviewee No. 8 is consultant for chemicals safety management in a consultancy in the field of environmental protection. She has published several papers about different aspects of REACH.

12.1.9 Interviewee No. 9

Interviewee No. 9 is a director of the ECHA.

12.1.10 Interviewee No. 10

Interviewee No. 10 is a consultant for supply-chain-management in the fine-chemical industry. He has more than 30 years experience in this industry and was general manager of the fine chemicals branch of a large chemical company. Moreover he is the author of several papers about this industry.

12.1.11 Interviewee No. 11

Interviewee No. 11 is the general manager of a medium-sized chemical company, which manufactures, formulates and trades in chemical auxiliaries for diverse industries. Moreover he is one of the proponents of the “initiative for a better REACH”.

12.1.12 Interviewee No. 12

Interviewee No. 12 is a consultant and head of a REACH-team within a scientific service provider.

He has published several papers about how to comply with the new requirements.

12.1.13 Interviewee No. 13

Interviewee No. 13 is an Environment, Health & Safety professional within a medium-sized importer and formulator. He has published several papers about how to comply with the new requirements.

12.2 Short information about REACH for interviewees

In Europe the EC-regulation "Registration, Evaluation, Authorisation and Restriction of Chemicals" (REACH, 1907/2006/EC) has entered into force on June 1st., 2007. The aim of this backbone of the new EC-legislation for hazardous chemicals is to better understand and document the risks associated with the application of chemicals. Producers and importers of chemicals will be forced to register their products formally at a new European Chemicals Agency (ECHA) in Helsinki, Finland before they are allowed to (further) sell them in the EC. Chemical and physical data of substances have to be specified. Hazardous substances must undergo expensive toxicological tests, which have to be paid by those groups.

Timetable for REACH

Date	Duties for producers, importers and importers
June 1st., 2007	Material Safety Data Sheets (MSDSs) must comply with REACH Extended communication up and down the supply chain (applicable for substances not requiring a MSDS as well) Marketing and use restrictions for certain substances Harmonisation of classification and labelling at Community level for substances with Carcinogenic, Mutagenic or toxic for Reproduction (CMR) properties and respiratory sensitisers
June 1st., 2008	Start of pre-registration of substances over 1 t/year (Caution: Only half a year time for pre-registration!)
December 1st., 2008	Pre-registration completed of so-called „Phase-In-" (existing) chemicals, which are already marketed in the EU
June 1st., 2009	ECHA starts to publish the names of chemicals subject to authorisation in Annex VIV of REACH. For further use of these substances special time-limited permissions will be required.
December 1st., 2010 *	Registration completed of substances, which are marketed by at least one producer or importer in quantities exceeding 1000 t annually within the EU. The same applies for Substances of Very High Concern (SVHC) such as CMRs over 1 t/year. Applies as well for substances classified as very toxic for aquatic organisms over 100 t/year
June 1st., 2013 *	Registration completed of substances over 100 t/year, which are classified as toxic for aquatic organisms
June 1st., 2018 *	Registration completed of all substances left over 1 t/year

* This transitional time limit is only valid for phase-in-substances pre-registered until December 1st., 2008.

12.3 Proposed steps to REACH-registration

General preparations

Build a chemicals inventory for all substances (or substances in compositions) used by the company in quantities exceeding 1 ton/year.

For each substance

Define the role of your company under REACH for the respective chemical (Manufacturer, Importer, Downstream User)

Collect all relevant data related to these chemicals.
Extend existing databases or build a new one. Include:

- Identification of the compound
  (EINECS or ELINCS and CAS-No., in case of polymers: Monomers)
- Classification and labelling information
- Material Safety Data Sheet (revised according to REACH?)
- Turnover (tons/year)
- Customer and supplier information
- uses, hazard and environmental data for the respective chemical,
- Subject to REACH?
- Costs of relevant substance tests or studies or missing data
- financial measures
  (e.g. margin, contribution to the coverage of fixed costs, …),
- marketing analyses,
- competitor intelligence,
- development plans, …

Keep all this information up-to-date

Make sure that
relevant information remains the intellectual property of your company!

