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Analysis of the costs and benefits of the new EU chemicals Policy

An examination based on selected sectors taking into account effects on competitiveness, innovation, environment, and health

Forschungsbericht

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I Introduction

I.1 The REACH system

On February 27, 2001, the Commission of European Communities presented a White Paper on a "Strategy for a Future Chemicals Policy". The centrepiece of this future chemicals policy will be a European regulation on the registration, evaluation, authorization, and restrictions of chemicals[1] as specified in the draft of October 29, 2003 (CEC - Commission of the European Communities 2003a). This draft serves as the basis for the present assessment of REACH. This regulation is to ensure that the following goals are met:

- protect people and the environment from the damaging effects of the production, processing, application, and disposal of chemical substances;
- increase the competitiveness of the chemicals industry;
- prevent the Common Market from disintegrating, for instance as a result of different standards for risk assessment and communication in legislation on chemicals;
- greater transparency, for instance with respect to the dangerous properties of chemicals and possible exposure to them;
- the integration of European policy in international programs such as GHS[2] and the objectives of the Johannesburg Summit;
- the promotion of research methods not based on experiments with vertebrates;
- conformity with the EU's international obligations (such as towards the WTO).

The new REACH system represents a paradigm shift for the production and marketing of chemicals which have already been on the market since 1981: while the authorities used to have to identify critical substances and call for their evaluation[3], this task will now be the responsibility of manufacturers and importers under the REACH system (reversal of burden of proof). This switch is to help speed up the processing of the drastic backlog of established chemicals[4].

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1 REACH

2 Globally Harmonized System of Classification and Labelling of Chemicals

3 In Germany, the "Advisory Committee for Established Environmental Substances" (BUA) at the Society of German Chemists handles this task on behalf of the Federal Environmental Ministry.

4 Since its foundation in 1993, the EU's established chemicals programme has only managed to evaluate some 40 substances for health and environmental risks (Lahl 2003; Umweltbundesamt 2004). Internationally, work in the initiative of the International Council of Chemical Associations (ICCA) and the "OECD HPV Chemicals Programme" has focused

REACH covers all substances produced or imported in amounts exceeding 1 t per year/manufacturer (some 30,000 substances, not including polymers and internal intermediate products). They have to be registered according to a binding schedule (from 3 to 11 years after the REACH regulation takes effect) with a central EU authority with a defined set of information data (Annexes IV-VIII of the draft regulation).

Based on a minimum set of obligatory data for all substances (Annex V), the scope of the data records on the properties of the substance is generally relative to the substance's market volume unless the substance is an internal intermediate product. Depending on the intended application and exposure, the scope of the substance test actually required can be reduced or modified. The information required for substances > 100 t/year can basically be modified based on evaluations of exposure. For substances between 10-100 t/year, this is only true of certain information requirements (such as tests of the reproductive toxicity of a substance). To make animal testing superfluous and to limit the amount of new data that needs to be gathered, the draft regulation contains: various mechanisms for the use of existing data records (preregistration of substances [Article 26]; an Internet platform for information exchanges about substances among manufacturers and importers of a particular substance [Article 27]; and the criteria for the recognition of existing data and the possibility of conclusions by analogy and group evaluations [Annex IX].

Substances with a market volume (per manufacturer) exceeding 10 t (some 11,000 substances, not including polymers and internal intermediate products) require a chemical safety assessment (CSA). If the substance is judged to be hazardous, an exposure assessment and risk characterization is required for all stages of the substance's lifecycle. The substance manufacturer shall derive practical, plausible information/specifications for its customers (formulators of preparations) from this assessment for the safe use of the substance and communicate this information / these specifications in the safety data sheet. Such specifications not only refer to the formulator's procedure, but also to the application of the formulation for its industrial, commercial, or private customers. If the formulator deviates from these specifications, it assumes the obligation of assessment. Articles 34 to 36 of the draft regulation set forth rules for communication between the substance manufacturer and the downstream user.

The substance manufacturer / the downstream user is responsible for the quality and correctness of the safety assessment. No inspection by the authorities is required, though the authorities may chose to perform one.

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on substances with large world-wide production volumes (some 1000 substances). However, only a hazard assessment, not a risk assessment, is envisioned here, which limits the requirements for exposure data (Greim 2003).

Substances themselves or as ingredients in preparations can either be made in the EU or imported. The REACH draft does not treat these two categories of market placement differently. In the long term, REACH will cover the import of hazardous substances in products that exceed 1 t/year per importer / article. Starting in 2017 (11 years after the regulation takes effect), importers of products will be obligated to

- register hazardous substances in these products if the substance is intended to be released and
- check whether hazardous substances can be released in amounts relevant for risks and inform the agency if this is the case (Article 6).

An authorization option is provided for the application of especially hazardous substances (for the criteria, see Article 54 of the draft regulation), i. e. the Commission can issue a general or restricted ban with a reservation to reinstate authorization in the event of especially hazardous substance properties.

In addition to the greater requirements on existing substances, the new system makes it easier to register substances distributed for the first time and in small amounts (< 10 t/year) or used for R&D purposes.

Overall, the REACH system levels the playing field for existing and new substances in terms of legal requirements. Furthermore, the new system contains various mechanisms to localize responsibility for the generation, assessment, and communication of risk-related information in the supply chain. Annexes I, VI, V-VIII, and IX in the REACH regulation constitute a standard scheme for the flow of an assessment of the safety of substances and relevant information requirements (Annex IV-VIII).

I.2 The incremental development of the REACH system

I.2.1 From a consultation paper to a draft regulation

The preliminary draft of the Directorates-General of the Environment and Enterprises of May 2003 ("Consultation Document Concerning the Registration, Evaluation, Authorization and Restrictions of Chemicals (REACH)") was widely commented on in a public Internet consultation (6000 comments). Some essential, cost-relevant changes to the version of the preliminary draft of May 2003 were made in the draft regulation of October 2003:

- No exposure evaluation or risk characterization need be performed for substances that do not have to be registered and have not yet been registered.

- Likewise, no exposure evaluation or risk characterization need be performed for some 20,000 substances (2/3) of the substances to be registered (excluding polymers and intermediate products).
- The obligation to assess exposure and risk characterization above 10 t/a only applies to hazardous substances. Here, the threshold criteria for portions of preparations too minute to be taken into consideration are also specified (generally 0.1 – 1 %).
- The originally proposed new instrument of risk communication in supply chains - the "chemicals safety report" (CSR) - was abandoned in favour of a modified version of the current safety data sheet.
- Some 40,000 to 240,000 polymers shall initially be exempted from mandatory registration until the Commission has come up with an efficient solution for the treatment of polymers in REACH.
- The information requirements in Annex V for substances below 10 t/a were reduced.

Compared to the cost estimations of RPA 2003 and BDI 2003, these changes in the draft regulation of October will probably lead to clear cost reductions.

I.2.2 From the draft regulation to a regulation and its implementation

The present study is based on two assumptions: 1. The REACH system will be implemented in the European Union. 2. ***How*** this happens will continue to be a hot topic and the subject of a lot of development. This development work will draw upon numerous current European work processes, among other sources:

- in the *REACH Implementation Projects* (RIP), industry, member states, and the Commission worked together to develop the technical guidelines and instruments for the implementation of the *REACH* system.
- The REACH task force of the member states - the *Ad-hoc Working Party on Chemicals* - is currently formulating its ideas about modifications of the draft regulation (one registration per substance, categorization of exposure patterns, modified prioritization for the registration of existing substances, the role of agencies).
- The practical experience of the Commission, the member states, and industry from the SPORT initiative[5] will help prevent clearly detectable implementation problems in the design of the registration system from the outset.

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5 Strategic Partnership on REACH Testing. A management business game on the registration and evaluation of 9 substances based on a strategic partnership between the EU Commission, various member states and industry: "SPORT will be a partnership among equals between the Commission, Member States and industry" mainly to "provide input to and to use the (intermediate) results of REACH Implementation Projects to try out and feed

- In additional studies conducted at the EU level by stakeholder task forces on the economic effects of REACH[6], case studies of four supply chains investigated the following: the mechanisms that can lead to the rationalization of substance portfolios and subsequent effects in user areas; the mechanisms that influence innovation; and the mechanisms that are especially important in EU Accession States.

In the context of these work processes, the results of the present study aim at a better understanding of the mechanisms that affect the relation between the benefits and costs of the REACH system.

I.3 A short synopsis of the most important impact studies on REACH

In the run-up to this study, a number of hotly debated analyses of the economic effects of REACH came to quite different conclusions[7]. For instance, the EU Commission's "Extended Impact Assessment" (CEC - Commission of the European Communities 2003b) or the German Council for Environmental Issues (2003; 2004b) basically concluded that the burdens arising from REACH were acceptable when compared to the benefits. In contrast, Arthur D. Little (2002; 2003b; 2003a; 2004) and MERCER (2003; MERCER, NERA 2004) found that the economic effects of REACH would be prohibitive. The studies vary - sometimes considerably - with respect to the level of analysis (macroeconomic effects versus effects at the level of companies), methodology, and the focus of content. In the following, some of the controversial REACH studies are briefly discussed and light is shed on individual aspects that are crucial for the present examination. Reviews of the direct registration costs of REACH are dealt with in Chapter II.

I.3.1 Studies of the macroeconomic effects of REACH

Both in Germany and at the European level, the discussion about REACH largely revolved around a study that the BDI commissioned from Arthur D. Little, which has since been adapted several times to the various stages of the REACH drafts (from the White

into the guidance and tools being developed; to identify additional requirements for guidance, guidelines, tools, methodologies, approaches beyond those already incorporated in the Commission's Interim Strategy work plan and to test and to establish the workability of the pre-registration, registration and evaluation steps in REACH, i. e. organisational set up and requirements" (see http://www.cefic.be/files/Publications/SPORT_040702.pdf).

6 REACH Working Group on *"Further Work on Impact Assessment"* under the joint direction of the Directorates-General of the Environment and Enterprises of the EU Commission

7 For an overview, see (Nordbeck, Frohwein 2003).

Paper to the draft regulation) (Arthur D. Little 2002; 2003a; 2003b; 2004). In the latest version, Arthur D. Little (ADL) forecasts a 2.7 - 3.3 % drop in the gross production value for German industry and a loss of 1-1.23 million jobs. ADL assumes the main drivers behind these economic losses to be the costs of substance registration, the time needed for registration / authorization, and the degree to which expertise has to be disclosed. "Industry factors" also play a role in assessments of the effects of costs: can the various industries pass on cost increases directly to customers? These factors are a result of the intensity of competition within and without the EU, the ease with which production can be relocated abroad, and the necessity of being close to the market.

The studies of Arthur D. Little have been criticized from many different angles, among others because the analysis neglects possible beneficial effects but also due to the overall methodology (cf. Berkhout et al. 2003; SRU - Rat von Sachverständigen für Umweltfragen 2003; 2004b). For instance, the industry factor is based on the ordinally scaled results of polls that were then interpreted cardinally. Production losses due to the time needed for registration were assumed to be proportional to the ratio of the time lost to the product lifecycle for the substance - an assumption that has been called into question. In addition, the extrapolation of the production losses for the processing industry to the whole German economy was based on a static input-output model that did not take possible adaptations into consideration despite the relatively long time frame involved. Finally, there is no reference scenario.