Define overall company strategy

Define (iteratively):

1. Position of the substance in the product portfolio
2. Future tonnage band
3. Registration budgets
4. Data gaps
5. Strategic position (market, SIEF)
6. Net Present Value (NPV) of the product (consider complete product portfolio!)

Strategy (alternatively):
- Registration (SIEF, cooperation, consortia, purchase or selling of data, scheduling),
- Authorisation,
- Drop of the product?
- Relocation?

12.4 Questionnaires for semi-structured interviews

For interviewees from the pharmaceutical industry

1. How does your company decide about its medium- and long-term portfolio (products) strategy? (Underlying pieces of information, criteria)

2. Which damage can result from disclosure of confidential information in authorisation processes?

- Which information must be protected?
- Loss of “surprise effect” of strategy?
- Competitors might get interested in own high-volume products?
- Loss of know-how?
- Other?

3. Did your company need additional information systems to comply with data provision and storage prescriptions? If yes: Why? Which kind of ISs?

4. Which measures do you find most important in order to store information security (prevention of unauthorised access)?

5. Were corporate changes or new resources required for 2309/93/EC compliance?

6. Is the concept of communicating via a Third Party Representative in order to exchange data in cooperations an interesting option? Why – Why not?

7. Is cooperation with other companies (e.g. joint authorisation) an interesting option?

a) how far do cooperations make sense – or impose additional risks
b) under which circumstances and
c) how can such cooperations become successful

8. Has 2309/93/EC provided extra opportunities for your company to earn additional money?
Do you see additional business opportunities in such legal initiatives? Which ones?

9. What can SMEs in the chemical industry learn from your experiences for REACH compliance?

10. What where the financial implications of the 2309/93/EC (authorisation) efforts?

11. How far did the Council Directive 65/65/EEC hinder the development of new products?

Example for interviewees from the chemical industry

1. Do you have any comment on the framework: “Proposed steps to REACH-Registration”?

2. Identify the key factors for developing a substance registration strategy (Please rank: 1: Most important; highest number: lowest priority):

- Financial considerations (i.e. DCF), keeping costs low ___
- Business opportunities ___
- Distrust in potential cooperation partners ___
- Potential time loss (e.g. through required contract negotiations) ___
- Confidentiality issues ___
- Others? ___

3. How does your company decide about its medium- and long-term strategy? (Underlying pieces of information, criteria)

4. Which damage can result from disclosure of confident information under REACH?

- Which information must be protected?
- Loss of “surprise effect” of strategy?
- Competitors might get interested in own high-volume products?
- Loss of know-how?
- Other?

5. Will your company need additional information systems to comply with the data provision and storage prescription of REACH (i.e. relevant data must be stored for further 10 years after withdrawal of a chemical from the market)? Which kind of ISs?

6. Which measures do you find most important in order to secure information security (prevention of unauthorised access)?

7. Are other corporate changes or new resources required for REACH compliance?

8. Is the concept of communicating via a Third Party Representative in order to hide the own identity in consortia (SIEF-process) an interesting option? Why – Why not?

9. Is the concept of a Third Person an interesting option e.g. for data exchange in consortia? In which cases? Why? – Why not?

10. Is the concept of cooperation (e.g. in registration consortia initiated by a SIEF) an interesting option?

- how far do cooperations make sense – or impose additional risks
- under which circumstances and

- how can such cooperations become successful
- Is registering alone (not cooperating with others) an option? Why?

11. Is earning additional money through REACH an extra opportunity for your company (e.g. carrying out research and sell the results to other companies)? Do you see other additional business opportunities? Which ones?

12. How can Small and Medium-Sized companies (SMEs) minimise the risk that their suppliers withdraw chemicals, which are key for their processes?