Likewise, a macroeconomic study on the effects of REACH was also conducted for France. It, too, has been updated to reflect the current draft regulation (MERCER 2003; MERCER, NERA 2004). In the current version, the study finds that the French gross national product would drop by 1.6 % (28 billion euros) annually over a period of 10 years as a result of REACH. At the same time, 360,000 jobs (1.5 %) would be lost, and investments would fall by 52 billion euros. The study pursues a bottom-up approach: first, the additional expenses for 14 segments in the chemicals industry and individual user fields are quantified and the reaction of the market actors concerned investigated. The results were extrapolated to the entire French economy based on a macroeconomic model. The study has been criticized for many of the same reasons as the study by Arthur D. Little: no reference scenario, and the use of an input-output model (SRU - Rat von Sachverständigen für Umweltfragen 2003).

As the determination of macroeconomic effects is not the goal of the present study, the critical discussion of these two studies is not pursued here. However, we will come back to them below concerning the withdrawal of a substance.

I.3.2 Workability

In a management business game for North Rhine-Westphalia in autumn of 2003, the workability of the preliminary draft of the REACH regulation was tested for companies and authorities, current proposals for improvement were evaluated, and some new proposals developed. Companies, authorities, trade associations, environmental and consumer organizations, and labour unions took part in this project launched jointly by the government and the economic sector. The business game did not focus on tests of the whole regulation, but rather on the workability of selected flows, assessment requirements, and the communication processes linked to the registration of substances and the creation of expanded safety data sheets. The results of these task forces for the four supply chains studied, the results of workshops, and the report which was coordinated with all the stakeholders involved, are documented under http://www.europa.Nrw.de/. The joint description of the problem by the actors is summed up as follows in the coordinated project report (ARGE Planspiel 2003):

"Many substance manufacturers and practically all users face new tasks both concerning quality and quantity, such as the creation of a registration portfolio and a chemicals safety assessment (CSA), including user-specific exposure assessments (especially in terms of environmental and consumer risks). ***The joint assessment of the actors:*** *In the next few years in particular, the implementation of the REACH requirements studied in the management business game will require considerable additional person-hours.*

- *Companies (and authorities) face the challenge of registering phase-in substances (and new substances).*
- *For certain companies, individual REACH requirements represent considerable burdens in terms of time, staff, expertise, and money. It has become clear that the majority of these companies cannot ensure a professional assessment of their products in the depth and scope required by REACH. Many small and medium-sized companies - especially at the end of the product chain - would not be able to fulfil the current legal requirements without external support (the government, associations, service providers, upstream suppliers) and practicable instruments for implementation. Such companies include:*
  - *Small and medium-sized enterprises that have to register a large number of various substances (substance manufacturers, importers)*
  - *Small and medium-sized enterprises that have to produce their own chemicals safety assessment and report (CSA/CSR) as users or importers of substances or preparations if the respective upstream supplier's safety data sheet does not cover the specific application conditions.*

- *Such tasks would then have to be passed on to test institutes and external consultants, entailing the usual financial expenditures. Here, companies fear that they will simultaneously have trouble protecting their expertise.*

The REACH requirements may reduce the range of substances made and/or used. The cost effects in the various industries manufacturing chemical products with a large number of small volumes of various individual substances (concentration of registration requirements) and simultaneously facing global competition for these products (textiles) probably cannot pass on these costs completely to consumers. The resulting economic risk may be great. On the other hand, BUND feels that there is an opportunity to retain customers by selling superior products with REACH labelling. The effects on innovation and competitiveness were not quantified in this management business game.

*The actors agreed in their **joint assessment** that the process flows found to be inefficient or impractical in the management business game can be prevented or improved as follows:*

- *clarify the exact requirements in the draft regulation and in the text of the regulation where meaningful and necessary.*

Modify requirements in the regulation, especially in terms of

  - *simplified processes for the assessment of exposure and the communication of exposure scenarios and categories in the supply chains as well as*

- *the possibility of adapting the required scope of the test to the possible risks based on an assessment of exposure*

  - *reduced GLP requirements for the new tests to be conducted if other quality assurance systems (such as EN 17025[8]) apply.*

- *The manner in which REACH is practically designed for implementation, especially clear, pragmatic rules for the recognition of existing data and the evaluation of previous studies, and for the authorization of analogous conclusions and evaluations of groups of substances.*

- *The deployment of EU guidelines and other implementation instruments and aids **before the system is launched**, especially*

  - *the development of standard exposure scenarios and/or exposure categories for the various supply chains in cooperation with manufacturers of substances and preparations and users of substances.*

Decisions will be made on a case-to-case basis about whether details on the requirements will be given in the regulation's annexes or in EU guidelines (ARGE Planspiel 2003, Section 6.1.2).

8 DIN EN ISO 17025: Standard for accreditation as a test laboratory

Chapter VI makes reference to the results of the management business game that are relevant to the paint chain. While the workability of the REACH system was not the subject of the present UBA project, many of the estimations made above were reconfirmed in talks within the chains of coatings, detergents, and cleaning products.

I.3.3 Environmental and health benefits

The German Advisory Council for the Environment (SRU) has made several statements on the environmental and health benefits of REACH. In the process, it has made it clear that cost savings may result from better knowledge of the properties of hazardous substances and the use of products containing less hazardous substances in the medium to long term in the fields of health and environmental protection. The SRU sums up its position: *A **quantification** of such benefits entails considerable methodological difficulties, so that no reliable, specific figures can be given. However, current studies do underscore the plausibility of the expectation that the benefits in the health sector will exceed the costs of an effective control of chemicals in the mid-term (SRU 2004b, TZ 985/986).* Here, the SRU refers to the studies of PIERCE and KOUNDURI (2003) and RPA (2001). In the first study, the possible cost savings in the health sector of EU-15 are estimated at 4.8 to 283.5 billion euros by 2020, depending on how the costs and welfare losses are credited in the model used. The second study is limited to estimates of savings for job-related asthma and dermatitis, which it estimates at 1.2 billion EUR in 10 years (see SRU 2004b).

In its study on the effects of the new chemicals policy on the environment and health for the EU Commission, RPA and BRE Environment (2003) identify four central advantages of the REACH system compared to current systems based on four case studies:

- REACH has the potential to identify hazards before substantial damage has occurred due to the evaluation of substance properties and the quick availability of this information. In comparison, waiting for monitoring results to demonstrate damage is too slow and unsafe.
- The systematic provisioning of data allows for a thorough assessment of risks and the identification of effective risk management measures.
- The availability of information about risks allows industry to take voluntary measures, thus reacting to its customers or implementing its own corporate policies.
- Furthermore, REACH provides a basis for fast regulation measures for the most dangerous substances.

In the case studies, the detection of damage, the risk assessment process, and the regulation process was analyzed and evaluated for four substances: nonylphenol, short-chain chloroparaffins, perchlorethylene, and tributyltin.

The studies illustrate the methodological difficulties entailed by a quantifying estimation of the benefits for the environment and consumer protection. Here, there are neither documentation systems nor clear cause/effect relations, as is the case with job-related health impairments. Therefore, this project focuses on using practical sample cases and existing instruments (such as safety data sheets) to show where and in which way the REACH system can provide benefits.

I.3.4 Withdrawal of substances

The study by Arthur D. Little states, "the direct withdrawal of a supply of special substances, as forecast by the chemicals industry and retail, cannot be directly simulated" (Arthur D. Little 2002, p. 56). The study focuses directly on production losses in an industry or supply chain. The drivers include the cost increases per cent due to REACH registration, their relation to the assumed margin, and an industry factor used to estimate the degree to which registration costs can be passed on to the consumer. The study generally points out that end users who face higher prices for raw materials caused by REACH will cease their production and demand for substances if these price increases cannot be adequately passed on to the market. The drop in demand would then lead to a withdrawal of the substance. The study does not go into detail about the decisions and mechanisms at the level of the substance manufacturers or about the scope of the expected withdrawal of substances. Hence, the study cannot be taken as a starting point for an exact analysis of the withdrawal of a substance in this research project.

The current French study (MERCER 2003; MERCER, NERA 2004) estimates the quota of withdrawn substances at 10-30 %. These figures are based on portfolio analyses of selected enterprises that are greatly affected. Here, the registration costs were viewed with respect to the revenue from the particular substance. The payback time can be estimated with an assumed margin of 10 %. The companies surveyed were asked to indicate whether they would consider registering a substance given the figures calculated. In the opinion of the contracted research institutions, the quotas estimated seem too high given the skewed sample of companies. In addition, the portfolio analysis was only conducted for a very small group of companies[9] so that no statistical generalizations can be made. A contextual generalization is also not possible as the companies for which portfolio analyses were created are not described any further. In terms of their approach, MERCER and NERA view registration as an investment deci-

9 Of the initial 50 pilot companies surveyed in the first study (MERCER 2003), only 14 were included in the current study. They operate in various stages of the supply chain, i. e. the number of substance manufacturers surveyed is even lower.

sion - an approach the present study also criticizes. The analysis also fails to deal with the long forecast horizon on which the figures for the companies are based. Finally, the authors do not discuss whether a substance will be withdrawn from the market if a single company chooses not to produce it or whether the market volume will be re-concentrated among the other manufacturers of the substance who remain on the market. The present study deals with these remaining questions.

The VCI estimates the quota of withdrawn substances with 10-100 t/y at 20 %-40 % (VCI 2004). According to the VCI, this estimation is based on company surveys. Here, experience from the registration of new substances and the biocide directive was important. However, the contracted research institutions are of the opinion that the transferability of this experience is limited (see Ch. II).

In February of 2003, RPA presented a separate working paper on the rationalization of the substance portfolio (RPA 2003b). A written survey (see Ch. I.3.5) recorded companies' estimations of the quota of substances they would withdraw from the market. The results are given in Table I-1. The RPA survey only provided separate percentages for large enterprises, on the one hand, and small and medium-sized enterprises, on the other. As the number of substances is not known in terms of these two categories, the share of substances that would be withdrawn from the overall market cannot be properly derived from these figures. From the findings of the survey, RPA merely derives the *assumption* that the quota could be around 20 % and concludes that the highest estimations by industry (40 % of all substances) are improbable. RPA's estimation is also too high as it stems from February 2003 and is thus based on much higher test requirements (and hence registration costs) than stipulated by the draft regulation of October 2003.

The study's analysis approach for low-volume/low-value substances has also been criticized (cf. Berkhout et al. 2003). This term was not defined in the survey; the answers are thus hard to interpret. Low-volume cannot mean the same thing as low-value; on the contrary, the greatest profits are generated by the volumes of special and fine chemicals. RPA also fails to analyze the decision-making processes and criteria on which the figures from the companies are based. The present study aims to provide new insights.

In its Extended Impact Assessment, the EU Commission estimates that 1-2 % of substances will be withdrawn (CEC - Commission of the European Communities 2003b). This estimation is based on Enterprise DG's microeconomic model of monopolistic competition (Canton, Allen 2003). The insights from this model are hard to use for the

analysis of the supply chains envisioned in the present study because the model does not make a distinction between industries or supply chains.