13. How and how fast can your company react normally to such an event e.g. by substitution of the chemical.

14. What are the financial implications of all REACH-efforts for your company and how important are they in decision making?

Example for interviewees from the authorities

1. Please descibe the German national concept for the enforcement of pre-registrations (compare: Augestad: http://www.process.vogel.de/management_und_it/einkauf_handel/chemiehandel/articles/70358/)

2. Which measures do you find most important in order to prevent the disclosure of Confidential Business Information (CBI) under REACH effectively?
Which information has to be protected?

3. SMEs regard Chemical Safety Assessments (CSAs) and Chemical Safety Reports (CSRs) for substances up from 10 t/year turnover as a burden.
How can SMEs and the authorities as well cope with this issue?

4. Do you see risks for downstream users in case that their suppliers do not register their special uses? How problematic is this?

5. How threatening to you rate autorisation risks for SMEs?

6. How far do you regard relocation of chemical production sites and chemical products as a problem?
How do the authorities address this issue?

Example for the interviewee from the ECHA

1. Which impacts will the prescriptions made by the regulation REACH exert on SMEs – especially on producers/importers of chemicals in the tonnage band > 10 t/year?

2. Which measures do you find most important in order to prevent the disclosure of Confidential Business Information (CBI) under REACH effectively?
Which information has to be protected?

3. Is there a risk that too much information is collected within the REACH-process in the ECHA so that it cannot be processed and evaluated within the existing time frame?
a) When might this eventually happen?
b) How do you address this issue?
c) Which problems can result from such a piling up of information?
d) Will execution problems arise, when it comes to carry out measures, which were concluded from the information?

4. . Is there a risk that REACH will be executed differently in the EU-countries. What might bet the result of such distortions?

5. Do you see risks for downstream users in case that their suppliers do not register their special uses? How problematic is this?

6. How threatening to you rate autorisation risks for SMEs?

7. Which recommendations do you have for SMEs, so that they can find optimum ways to cope with REACH?

8. Will REACH exert impacts on the structure of the chemical industry?
If so, which ones?

Example for the interviewees from consultancies

1. In your publication: " … " you state, that there are chances for companies to profit from REACH. Which concrete chances do you see – apart from those for consultants?

2. Do you think that cooperations (e.g. in registration consortia) are an interesting option for SMEs?
a) How far do they make sense or impose additional risks?
b) Under which circumstances and
c) how can such cooperations be successful?
d) Is registering alone (without any cooperation partner) a good option? If so, why?

3. Is communicating via a third party representative a good way in cooperations in order to hide the own identity? How far does this help or is not helpful?

4. Is exchanging data via a third party a god way in cooperations? How far does this help or is not helpful?

5. What do companies gain in case that they buy data in the SIEF-process without joining a consortium? As long as they want to register a substance they have to take part in a joint registration according to the OSOR-principle. Does this mainly concern the notification of uses and data e.g. for chemical safety reports?

6. Do you find that the definitions of use- or exposition scenarios need improvement? If so, how should they be improved?

7. Do you see other problems for SMEs regarding the protection of their Confidential Business Information (CBI) or their know-how?

8. I did not find any information about ECHA-fees fort he notification of special uses by downstream users. Will there be internal costs only e.g. for preparing a chemical safety report?

9. Which impact will REACH exert according to your opinion on strategy development in SMEs?

10. Do you think that SMEs will alter their approaches while planning their strategies?

11. Which strategies from the management-perspective to you recommend for SMEs so that they can respond to the requirements imposed by REACH adequately?

12.5 Acronyms

API	Active Pharmaceutical Ingredient
BAuA	Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (German Federal Institute for Occupational Safety and Health), among other activities national authority for the notification of new chemicals, www.baua.de
BDI	Bundesverband der deutschen Industrie, www.bdi.de
BfR	Bundesinstitut für Risikobewertung (German Federal Institute for the Evaluation of Risks), www.bfr.bund.de
BMU	Bundesministerium für Umwelt (German Ministry of Environment)
C&L	Classification and Labelling
CAS	Chemical Abstracts Services
CAS-#	“Chemical Abstracts Service Registry Number” of the “American Chemical Society” (ACS), identification number for substance retrieval
CBI	Confidential Business Information
CLAP	Classification, Labelling and Packaging, EU-regulation planned for 2008 for implementing the GHS
CM	Custom Manufacturing
CMR	Carcinogenic, Mutagenic or toxic for Reproduction according to 67/548/EWG
CRO	Contract Research Organisation
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report, required by REACH for substances registered in excess of 10 tonnes per annum sales volume and producer/importer/applicant
CWG	Commission Working Group
DSF	Discounted Cash Flow. Financial analysis method to compare historic or future cash flows at a given date by taking interest rates and commercial risks into account.

DNEC	Derived No-Effect Concentration or Level (DNEL). Refers to the exposition path identified
DSS	Decision Support System
DU	Downstream User
EBW	Exposure-Based Waiving
ECB	European Chemicals Bureau in Ispra, Italy, www.ecb.it
ECHA	The new European Chemicals Agency in Helsinki, Finland, http://ec.europa.eu/echa [31.7.07]
ECOTOC	European Center for Ecotoxicology + Technology of Chemicals
ECVAM	European Centre for the Evaluation of Alternative Methods
EINECS	European Inventory of Existing Chemical Substances. A database of approximately 100000 chemicals, which were already marketed before the German Chemicals Law came into force in 1981
ELINCS	European List of Notified Chemical Substances. Database of chemicals, which have been notified since September, 18th., 1981. No further so-called “New Substances” will be included in ELINCS from June 1st., 2008 on.
EMEA	European Medicines Agency, www.emea.eu.int
EPA	(United States of America) Environmental Protection Agency
ES	Exposure Scenario
ES&H	Environmental Safety and Health = EHS or SHE
ESIS	European Chemical Substance Information System, http://ecb.jrc.it/esis/esis.php [31.7.07]
EU	European Union
EuGH	Europäischer Gerichtshof = European Court of Justice, http://curia.europa.eu [31.7.07]
EUSES	European Union System for the Evaluation of Substance, http://ecb.jrc.it/euses
FDA	(United States) Federal Drug Administration

GHS Globally Harmonised System (of Classification and Labelling of Chemicals), http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html [31.7.07]

GLP Good Laboratory Practice, Quality Assurance System, originally laid down in the Appendix of the German Chemicals law in 1981

H-Statements Hazard statements, set of new statements to be introduced by GHS, replacing R- (Risk-) Sentences

HPV High Production Volume Chemicals i.e. in excess of 1000 tonnes per annum sales volume and per producer/importer/applicant

IARC International Agency for Research on Cancer, http://www.iarc.fr [31.7.07]

IS Information System

ISO International Standards Organization, http://www.iso.org [31.7.07]

ICH International Conference on Harmonization of the Technical Requirements for Registration of Pharmaceuticals for Human Use

IUCLID International Uniform Chemical Information Database. Software (current version UCLID 5) provided by the EU free of charge to compile substance data and database format for submitting substance data to the ECHA or the ECB respectively

IUPAC International Union for Pure Applied Chemistry, http://iupac.org [31.7.07]

JRC Joined Research Centre, Research institution of the EUROPEAN COMMISSION based within the ECB in Ispra, Italy, http://ecb.jrc.it [31.7.07]

KM Knowledge Management

LD_{50} Lethal dose (mass/kg of body weight or concentration) of a substance, which causes death of 50 % of the test organisms

LOEL Lowest Observed Effect Level, lowest dose of a substance, where an effect on humans or other organisms is observed

M/I Manufacturer/Importer

MoE margin of exposure

MS Member State

MSDS Material Safety Data Sheet

NOAEL No Observed Adverse Effect Level, dose of a substance, where no adverse effect on humans or other organisms is observed