Table I-1: The share of substances not intended for registration

Tonnage range	Registration costs (1,000 euros)	Large enterprises	SMEs
1 – 10 t/y	< 100	12%	6%
10 -100 t/y	100 – 250	8%	9%
100 -1,000 t/y	250 – 500	3%	16%
> 1,000 t/y	> 500	4%	4%

Source: (RPA 2003b, p. 9)

I.3.5 Innovation effects

A study that is often cited for the assessment of the innovation effects of REACH is a comparison of the innovation profiles and rates in the chemicals industry in the EU, the US, and Japan by Fleischer et al. (2000)[10]. Here, the authors find that European companies have fallen behind in marketing new chemicals. The rigid European regime for new chemicals is said to be responsible for the ground lost. Four indicators are quantified using statistical methods based on a sample of several hundred companies. These indicators include the *number of product innovations marketed* in 1996 and 1997. These figures were partly gleaned from the content of corporate reports[11]. Furthermore, patent productivity is measured based on the number of US patents granted, while R&D productivity is based on an expanded production function with the production factors labour, capital, and R&D. For the first three indicators, only slight differences between the regions studied were detected. In addition, no direct influence of the regulation regime could be demonstrated. Hence, these indicators were not used in the present study, especially since they cannot be quantified based on case studies. The fourth indicator used by Fleischer et al. is the *number of notified new substances.* The present study also pursues this approach. However, Fleischer et al. do not make a distinction between notifications by foreign and domestic companies. The present study remedies this error.

The development of new substances is an issue dealt with by several studies of the innovation effects of REACH. Nordbeck and Faust (2002) qualify the negative assess-

10 Cf. (Fleischer 2002; Fleischer 2003)

11 Hence, they are based on the subjective information provided by the companies. Among others, SRU (2003) finds this approach unconvincing.

ment of the current new substance regime in an international comparison mentioned above. They point out that the backlog of existing substances in 1981, when the new substance regime was instituted, was greater than in the US so that the pressure to notify new substances was smaller in the beginning. Furthermore, the trend curve of the number of notifications is dropping in the US, while it is rising in the EU; in the meantime, the notification curves have converged. Several studies assess the effects of REACH on the development of new substances by juxtaposing the requirements of REACH with those of the current regime (CEC - Commission of the European Communities 2003b; 2003; SRU - Rat von Sachverständigen für Umweltfragen 2004b; Wolf, Delgado 2003).

The easing of restrictions[12] and the equal treatment of existing and old substances with regard to registration requirements is taken as an indication that REACH promotes the development of new substances. The present study aims to trace the effects of REACH on the development of new substances more closely back to the supply chains investigated and to provide an empirical basis for the findings.

Berkhout et al. (2003) derive additional positive innovation effects from REACH. With reference to the literature on innovation impulses, they find REACH to be innovation-friendly as it strengthens some of these impulses, for instance close customer relations, access to external sources of expertise, and effective internal communication (cf. CEC - Commission of the European Communities 2003b). The SRU (2003, Ziffer 23) refers to the proven empirical knowledge that companies react to strict specifications with product and process innovations and lists a multitude of sources. Porter and van der Linde (1995) develop a comprehensive catalogue of principles for the design of regulations to promote innovation, productivity, and competitiveness. These include a high degree of consistency, focusing on results rather than technology, a stable regulation process, and predictability. Berkhout et al. (2003) assess REACH according to these principles based on a document analysis. The resulting evaluation of REACH is positive, based, among other things, on the breadth of the approach (entire supply chains), the clear assignment of competence between industry and the authorities, and the demanding, but clear timeframe. They viewed a number of remaining uncertainties negatively, such as the capacity of competent authorities and costs. However, the authors point out that these shortcomings can be remedied in the course of implementation. While they thus expect the innovation rate to drop in the short term, in the long term this can be compensated by steering innovations in the socially desired direction.

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12 Among other things, the increase in the tonnage threshold above which registration is necessary; (an expansion of the) exceptions for R&D, intermediates, and polymers; reduced test requirements for substances with production quantities of 1-10 t/y

The innovation hindrances caused by REACH are also discussed in the literature. One possible obstacle is that the pool of old substances which can be accessed flexibly may drop from some 100,000 substances on the EINECS List to around 30,000 registered substances after the phase-in period of REACH (SRU - Rat von Sachverständigen für Umweltfragen 2004b). The present study thus investigates the importance of "hidden reserves", i. e. substances manufactured in amounts below one ton per year that are therefore not counted among the phase-in substances. There are also concerns that REACH might reduce the resources available for R&D (RPA 2003c). The EU Commission argues the contrary: the direct registration costs of REACH only amount to 3 % of the current R&D expenditures of the chemicals industry in Europe (CEC - Commission of the European Communities 2003b). In RPA's revised "Business Impact Assessment", possible delays in product development are also discussed. They may result from new applications having to be registered / authorized before production begins. Another negative effect on innovation capacity may stem from the withdrawal of a substance: product quality and variety may suffer as a result.

These assessments reflect the findings of a written survey of companies and associations in various stages of the supply chain[13]. The positive and negative innovation effects of REACH were incorporated into the catalogue of hypotheses of the present study and were empirically tested in the analyses of the supply chains.

Finally, Nordbeck and Faust (2002) point out that an assessment of the innovation effects of REACH not only has to include the quantitative aspect, but also the effects on the direction of innovation. Steering innovation in a certain direction is seen as justified because the regulation aims at a change desired by society (Berkhout et al. 2003). Here, the main question is whether REACH will promote sustainability in terms of safe chemicals and processes. Nordbeck and Faust find that REACH will indeed do so because it improves the information basis for existing substances. Experience with new substances shows that a better information basis fosters a shift to safer chemicals; the German Institute for Occupational Safety and Health (BAuA) has published white lists with recommended substances for certain applications on this basis. As the information provided by the REACH system is crucial for this steering effect, the authors find it disturbing that substances with a volume of less than one ton per year need not be registered. In addition, the transparency and public accessibility of test data - such as for quality inspections or the development and validation of QSARs - are essential. The

13 Some 100 questionnaires from substance manufacturers and formulators (and their associations) and some 160 questionnaires from companies outside the chemicals industry were assessed in the original survey. Another 60 companies were surveyed for the revision, with a response rate of approx. 30 %.

SRU (SRU - Rat von Sachverständigen für Umweltfragen 2004b, number 1059) does not see REACH as exemplary environmental policy in terms of innovations as its steering effect is largely based on the information provided by the REACH system, while the authorization procedure only offers weak incentives for substitutes. Wolf and Delgado (2003) find that REACH will have more positive effects on the direction of innovation than current chemicals law due to its stronger risk-oriented focus (priority for “substances of very high concern” and substances with large tonnages).

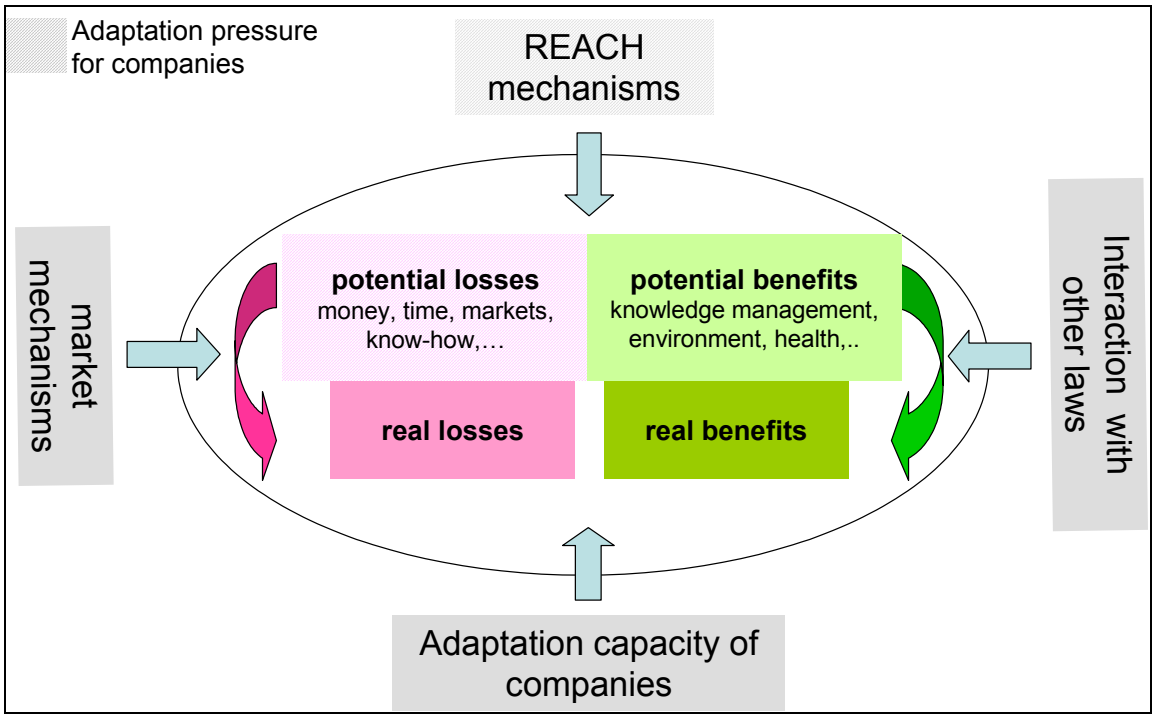
I.4 Formulation of the problem and research questions

The goal of this research project is to analyze the costs and benefits caused by REACH as part of the new chemicals policy based on the example of selected supply chains. The work focuses on the analysis of impact mechanisms; economic impacts are only quantified in a few examples. This approach is designed to address the study’s basic concerns which are to identify starting points for a change management strategy that can serve as the basis for the realization of REACH and to keep the costs involved as low as possible.

The starting point of the study is the REACH model shown in Figure I-1. Here, the study refers to the draft of the regulation of October 29, 2003. “REACH mechanisms” are defined as the obligations and workflows specified in the draft regulation for the various stages in the supply chain. They include, for instance, the registration obligation of substance manufacturers and the obligation of formulators to keep the application of a substance within the registered pattern of applications and exposures or to conduct their own safety assessment (cf. Ch. I.1). The REACH mechanisms have various possible effects. On the one hand, they may lead to a better understanding of the substance properties and exposure patterns and reveal potential benefits for human health and the environment. On the other hand, there are also risks of losses from the time and money spent and the (out)flow of expertise linked to REACH mechanisms. The real effects - i. e. the scope and type of the potential benefits and losses actually realized – are dependent on the other market mechanisms (competitive situation, development of demand etc.) under which companies do business. The interaction of REACH with other laws also influences these developments. These determine, for example, to what extent REACH really increases knowledge of substance properties and exposure patterns, and how much additional work (collecting data, documentation, etc.) this entails for companies. REACH mechanisms and the risks of losses resulting from them put pressure on companies to adapt, and the companies only have a certain capacity to do so. The extent to which the capacity can withstand the pressure will also affect the actual economic effects.