NOEC No Observed Effect Concentration, concentration of a substance, where no effect on humans or other organisms is observed

NOAEL No Observed Effect Level, dose of a substance, where no effect on humans or other organisms is observed

OC Operation conditions

OECD Organization for Economic Cooperation and Development (within Europe), http://www.oecd.org [31.7.07]

OSOR One Substance One Registration

OSPAR The Oslo and Paris Commissions, which have the objective of protecting the Northeast Atlantic against pollution. Member countries range from Finland to Portugal and Iceland. Source: http://www.eurochlor.org/mainglossary

P-Statements Precautionary statements, set of new statements to be introduced by GHS, replacing S- (Safety-) Sentences

PBT Persistent, Bioaccumulative, Toxic

PEC Predicted Environmental Concentration, can be calculated by using the tool: http://ecb.jrc.it/euses

PESTLE Political, Economic, Social, Technological, Legal and Environmental outer influences on organisations

PFC Pharmaceutical Fine Chemical

P_{OW} Octanol-water partition coefficient, a measure for the hydrophilic or lipophilic behaviour of a substance

PPORD Intermediate Substances used in Production and Process Oriented Research & Development

PNEC Predicted No-Effect Concentration or Level (PNEL). They can be calculated for different environmental compartments:
- for water and continuous emission
- for water and discontinuous emission
- for sediments
- for soil

- for waste treatment
- for air

PRODUCE Piloting REACH on downstream use and communication. Project, in which the practicability of the REACH prescriptions were tested by 25 downstream users. See literature.

QSAR quantitative (or qualitative) Structure-Activity Relationship between the chemical structure of a molecule and its anticipated effects derived from a series of similar other molecules with known properties

R&D Research & Development

RA Risk Assessment

RAR Risk Assessment Report

RCR Risk Characterisation Ratio = PEC/PNEC

RDBMS Relational Database Management System

REACH EC-regulation “Registration, Evaluation, Authorisation and Restriction of Chemicals” (1907/2006/EC)

RIPs REACH Implementation Projects, where guidelines for achieving REACH compliance are developed

RMM Risk Management Measure

SAICM Strategic Approach to International Chemicals Management. A policy framework for international action on chemical hazards, http://www.chem.unep.ch/saicm [31.7.07]

SAR Structure Activity Relationships

SCOEL Scientific Committee on Occupational Exposure Limits, http://ec.europa.eu/employment_social/health_safety/scoel_en.htm [31.7.07]

SDS (Material) Safety Data Sheet

SEA Socio-Economic Analysis

SEG Stakeholder Expert Group within a RIP

SIEF Substance Information Exchange Forum, to be founded after pre-registration to negotiate registration of substances in cooperation

SME	Small and Medium-Size Enterprise, EU commission recommendation for the definition see: 2003/361/EC http://eur-lex.europa.eu/LexUriServ/site/en/oj/2003/l_124/l_12420030520en00360041.pdf
SR&D	Scientific Research and Development
STN	Scientific Technical Network in Karlsruhe. A scientific information and database provide (host) owned by the public
SVHC	Substances of Very High Concern, subject to authorisation
t/a	tonnes per anno (annual turnover of a substance produced, imported or handled by a manufacturer, importer or applicant)
TGD	Technical Guidance Dokument, developed within a RIP
TRA	Target Risk Assessment, web-tool under: https://www.ecetoc-tra.org.
TSCA	Toxic Substance Control Act, US law for controlling chemicals, http://www.epa.gov/Region5/defs/html/tsca.htm
UBA	(German) Federal Environment Agency, an affiliate organisation of the BMU, www.uba.de
UEC	Use and Exposure Category (of a certain chemical)
UNECE	United Nations Economic Commission for Europe, www.unece.org
UVC	Unknown, Variable or Complex Composition (refer to RIP 3.10)
UVCB	(Substances of) Unknown Variable Composition, complex reaction products or Biological materials. Definition see: RIP 3.10
VCI	Verband der Chemischen Industry (Organisation of the Chemical Industry in Germany)
vPvB	very Persistent, very Bioaccumulative (substance)
WTO	World Trade Organization, http://www.wto.org

12.6 Glossary

Agency
see ECHA
German: Agentur
French: Agence
Spanish: Agencia.