One aspect of REACH is that it affects various stages in the supply chain in different ways, both directly and indirectly. To make these relations clear, some of the main impact mechanisms of REACH in the supply chain are shown relative to the supply chain in Figure I-2. Chapter II provides more detailed hypotheses.

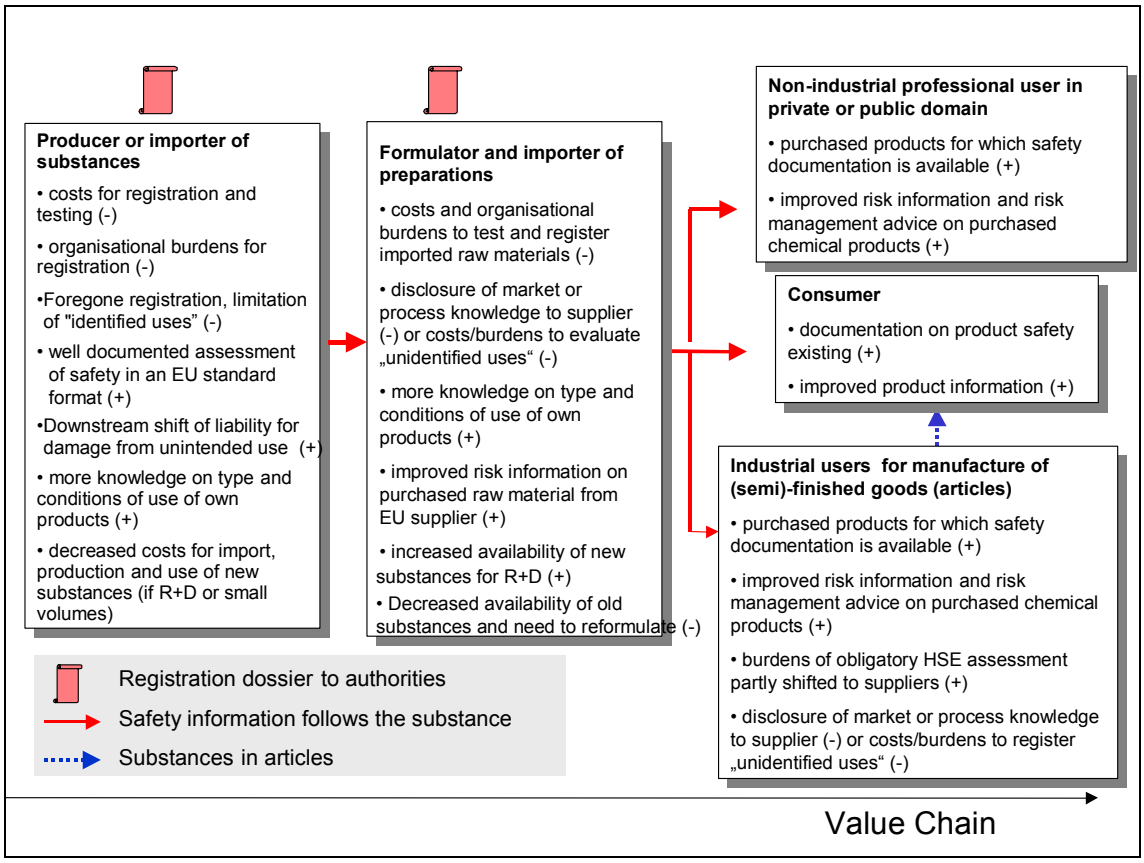
Figure I-1: The impact model for REACH



Given the inherent methodological difficulties, no effects are derived at the macroeconomic level, unlike the studies by the EU Commission, ADL, and MERCER. Compared to the earlier studies on REACH, which are presented in the brief synopsis in Chapter I.3, the present study basically contributes new insights in the following three areas:

- the potential benefits with regard to improved risk information and knowledge management in chemicals safety are made concrete; possible environmental and health effects are illustrated using examples to analyze REACH's underlying impact mechanisms (cf. Chapter IV, V.3 and VI. 3);
- data gaps for the analysis of effects at the level of supply chains are identified;
- innovation effects, adaptation mechanisms and adaptation capacity for REACH are made concrete at the level of companies and, to some extent, made measurable; and
- proposals are devised to improve the ratio of the costs and benefits of REACH.

Figure I-2: Examples of the effects of REACH in the supply chain



The methodological spectrum of previous analyses should be expanded. The present study places great store on detailed case studies. The development of the reference scenario (development without REACH) is also consistently studied, e.g. regarding price formation or substance range. The additional effects generated by REACH cannot be identified without this reference.

The focus of the study is on registration within REACH. Due to a lack of capacity, the advisory committee agreed not to include an investigation of the authorization process. This means, for example, that discussions about the criteria for the authorization of substances (such as SRU - Rat von Sachverständigen für Umweltfragen 2004a) are not part of this study. Overall, all the existing studies agree that the costs and possible effects of the registration process will be much greater than the effects of the authorization process.

I.5 The methodology and procedure of the study

The existing studies of the effects of REACH agree that there are still certain methodological problems in this field. As no single analytical approach can provide satisfactory

results, this project uses several methods to analyze the effects thoroughly in different ways. They are based on the methods of Regulatory Impact Assessments (cf. OECD 2003). Figure I-4 gives an overview of the procedure. The elements are briefly described below.

Chapter II presents detailed, theory-based hypotheses on the effects of REACH. For instance, hypotheses about the adaptation capacity of an industry are derived from innovation economics. This chapter also discusses how these hypotheses are tested in the course of the study. If this is done based on quantitative indicators, their derivation and interpretation are explained.

The first issue discussed in Chapter III regarding the effects of REACH concerns the direct costs of registration, i. e. the costs for testing substances and the administrative costs that registration entails. Here, the focus is on the documentation and explanations of the EU Commission's estimates, which are compared to those of VCI and other institutions. In addition, studies are compared and the causes of discrepancies identified. The study does not make its own estimates of direct registration costs.

Chapter IV then discusses the potential benefits of REACH: the prevention of environmental and health damage caused by chemicals. A sound, comprehensive quantification of this damage is beyond the scope of this study. Instead, the study is restricted to illustrating the possible beneficial effects and their order of magnitude. This study focuses on identifying the mechanisms with which REACH can remedy the weak points in current chemicals law and its enforcement. In addition, the magnitude of selected cases of damage (including chronic water contamination) caused by chemicals is quantified and the causes investigated. Based on the impact mechanisms of REACH, it can then be implied whether REACH would have been able to prevent the causes or would to able to do so in the future. This chapter also includes a discussion of selected related laws used as a basis of comparison for the additional effects of REACH. This basis is limited for practical reasons (cf. Sections I.6 and VIII.9).

The third and most comprehensive element in the present study on the costs and benefits of REACH is the analysis of its effects in selected supply chains, specifically paints/coatings and detergents/cleaners. These examples are considered to be especially relevant as the chemical sectors involved serve industrial customers as well as manufacturing products for consumers, and thus cover a very wide range of applications and users, and because of the predominance of SMEs here are well-suited to the study of the problems such enterprises will face. In addition, these two supply chains differ in ways that should reveal the different effects of REACH. For instance, paints/coatings are part of an end product, whereas detergents and cleaning agents as

process chemicals are no longer contained in the final product. Hence, a broad spectrum of the possible effects of REACH should be covered.

In the analysis of supply chains (Chapters V and VI), the section of the supply chain studied is first defined[14]. In each chain, face-to-face interviews were held with trade associations and companies at various stages of the supply chain (substance manufacturers, retailers, formulators, users of preparations[15]), i. e. both within and without the chemicals industry. Overall, 24 companies were surveyed; Figure I-3 provides an overview of their supply chains and stages. At the level of the chemical imports and users (outside the chemicals industry), a total of four companies were surveyed in both supply chains. The interviews were based on a set of questions adapted to the particular supply chain and stage.

An important basic component in the survey was the structure of the reference scenario. This scenario comprised the past developments and expected future trends without REACH, for instance in terms of innovation drivers or relocation abroad. The goal was to be able to make a better distinction between the additional effects of REACH and business-as-usual developments. In addition, certain adaptation processes in the past - such as voluntary commitments or legal changes - are discussed in order to draw conclusions "to draw conclusions about which prior conditions the companies have at their disposal for meeting the adaptation requirements under REACH. The interview guidelines are summarized in the Annex.

In addition to the interviews, two workshops took place with the companies surveyed[16]. The first workshop was held before the interview phase and was designed to provide a common understanding of the most important elements of REACH and the amendments made in the draft of October 2003 compared to the version of May. Furthermore, the research questions and the concept of the survey were presented. The second workshop with the companies was held after the interviews. Here, crucial aspects of the evaluation of the interviews were discussed. This kind of group discourse and the participation of those affected play an important role in regulatory impact assessments. In addition, in this project, the actors from different stages of the supply chain could share their perspectives.

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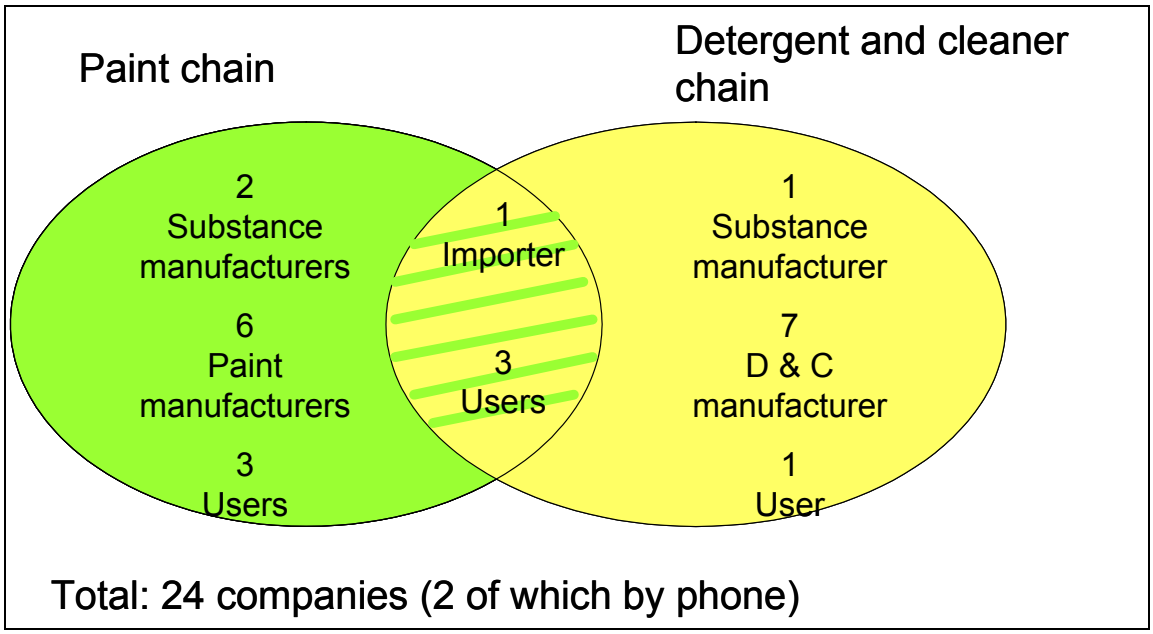
14 For the selection and the reasons behind it, see Chapters V and VI.

15 When “users” are referred to in this study, users (of chemicals) outside the chemicals industry are meant.

16 The programmes of the two workshops are documented in the annex.

Figure I-3: The structure of the empirical base of the supply chain analysis



Alongside the interviews and workshops with the companies surveyed, document analyses were included in the case studies (including position papers, annual company reports, and information brochures of those involved). Finally, experts - such as authorities or test institutes - from these sectors were interviewed on particular aspects. These included details about certain authorization methods or the enforcement of specific laws. On one special aspect - the development of new substances as defined in directive 67/548/EEC - the database of notified new substances was also evaluated to determine its relevance for the supply chains studied in Germany.

Any generalizations drawn from the empirical data collected in this manner must be viewed against the background of the case study method applied. The limited number of companies and supply chains studied does not allow for any statistically representative generalizations to be made. However, the theories presented in the hypotheses do make analytical generalizations possible (see Yin 1989); at the same time, the context is presented as accurately as possible to allow readers to draw their own general conclusions for other analogous cases (see Kennedy 1979). On this basis, the results of the two supply chains are compared in Chapter VII and conclusions drawn from them in Chapter VIII.

An advisory committee made up of research institutes, labour unions, the authorities, NGOs, and trade associations accompanied the development of the project at every stage. This team discussed methodological questions, decided what the content should

focus on, and discussed the results of the project. The project's schedule is shown in Figure I-5.

Figure I-4: An overview of the procedure

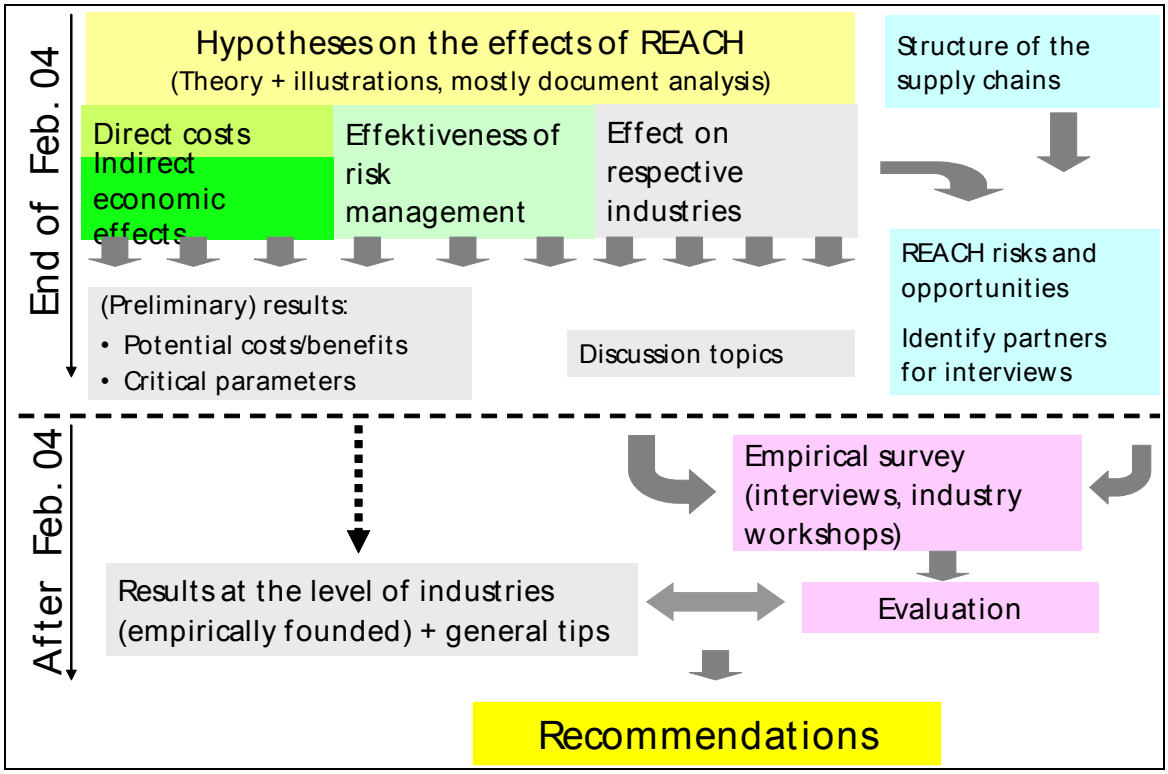
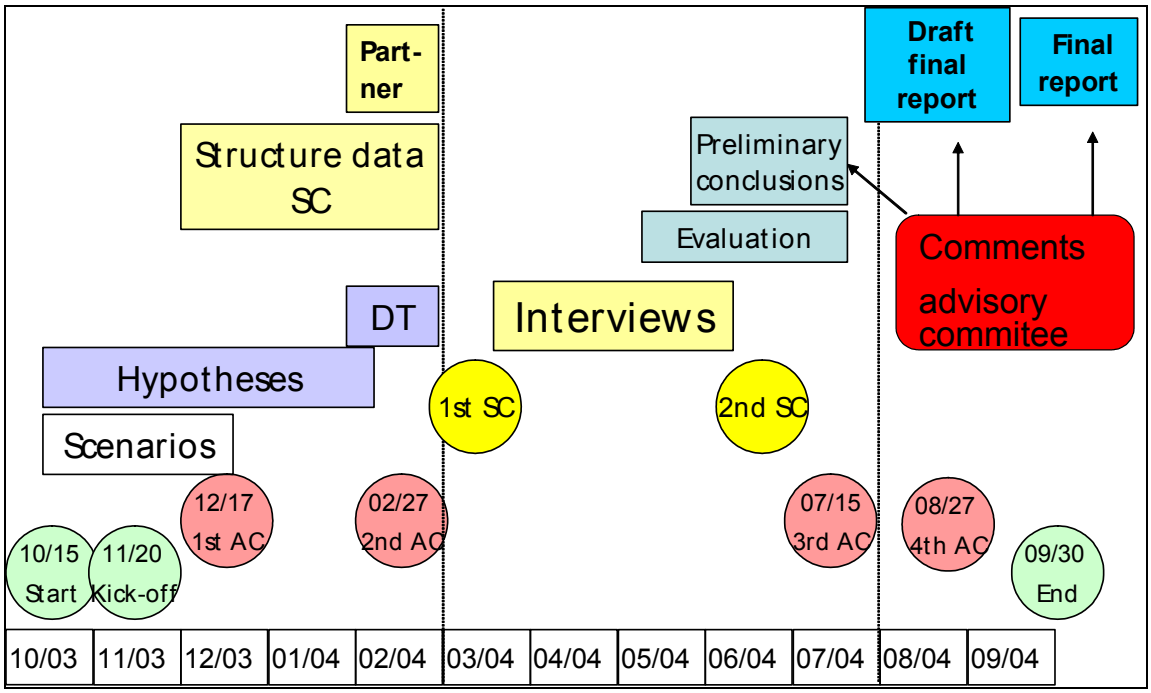


Figure I-5: Project schedule[17]



I.6 Boundaries of the study

The empirical approach applied here to studying the REACH mechanisms - case studies at the level of enterprises in selected supply chains - does not permit statements to be made about the overall benefits for the environment and health, nor about the macroeconomic effects of REACH. In other words, quantitative statements about the environmental and health effects of REACH at the aggregated level and about the effects on gross national product, the job market, or the trade balance and similar macroeconomic parameters are not the subject of this report.

Like the other effects of REACH, effects on trade are analyzed in terms of the basic incentives they provide based on the figures and estimates provided by the companies studied. It must also be added that the actual relevant contexts cannot be realistically represented here - especially the actual range of users in the supply chain - despite the multitude of application sectors investigated. Furthermore, there is no comparison with users in similar industrial contexts and - for capacity reasons - no industry-specific reference scenarios as described in Chapter I.7 for the chemical industry. This also limits the generalizations that can be made for this stage of the supply chain (cf. Ch. VII). The same holds true for the import of chemicals.

17 AC = advisory committee, DT = discussion topics, SC = supply chain

To reduce the complexity, the study had to focus more narrowly. First, actors in the supply chains directly affected by the REACH regulation were studied; hence system suppliers were not surveyed, for example. Thus, aspects of the interdependence between REACH and process development could only be dealt with from the perspective of the users of processes (and chemicals). Furthermore, only the registration components of REACH were investigated. The reference scenario assumes that current legislation on chemicals continues, i. e. other alternatives to REACH were not considered. Likewise, as a result of its focus, the present study does not comprehensively analyze the interfaces between REACH and other substance-based legal stipulations regarding environmental protection, job safety, and consumer protection.

I.7 Basic trends in the chemicals industry in Germany

This section outlines the major trends in the economic development of the German and, to a certain extent, the European chemicals industry. It thus sets the framework for the reference scenario in which the developments for specific supply chains and developments at the level of the companies surveyed (see Ch. V and VI) are set. This section is restricted to the chemicals industry. The customers of the chemicals industry are a very mixed group; no general statements would do them justice. This heterogeneity also holds true for the companies in the user supply chains included in this study. Therefore, this project was not able to construct industry-specific reference scenarios as these would have been too numerous. For downstream users outside the chemicals industry, the study focuses on company-specific developments in the reference scenario in the chapters that analyze supply chains.

The average annual growth of the chemicals industry in Germany from 1993 to 2000 was 3.4 %, slightly above the 3.2 % rate for the overall processing industry. In 2001 and 2002, the production rate fell. One reason may be that the chemicals industry as an upstream supplier is generally ahead of the world market (all information from Rehfeld et al. 2004).

The macroeconomic importance of the sector is reflected in the close relations of the chemicals industry with the rest of the economy, on the one hand, and in its contribution to macroeconomic added value, on the other.

This contribution dropped in the 1990s; in 2000, it constituted a good 1.7 %[18]. Internationally, this rate is quite high. In the USA, the rate is only 1.3 %; in Japan, 1.2 % (Rehfeld et al. 2004). The decrease in importance is partly the result of the world-wide

18 The chemicals industry without pharmaceuticals.

trend towards a service economy. Some 1,700 chemistry companies are based in Germany; a large number of them are medium-sized companies (90 %). But the market is very concentrated, i. e. these medium-sized companies generate only 1/3 of total revenue (VCI 2003). Since 1991, employment figures have dropped. Except for the phase from 1997 to 2001[19], this corresponds to the overall development in the processing industry (Rehfeld et al. 2004). However, the intensity of labour in the chemicals industry fluctuates greatly between the various industries (for instance, special chemicals are much more labour-intensive than basic-chemicals).

World-wide, the chemicals industry is heavily dependent on exports. For instance, in all highly developed national economies, exports and imports of chemicals account for a much greater share of the international trade with industrial goods than of the value added. In the EU, the chemicals industry is responsible for an important and growing trade surplus with non-EU countries. In 2002, some 45 % of the processing industry's international trade surplus was due to the chemicals industry (CEFIC 2004). In terms of its share of world-wide chemicals production, the EU was still the leader in 2002 with 360 billion euros. However, its share has fallen from 32 % to 28 % in the past decade (CEFIC 2004). In Germany, the chemicals industry has always been one of the strongest export industries: more than half of the revenue generated in Germany is made abroad (VCI 2003). Production is increasingly following the markets, which is why German chemicals companies generate roughly as much revenue from production abroad as from sites in Germany.