Actors in the supply chain
All manufacturers and/or importers and/or downstream users
German: Akteur der Lieferkette
French: Acteur de la chaine d'approvisionnement
Spanish: Agentes de la cadena de suministro.

Alloy
A metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means
German: Legierung
French: Alliage
Spanish: Aleación.

Article
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
German: Erzeugnis
French: Article
Spanish: Articulo.

Bioaccumulative
a substance, which shows this behaviour can build high concentration levels in living organisms (humans, animals or plants)
German: Bioakkumulierend

Chemical safety assessment
shall be performed and a chemical safety report completed for all substances subject to registration in accordance with this Chapter in quantities of 10 tonnes or more per year per registrant
German: Stoffsicherheitsbeurteilung, -bewertung

Chemical safety report CSR
documents the findings of a chemical safety assessment (see Annex I of REACH)
German: Stoffsicherheitsbericht

Competent authority
The authority or authorities or bodies established by the Member States to carry out the obligations arising from this Regulation
German: Zuständige Behörde
French: Autorité competénte
Spanish: Autoridad competente.

Consortium (Plural: Consortia)
A cooperation of registrants within a SIEF in order to register the same substance together. This term was originally used when REACH was negotiated. But it was not included into the final version (see Article 11)
German: Konsortium

Distributor
A natural or legal person placing on the market a substance, on its own or in a preparation, or a preparation. Note that a distributor is no downstream user (DU)
German: Händler
French: Distributeur
Spanish: Distribuidor.

Downstream user
Any natural or legal person established within the Community other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user
German: Nachgeschalteter Anwender
French: Utilisateur en aval
Spanish: Usuario intermedio.

Endocrine disrupters
Substances of Very High Concern (SVHCs) that mimic or inhibit the effect of hormones
German: Endokrin disruptiv wirkender Stoff (hormonelle Effekte auslösend oder verhindernd)

Existing Chemical
A substance listed in EINECS according to 67/548/EWG Art. 2(1) h (see Acronyms)
German: Altstoff

Exposure
A toxicological term, which means that a human or an organism is directly in contact with with a substance
German: Exposition
French: Exposition
Spanish: Exposición.

Exposure scenario
the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate
German: Expositionsszenario
French: Scénario d'exposition
Spanish: Escenarios de exposición.

Fine Chemical [definition given by Pollak (2007)]
complex, single, pure chemical substance. Fine chemicals are produced in limited quantities (< 1000 metric tons per year) in multipurpose plants by multistep batch chemical or biotechnological processes. They are sold for more than US$10 per kg, based on exacting specifications, for further processing within the chemical industry.
German: Feinchemikalie
French: Produit chimique raffiné

Full study report
A complete and comprehensive description of the activity performed to generate the information. This covers the complete scientific paper as published in the literature describing the study performed or the full report prepared by the test house describing the study performed
German: Umfassender Studienbericht
French: Rapport d'étude complet
Spanish: Informe exhaustivo de un estudio.

Grouping
see Read across

Identified use
A use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user
German: Identifizierte Verwendung
French: Utilisation identifiée
Spanish: Uso identificado.

Import
the physical introduction into the customs territory of the Community
German: Einfuhr
French: Importation
Spanish: Importatión.

Importer
Any natural or legal person established within the Community who is responsible for import
German: Importeur
French: Importateur
Spanish: Importador.

Intermediate
A substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as "synthesis"):
a) non-isolated intermediate: means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipework for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture;
b) on-site isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities;
c) transported isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites;
German: (nicht isoliertes) Zwischenprodukt
French: Intermédiaire
Spanish: Sustancia intermedia.

***In-vitro*-testing**
tests carried out by using cell cultures as opposed to test with humans or big animals
German: *In-vitro*-Untersuchung/Test

***In-vivo*-testing**
tests carried out by using humans or big animals as opposed to *in-vitro*-testing
German: *In-vivo*-Untersuchung/Test

Letter of access
A document which gives the holder access to studies carried out under REACH
German: Zugangsberechtigung, Nutzungsberechtigung

Manufacturing
Production or extraction of substances in the natural state
German: Herstellung
French: Fabrication
Spanish: Fabricación.

Manufacturer
Any natural or legal person established within the Community who produces a substance within the EU
German: Hersteller
French: Fabricant
Spanish: Fabricante.

Mesocosm
Laboratory or small (ca. 1-4 m^2) outdoor field setting where the effects e.g. of pesticides on plants and/or animals is studied.

Monomer
A substance, which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process (“bricks” from which polymers are “built”)
German: Monomer
French: Monomère
Spanish: Monómero.

New chemical
A substance registered under the German chemicals law and listed in the ELINCS database
German: Neustoff

No-Longer Polymers
European chemicals legislation did not prescribe that polymers had to be notified. The 7th amendment (92/32/EWG) provides a more specific definition of the term “polymer” in chemicals legislation. Consequently some former polymers ceased to fall into this category. For them a new list has been created. Each compound is identified by a 7-digit “no-longer-polymer-number”.
German: Nicht-länger-Polymere

Not chemically modified substance
A substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities
German: Nicht chemisch veränderter Stoff
French: Substance non modifiée chimiquement
Spanish: Sustancia no modificada químicamente.

Notified substance
Substance, which was notified according to 67/548/EWG after September, 18th, 1981 and which can be legally marketed within the EU.
German: Neustoff
French: Substance notifiée
Spanish: Sustancia notificada.

Opt-out
Not taking part in a group for joint registration in a SIEF under REACH
German: Nichtteilnahme

Per year
Per calendar year, unless stated otherwise, for phase-in substances that have been imported or manufactured for at least three consecutive years, quantities per year shall be calculated on the basis of the average production or import volumes for the three preceding calendar years
German: Pro Jahr
French: Par an
Spanish: por año.

Persistence
The behaviour shown by substances that they are not easily chemically or biologically degraded in the environment
German: Persistenz
French: Persistance.

Phase-in substance
A substance, which meets at least one of the following criteria:
a) it is listed in EINECS
b) it was manufactured in the Community, or in the countries acceding to the European Union on 1 January 1995 or on 1 May 2004, but not placed on the market by the manufacturer or importer, at least once in the 15 years before the entry into force of this Regulation, provided the manufacturer or importer has documentary evidence of this;
c) it was placed on the market in the Community, or in the countries acceding to the European Union on 1 January 1995 or on 1 May 2004, before entry into force of this Regulation by the manufacturer or importer and was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC but does not meet the definition of a polymer as set out in REACH, provided the manufacturer or importer has documentary evidence of this;
German: Phase-in Stoff

Placing on the market
supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market
German: Inverkehrbringen
French: Mise sur le marché
Spanish: Comercialisación.

Polymer
A substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises

the following:
a) a simple weight majority of molecules containing at least three monomer units, which are covalently bound to at least one other monomer unit or other reactant;
b) less than a simple weight majority of molecules of the same molecular weight.
In the context of this definition a "monomer unit" means the reacted form of a monomer substance in a polymer;
German: Polymer (Kunststoff, Makromolekül)
French: Polymère
Spanish: Polímero.

PPORD
Article 9 of REACH
Exemption from the general obligation to register for Product and Process Orientated Research and Development (PPORD)
Articles 5, 6, 7, 17, 18 and 21 shall not apply for a period of five years to a substance manufactured in the Community or imported for the purposes of product and process orientated research and development by a manufacturer or importer or producer of articles, by himself or in cooperation with listed customers and in a quantity, which is limited to the purpose of product and process orientated research and development.