Germany's chemicals industry contributes to the trade surplus. At 12.6 %, it had the biggest share among the OECD states of the total world trade with chemical products in 2003, ahead of the US with 11.7 % and Belgium with just under 10 %[20]. However, Germany's overall share of world trade has shrunk for both chemical goods (1991: 19 per cent) and processed industrial goods (1991: 17 per cent). One major reason for this is the effect of exchange rates.

The relative shares of world trade (RWT values) - also known as RCA values ("revealed comparative advantages" - are more telling[21]. Both values were positive for the

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19 During this time, the number of jobs in the processing industry stabilized.

20 These figures are from the comments made by VCI on the draft report of 08/16/04. In 2000, Germany was second at 14 % behind the US at 17 % and ahead of France at 9 % (Rehfeld et al. 2004).

21 The RWT value indicates the share of the various sectors in the world market relative to the share of the world market for processed industrial goods overall. The RCA value measures the ratio of exports to imports in specific sectors in terms of overall processed industrial goods.

German chemicals industry from 1991 to 2000, but with a decreasing tendency. For the RWT value, this means that there is a specialization in chemical products, but that this is decreasing. For the RCA, this means that there are specialization advantages, but these are diminishing (Rehfeld et al. 2004). The main buyers for German chemicals exports are the EU and NAFTA countries. Central and Eastern Europe have been the third largest export region ahead of East Asia since 2001 (VCI 2003).

The visible demand for chemical products, i. e. domestic production less exports plus imports, has developed in line with the production figures. There are certain areas, however, such as the basic chemicals industry, which are exposed to increasing import pressure that becomes clear when production exceeds visible demand. Other areas, such as special chemicals, are export-driven, i. e. production has grown more than visible demand (Rehfeld et al. 2004).

The chemicals industry is one of the most research-intensive industries world-wide. The German chemicals industry is particularly R&D-intensive: the 4-4.5 % share of revenue it spends on internal R&D is clearly above the global average of 3 %. The cross-cutting character of the chemicals industry also reveals itself in the R&D networking with other industries. Just under a quarter of the expenses for R&D are for product fields actually belonging to other industries (Rehfeld et al. 2004).

The chemicals industry is currently undergoing several restructuring processes. The trend is towards greater specialization and focusing on core business activities. Conglomerates are reorganizing and abandoning business areas. This restructuring aims to find the optimal path between various lines of business, i. e. between substances (coupled production), research, and customer-orientation. The companies are pursuing various approaches to this end.

Overall, the chemicals industry in Germany and Europe is currently facing major challenges[22]:

- The growth centres of chemicals production and demand are shifting due to the industrial progress of emerging countries and demographic factors, due to important customer industries moving out of Europe, and due to the necessity for chemicals producers to be close to their customers.
- Technological knowledge is increasingly available world-wide, and the advantage of the German chemicals industry in terms of its competence and expertise is decreasing.

22 These figures are from the comments made by VCI on the draft report of 08/16/04.

- The chemicals industry has a poorer position in politics and public relations in Germany and Europe than in other regions (cf. CEFIC 2004).
- The increasing influence of international capital markets is focusing corporate activities on short-term success.

Excursus: speciality chemicals

Some 34 % of revenue and 37 % of profit in the chemicals industry in Europe (without pharmaceuticals) is generated with **special and fine chemicals**, which are generally defined as substances or preparations manufactured in smaller volumes than basic chemicals and used for specific purposes as functional components or as process aids in the manufacture of a wide range of goods. Fine chemicals are defined as intermediate products, pharmaceutical substances, and aromatic substances manufactured in small amounts and a high degree of purity. The research and development share is 8-12 %. This sector also includes substances for the manufacture of semiconductors, for example.

Special chemicals include pigments and additives, certain oleo chemicals and surfactants, i.e. substances from the supply chains examined in this project. It must be kept in mind that many surfactants and oleo chemicals are also bulk chemicals. The share of research and development for special chemicals is generally around 5 - 8%. 90 % of innovations are in the formulation of new products based on existing substances. The prices for special chemicals have been and still are based on the value of the application for the customer and not on the production costs. Their share in the overall costs of customers is generally very low, but they are essential for increasing performance and productivity. Traditionally, special chemicals have thus had large profit margins and more stable prices than basic chemicals.

However, this structure has been changing in the past few years. The relocation of major consumer industries from Europe to Asia has resulted in a growth in the market for special chemicals there and corresponding competition from Asian companies. At the same time, the growth in demand has slowed down, and the supply chain management of major consumer industries has led to an erosion of the prices and margins (all information from CEFIC 2004).

II Hypotheses and measuring approaches

In this chapter, we will explain the more complex hypotheses and measuring approaches on which Chapters IV – VI are based. In regard to supply chain analyses, this will also help clarify discussion topics (see Annex) and the evaluation categories. The first set of hypotheses deals with the effects of REACH on occupational safety and environmental protection, as well as product safety. They form the background for Chapter IV and, in the context of supply chain analyses, for Sections V.3 and VI.3. In addition, hypotheses and indicators are presented that deal with REACH's effects on innovation, price and production structures. These subjects are found in sections 4 and 5 of Chapters V and VI, which cover supply chain analyses.

We will wait to explain simple hypotheses directly in conjunction with the data and its presentation. This concerns in particular the evaluation of registration costs directly generated by REACH in the respective supply chain (see Sections V.2 and VI.2). The basic goal is to examine how the factors influencing these costs and presented in Chapter III are manifested in the respective supply chain (such as the number of substances requiring registration, relevant tonnages, hazardous substance rating, etc.).

II.1 Adaptive pressure and capacity as higher-level evaluation criteria

The hypotheses cited in the following sections identify various mechanisms and effects of REACH. Two higher-level categories are formed to collectively portray the results of examining the hypotheses (see the impact model in Chapter I). On the one hand, this includes the *"adaptive pressure"* generated by REACH. This essentially includes:

- Registration costs (including their relationship with the material price), expended time, knowledge drain due to the registration process
- the withdrawal of substances
- the necessity of reformulating due to substantially altered (raw) material prices or limited availability of substances;
- necessary user adaptations to altered preparations and prices, and
- competition from market actors not subject to REACH.

The adaptive pressure thus defined is contrasted with the *"adaptive capacity"* of the various actors in the supply chain. This essentially includes:

- Resources and procedures for knowledge management (especially in regard to the chemical safety);

- Innovative capacity including past adaptations. The latter can for example be related to formulation changes, raw material replacements, price increases or the unsatisfactory fitness of substitutes in the past.
- "Innovative capacity" is understood as the ability to generate innovations, i. e., realize profits from progress. In the context of regulatory impact assessment, the present study uses innovative capacity as a reference point of how fast and effectively a company can adapt to changing market and underlying conditions (see also Section II.3).

In regard to the categories of "*adaptive pressure*" and "*adaptive capacity,"* there exits some gray area between effects that reduce adaptive pressure, and those that increase adaptive capacity. One example would be favorable prospects for overcoming additional costs that could be defined either as reducing adaptive pressure or increasing adaptive capacity. Despite these ambiguities of categorization, the researchers nevertheless feel that this modality of collectively representing results is recommendable.

II.2 Hypotheses concerning effects on chemical safety

In analyzing the benefits of REACH for the environment and health (see Chapter IV), this study is based on the assumption that the present instruments of chemical law have several systematic gaps that cannot be eliminated solely by giving teeth to or improving the implementation of existing legislation, but which will be partially closed by REACH. Such a hypothesis is supported for example by experiences with existing recycling programs on the EU level and the resulting unresolved questions concerning the systematic identification and elimination of informational gaps. Prior experience with using safety data sheets as key instruments for communicating information about substance-related risks in the supply chain indicates that a series of systematic problems exist that can be partially addressed by REACH.

This hypothesis is examined in Chapter IV in a comparative analysis of documents where the regulatory draft of REACH is compared with selected elements of existing chemicals law. In addition, chemical-related harm (including chronic water pollution) is quantified and its origin investigated. The modes of action of REACH then suggest whether REACH would have been able to prevent the causes or would be able to in the future.

Some of the beneficial aspects of REACH are explored in greater detail in supply chain analyses, especially addressing the conditions to realize them and the required implementation instruments of REACH. Sections V.3 and VI.3 deal with existing management capacity and the current status of information relating to substances and applica-

tions. One aim in this regard is to investigate which existing information (concerning for example exposure of a user of a preparation), management tools and resources can be employed for REACH. In addition, the informational deficits and difficulties in current chemical management cited by those surveyed are compared with the innovative elements of the REACH system. The aim is to illustrate REACH's potential for making things both easier and more difficult. This includes specifying factors influencing existing chemical management that will not be changed by REACH. Indicators of some of the benefits will be developed within the project to render them measurable in the supply chain analysis. The underlying hypotheses, the survey contents and the indicators and their interpretation will be explained in the following.

In the supply chain analysis, the hypothesis is posed that the present EU safety data sheet and its implementation in the *Technical Rules for Hazardous Substances* (TGRS 220) represent an acceptable and highly suitable instrument for transmitting required risk management information in the supply chain. However, practical operationalization for all protected goods (such as exposure-related information) has been missing in certain areas of information. In addition, there are no mechanisms for actually implementing the potential of the available instruments in the supply chain. If and to what extent REACH can be of assistance should be determined in the interviews and by testing the hypotheses. The survey therefore posed questions:

- about the knowledge of manufacturers of (raw) materials and preparations concerning the type and conditions of use in the downstream supply chain;
- about evaluating available information on exposure in different customer groups and using this information to specify safe-handling measures in the safety data sheet;
- about supplier information on the identity and contents of hazardous substances in the delivered products;
- about the existence of inventories of **individual substances** and/or hazardous substances as a springboard for specific questions to substance suppliers regarding any missing information about environmental and health-related properties of delivered hazardous and non-hazardous substances.

In addition, the supply chain analysis is based on the hypothesis that product safety management requires *"sufficient"* personnel and defined responsibilities. Without these, neither existing requirements nor requirements under REACH can be met. On the one hand, this concerns the responsible evaluation of conditions for safely handling raw materials (primary products)[1] and products (including identifying relevant informational

1 Usually, *raw materials* are not individual substances (with EINECS or CAS numbers) but formulations that contain several substances.

gaps). On the other hand, this concerns the capacity for communicating and consulting with industrial and business customers and suppliers about product safety issues. There is no absolute definition of what would be “sufficient.” Rather, the study seeks to determine available capacity and identify future needs. The following indicators were developed:

- The number of product safety data sheets for whose content the responsible manager is accountable;
- The rate of access to raw materials that make a new or updated safety data sheet necessary;
- The amount of hazardous raw materials and preparations on the formulator level as a measure of the importance of exposure analyses in the framework of REACH;
- The number of customers and the number of employees[2] in direct contact with the customer to measure the value of customer discussions about exposure and product safety issues.

II.3 Hypotheses on the innovative effects of REACH

In the regulatory impact assessment, the innovative effect of a regulation is viewed as the overall result of different restrictions and stimuli to innovation generated by the regulation. The overall result depends on a complex interaction between these factors and the content and formulation of this regulation. This is why studies in the regulatory impact assessment do not rate the effects on innovation as generally positive or negative but rather reach case-specific conclusions[3]. The aim of this study is to specify the restrictions and stimuli to innovation engendered by REACH. Innovative capacity is also addressed as a measure of adaptability to REACH.

To evaluate the innovative effects of REACH, we must first define the term "innovation." This study draws on Schumpeter, who used a results-oriented perspective to define innovation as everything that yields profit for a company from advancement. This “innovation margin“ tends to dissipate over the course of time from competitive processes (Grupp 1997). In the context of the regulatory impact assessment, the question arises: Which of the triggered processes of change and adaptation simultaneously represent innovation processes? There is no clear demarcation between the two types. In

2 These data were only gathered in the paint and coatings supply chain.

3 The assessment of companies can however be less differentiated. In a survey of chemical industry companies by Rehfeld et al. (2004), regulation assumes moderate importance among the inhibitions to innovation in the survey.

a broader sense, different rates of adapting to altered regulatory conditions can also yield potentially profitable advantages over the competition for individual companies.

In the discussion of REACH, a series of widely varying dimensions of innovative and adaptive processes play a role that can be found on different levels of the supply chain. The following two sections concentrate on hypotheses that refer to innovative capacity and strategy and the development of new substances to the extent that we have relevant, quantitative indicators to examine them. Section II.4.3 presents the prime adaptive processes on subsequent levels in the supply chain of formulators and users.[4]

II.3.1 Hypotheses and quantitative indicators of innovative capacity and strategy

One initial potential effect of REACH on innovative capacity relates to the greater dissemination and circulation of practical knowledge under REACH. This may for example be the reason why customer services in the chemical industry are being expanded. According to Hippel (1988), a close relationship between the manufacturer and user is an important source of innovation. If communication and practical knowledge arise from REACH, one may posit that REACH strengthens innovative capacity and represents a stimulus to innovation. In the interviews, we investigated on a qualitative level the degree to which fulfilling registration requirements leads to additional practical knowledge, and which level in the supply chain is affected. In addition, we asked about different drivers of innovation and REACH's effect on them. This allows one to determine any changes in innovative stimuli and direction under REACH. The assessment of such a policy-controlled directional shift is discussed in Chapters V and VI of the supply chain analysis.

One long-established indicator in innovation research for measuring the innovative capacity of a company or sector is **R&D expenditure in comparison to sales.** This is based on the assumption that as R&D input rises, the output of innovation also rises. A high R&D budget as a portion of business activity indicates a high innovative capacity. The end to which this innovative capacity is used, i. e., the direction of innovation, remains initially unclear. Frequently innovation is investigated in the context of proactive market positioning. Within the framework of regulatory impact assessment, this study

4 For reasons of capacity, potential innovative effects on test methods and synthesis processes will be excluded from the study. REACH may influence synthesis processes when for example certain impurities lead to additional registration effort that can be avoided by using a different process.

uses the indicator as a measure of a company's capacity to adapt to changing market and regulatory conditions, i. e., in a reactive context.

The advantage of this indicator is that it is relatively easy to measure; for this reason, it will also be used here. It must be added, however, that the efficiency of the utilized means and the degree to which innovation is attained are not considered on the output side of innovation; neither are other kinds of innovation input such as the inclusion of external R&D knowledge arising from participating in innovation networks[5]. The data basis for this indicator is the information from the companies questioned in the interview. The parameter of internal R&D expenditures is a bit broader than comparable statistical surveys by, for example, the Association of German Foundations since expenditures for R&D from other departments (such as the sales team, laboratories) are included.

On the level of the formulator, two additional indicators were used that serve to differentiate between various innovation and marketing strategies which must be evaluated differently in their relation to REACH. One of these is the **absolute size of the substance portfolio.** This indicator is held to meaning that the size of the raw materials portfolio is a yardstick for the role substance variety plays in innovation: as size increases, the role of substance variety also increases. Any restriction of the raw material base by REACH has a particularly negative influence on innovation, and adaptive pressure accordingly rises. This arises from the assumption that the range of raw materials has a rational basis, i. e., the position is not exaggerated from raw materials whose function is not or no longer required. Another conceivable interpretation of the indicator is that a large substance portfolio could also denote that redundancy has been provided for various functions, enabling a range of substitutions in a technical sense. In this case, a large substance portfolio would indicate a high level of adaptability to REACH. However, very little is now known about actual technical substitution options; hence this interpretation is not pursued in this study.

A second indicator of innovation and marketing strategy is the **number of formulas per million Euros in sales.** A high indicator value denotes a high degree of product differentiation. If one assumes that the size of the underlying raw materials portfolio increases with the number of formulas, this indicates that REACH would have a stronger effect since for example the probability of a dearth of raw materials would increase (see also II.5.2). A low indicator value results when formulators pursue a strategy of keeping a slim product portfolio and maximizing sales per formula to exploit the

5 For a critical assessment of the indicator, see for example Grupp (1997).

effects of scale, for example. They would be correspondingly less affected by the risk of a discontinued substance.

Finally, the length of the typical **product lifecycle** in the various market segments and the factors that terminate it play an important role in determining REACH's effects on innovative and adaptive capacity. At present, products change relatively frequently when the product lifecycles of (raw) materials or preparations are short. This can be an indication of the adaptability of the formulator or user. It is also useful to understand the factors leading a company to stop marketing a substance or preparation to help identify REACH's potential influence on this process.

II.3.2 Hypotheses on the development of new substances

There is also the question of how much REACH can accelerate the development of new substances. Comparing the existing new substance regime with the REACH draft regulation shows that REACH deals with numerous criticisms of the new substance regime and offers relief. For example, the registration requirement threshold of 10 kg/y has been raised to 1 t/y, the test requirements for tonnage up to 10 t/y have been reduced[6], and relief is provided for market-related research and development. In addition, the competitive advantage of existing substances over new substances from the prior absence of a registration requirement was eliminated by standardizing the registration regime. In the literature, these changes are viewed (see 1.3) as eliminating existing barriers to entering the market; it is hence assumed that the marketing opportunities for new substances will improve under REACH, and that their development will accelerate. This assessment based on a document review will be empirically tested in this study by surveying the expectations of substance manufacturers regarding their development of new materials under REACH.

In addition to information on the future development of new substances, past development is also relevant to the analysis of REACH's effects for two reasons: On the one hand, it would be interesting to know how much new substances can compensate for the discontinuation of existing substances due to REACH. The number of new substances developed in the past and their market relevance measured by their production volume are pertinent. It is not advisable to restrict the analysis to registrations by German manufacturers since the development of new substances in the rest of Europe can increase the availability of substances in Germany. On the other hand, it would be relevant to know the extent of companies' managerial experience with new substance noti-

6 Note: 90% of new substances notifications are for tonnages below 10 t/y.

fication that may be harnessed for REACH. A barometer of this is number of new substances notified in the past by German manufacturers in the supply chain under consideration.

In the following section, the basic data on new substance registration published by the European Chemicals Bureau are considered with reference to the cited questions. Their impact on the supply chain is analyzed in Chapters V and VI. However, only the German data basis will be evaluated since no corresponding evaluations of data on new European substances were available.

For the EU as a whole, the number of new substance registrations is approximately 250 – 350 per year according to the European Chemicals Bureau[7] which are distributed irregularly among the different tonnages (see Figure II-1). Approximately 30 % of registrations are for new substances below one ton per year. The majority of registrations lie within the range of 1 t/y and 10 t/y. Only 11 % (< 40 substances) of new substance registrations are for a market volume above 10 t/y. The available statistics do not reveal what percentage of new substance registrations

- fail because demand does not increase, or demand does not cover the costs for a registration above 10 t/y, and what percentage
- was developed for a continuous market volume < 10 t/y.

The VCI questions the relevance to REACH of new substances with a volume less than 10 t/y for two reasons. According to its assessment, most old materials in the tonnage range of 10 t/y – 100 t/y will be discontinued under REACH. New substances would then have to take their place in the same tonnage range, but the present number of new substances in this range is very low. In addition, the developmental effort and the risk of new substance development is so high that related projects only paid off for normal industrial chemicals (not fine chemicals) starting at a market volume much higher than 10 t/y.

The estimations presented in prior studies on the discontinuation of existing substances under REACH for economic reasons are very uncertain. The estimation by the RPA is 20 % in reference to approximately 30,000 existing substances (without intermediates) that are subject to REACH (RPA 2003b)[8]. Calculated in reference to a

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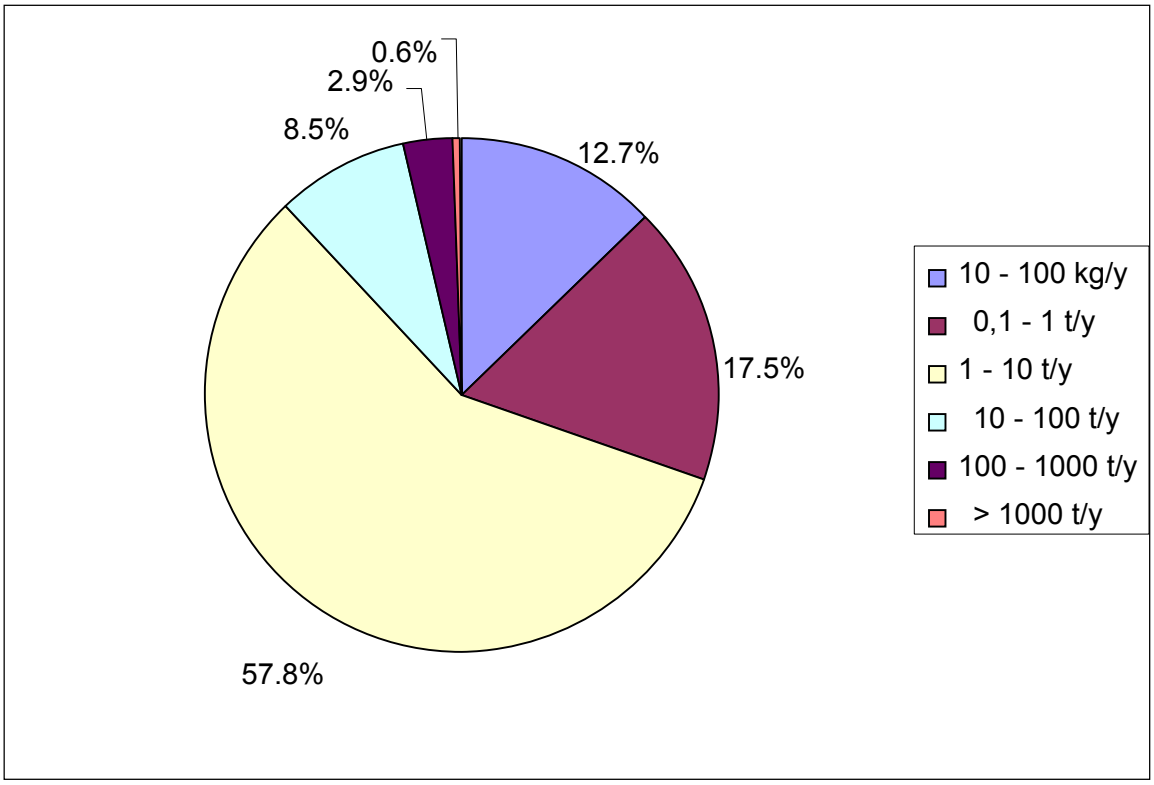
7 see http://ecb.jrc.it/new-chemicals/, 8/5/04

8 The estimation does not yet refer to the draft regulation but rather preliminary drafts of the consultation paper of the Commission of May 2003. The estimations may therefore be skewed upward. For reasons cited in section I.3, the tonnage-range specific percentages from (RPA 2003a) cannot be used to estimate the absolute number of discontinued substances.