Preparation (will be called Mixture according to GHS)
A mixture or solution composed of two or more substances
German: Zubereitung (Mischung)
French: Préparation
Spanish: Preparado.

PRODUCE
Piloting REACH on Downstream Use and Communication.
Project in which the practicability of the REACH prescriptions were tested by 25 downstream users. See literature.

Producer of an article
Any natural or legal person who makes or assembles an article within the Community
German: Produzent eines Erzeugnisses
French: Producteur d'un article
Spanish: Productor de un artículo.

Product and process orientated research and development (PPORD)
Exemption from the general obligation to register for product while scientific studies are carried out in pilot- or production scale
German: Produkt- und verfahrensorientierte Forschung und Entwicklung
French: Activités de recherché et de développement axées sur les produits et les processus
Spanish: Investigación y desarrollo orientados a productos y procesos.

Read-across
To generate information on intrinsic properties of substances by means other than tests, provided that the conditions set out in Annex XI are met. In particular for human toxicity, information shall be generated among others by means of qualitative or quantitative structure-activity relationship models or from information from structurally related substances (grouping)
German: Übertragung von Stoffeigenschaften (Analogieschluß)

Recipient of a substance or a preparation
Industrial or professional applicant of vendor to whom an article is delivered
German: Abnehmer eines Erzeugnisses
French: Destinataire d'une substance ou d'une préparation.
Spanish: Destinatario de una substancia o un preparado

Registrant
The manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance;
German: Registrant
French: Déclarant
Spanish: Solicitante de registro.

Registrant's own use
industrial or professional use by the registrant himself
German: Eigene Verwendung des Registranten
French: Utilisation propre du déclarant
Spanish: Uso propio del solicitante del registro.

Restriction
for the manufacture, uses or marketing of a substance
German: Beschränkung
French: Restriction
Spanish: Restricción.

Robust study summary
A detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report
German: Qualifizierte Studienzusammenfassung
French: Résumé d'étude consistant
Spanish: Resumen amplio de un studio.

(Material) **Safety data sheet** (M)SDS
A document according to Title IV of REACH used to communicate hazards connected with the use of a substance to industrial or professional users
German: Sicherheitsdatenblatt

Scientific research and development
Any scientific experimentation, analysis or chemical research carried out under

controlled conditions in a volume less than 1 tonne per year
German: Wissenschaftliche Forschung und Entwicklung
Spanish: Investigación y desarrollo científicos.

Site
A single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared
German: Standort
French: Site
Spanish: Emplazamiento.

SIEF
Substance Information Exchange Forum
Electronic platform provided by the ECHA to bring companies together, who intend to register the same substance.

Specialities (or Speciality Chemicals)
Formulations of chemicals containing one or more fine chemicals as active ingredients (Pollak, 2007, p. 5)

Study summary
a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study
German: Einfache Studienzusammenfassung
French: Résumé d'étude
Spanish: Resumen de un estudio.

Substance
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, but excluding any solvent, which may be separated without affecting the stability of the substance or changing its composition
German: Stoff
French: Substance
Spanish: Sustancia.

Substance, which occurs in nature
A naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means
German: Naturstoff
French: Substance présente dans la nature

Supplier
Any producer or importer of an article, distributor or other actor in the supply chain placing an article, a substance or a preparation on the market
German: Lieferant
French: Fournisseur
Spanish: Proveedor.

Use
Any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation
German: Verwendung
French: Utilisation
Spanish: Uso.

Use and exposure category
An exposure scenario covering a wide range of processes or uses, where the processes or uses are communicated, as a minimum, in terms of the brief general description of use
German: Verwendungs- und Expositionskategorie
French: Catégorie d'usage ou d'exposition
Spanish: Categoría de uso y exposición.

Waiving
Omitting a test while arguing that no exposure to a substance will happen. Acceptance criteria are currently developed within RIP 3.2-2.