REACH phase-in period of 11 years, approximately 550 substances may be removed from the market on average per year. However, clusters may arise around the registration deadlines. A dearth would arise in comparison to annual new substance registrations, but the number of substances would still be about the same. This comparison does not provide any information on the relationship between discontinued substances and new substances with comparable functions.

Figure II-1: Tonnage ranges of new substance notifications



(source: ECB, http://ecb.jrc.it/new-chemicals/, 8/5/04)

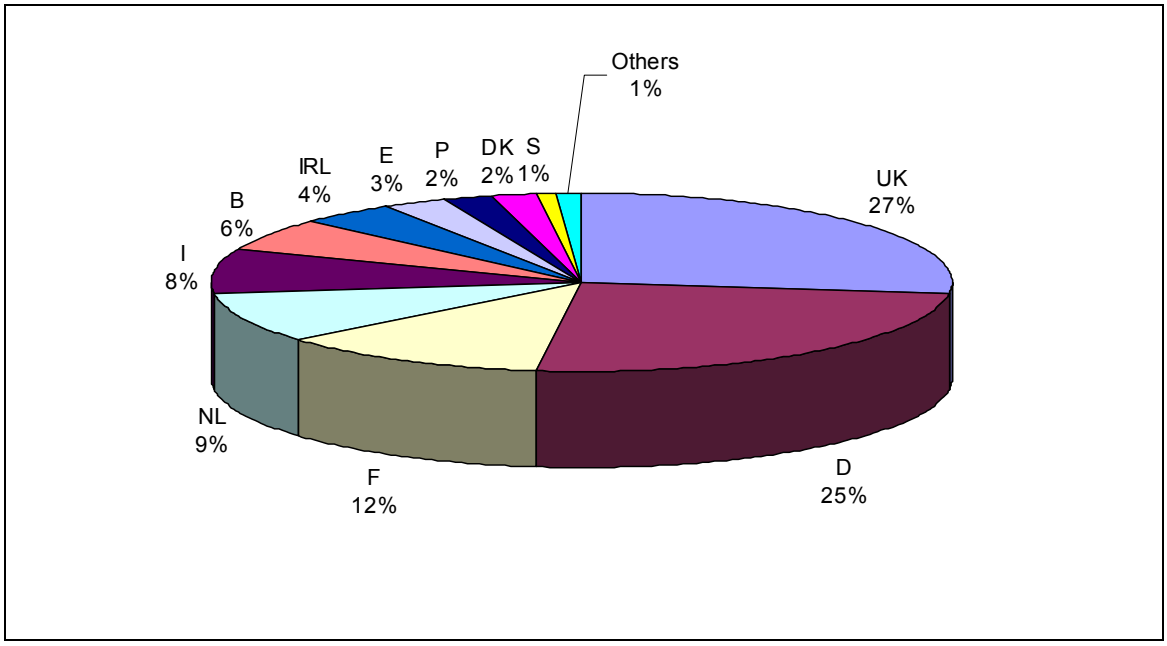
If, for the above reasons cited by the VCI, we concentrate on the tonnage range of 10 - 100 t/y, a comparison looks less favorable. The VCI estimates that the percentage of discontinued substances in this range is 20 % - 40 % (VCI 2004, see also Ch. I.3). The RPA estimates the number of existing substances needing to be registered in this range at 5,300 (RPA, Statistics Sweden 2002). This yields approximately 100 - 200 substances that could be removed from the market per year in this tonnage range. This is contrasted with only 20-30 new substances in the corresponding tonnage range. The issue of technical fitness is not considered. From the researchers' perspective, the comparison of tonnage ranges does not go far enough. If a new substance is technically considered a substitute for an unregistered existing substance, this can have a major influence on the development of its volume. Accordingly, new substances in low

tonnage ranges can be considered replacements at the next-highest volume threshold after they meet the registration requirements (that are easier under REACH).

Germany has a relatively high percentage of new substance notifications in comparison to the other 15 EU member states. Notifications in Germany between 1994 and 2002 comprise 25 % of all notifications in the EU, (see Figure II-2) which approximately corresponds to the percentage of production of the German chemical industry. This figure can, however, also include notifications by foreign manufacturers (such as from the USA). It is hence informative to categorize registrations by German manufacturers according to registrations by country of origin (see Figure II-3). Of these, 19 % of notifications are from Germany. We see that in comparison with other countries, a large percentage of notifications in Germany, i. e., 76 %, are actually from German manufacturers. This number is used as a corrective factor in Chapter V to derive notifications by *German manufacturers* in the supply chain from notifications in Germany.

To summarize, we find that the significance of new substances in Germany cannot be ignored[9]. How this plays out in the investigated supply chains is discussed in Chapters V and VI.

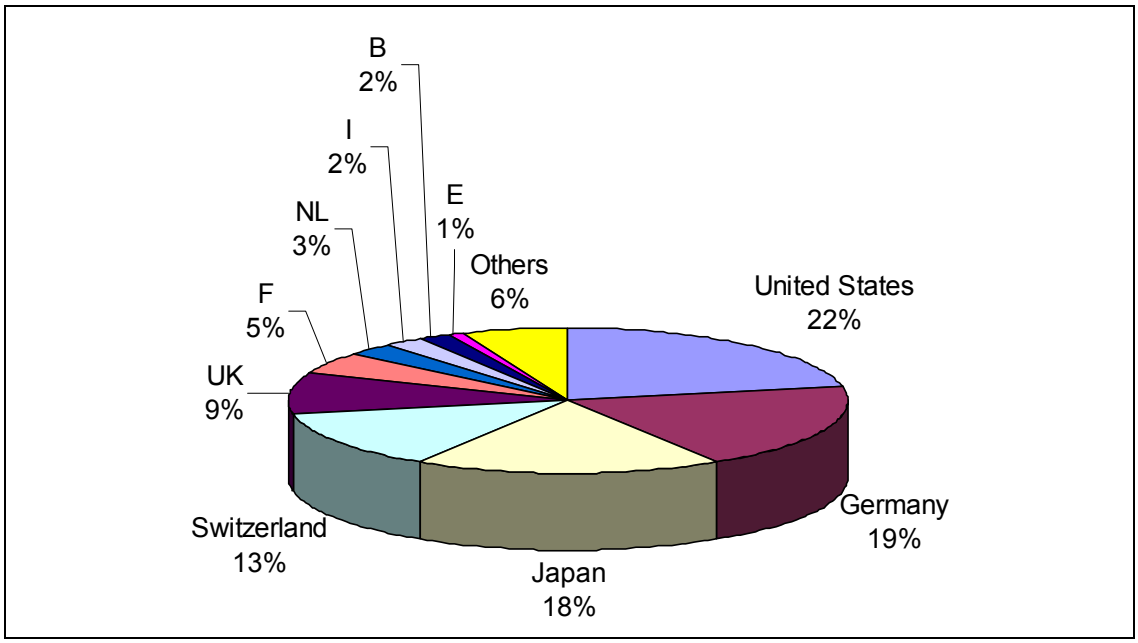
Figure II-2: Cumulative new substance notifications in 1994 – 2002



(Source: ECB, http://ecb.jrc.it/new-chemicals/, 8/5/04)

9 See also Nordbeck and Faust (2002)

Figure II-3: Origin of notified new substances in 1994 – 2002



(Source: ECB, http://ecb.jrc.it/new-chemicals/, 8/5/04)

II.4 Hypotheses relating to substance portfolio streamlining and the decision to register

II.4.1 Manufacturer registrations

On the level of individual companies, registering a substance is viewed as an investment decision: The (one-time) expense of registering corresponds to an investment that allows a substance to continue being marketed after the registration deadline. The attributable “net profits” of this “investment project” are the overall net profits from the sale of the substance after the registration deadline, and not just the realized price increases, since the alternative is to not register and discontinue sales.

In regard to the anticipated registration costs, the calculation is based on the hypothesis that the production volume and aspects of consortium formation are included in the manufacturer’s projection. In regard to anticipated net profits, the survey includes passing on registration costs to downstream actors, the influence of expectations on the registration behavior of potential competitors, and the anticipated residual substance marketing period (product lifecycle). According to the deadlines in the draft regulation, the final decision for or against registration must only be made 11 years after REACH takes effect for the majority of substances. This creates a problem, however. present conclusions about registration decisions as investments are based on

anticipated profits that, from a business perspective, are in the distant future and correspondingly uncertain.

The presently estimated percentages of withdrawn raw materials under REACH are not easily transferable to estimations relating to businesses or supply chains for the reasons cited in section I.3. Instead, taking into account the above considerations of investment theory, substance manufacturers were asked how much they felt that had to streamline their substance portfolio under REACH[10]. The survey focused on investigating the criteria that substance manufacturers used to form their expectations and set registration priorities, and it also focused on investigating their general decision-making approach (dealing with uncertainty, treating the issue as an investment decision).

Another goal of the survey was to place the decision to register under REACH in the context of decisions to stop marketing substances apart from REACH. The study is based on the assumption that portfolio streamlining is an ongoing process under present conditions for economic reasons, and that this is a normal market phenomenon. To evaluate the additional impact of REACH, this study contrasts the criteria responsible for normal fluctuations (development of a reference) with the REACH scenario. One aspect is the anticipated residual product lifecycle. If this is short, it has less of an effect on anticipated net profits and lowers the attractiveness of registration. This gives rise to the hypothesis that substances near the end of their lifecycle will tend to be registered less. The discontinuation of substances as a result of REACH can accordingly be interpreted as a shortening of the product lifecycle. This also means that the added effect of REACH is less than the overall discontinuation of substances occurring after REACH takes effect.

Excursus: Registration decisions in the context of joint production

In investigating decisions about registration, this study assumes that a substance manufacturer's decisions to register different substances are not interrelated, i. e., the decision whether or not to register is independent of whether a second substance should be registered or not. However, this assumption does not apply when two or more substances are jointly produced. If several substances are made in a single process for production reasons, all joint products must also be produced and hence registered if the marketing of one substance is to continue. Conversely, the production of all substances made in the joint process must be discontinued if one substance is not registered. From a theoretical vantage point, the entire investment program must be considered in such a case of interdependent investment decisions,

10 A similar procedure was pursued by RPA (2003a).

i. e., the cumulative registration costs of all substances from joint production are compared with their cumulative net profits. The problem of joint production was not treated in the empirical investigation of substance manufacturer supply chains. For this reason, this study does not discuss how to deal with the evaluation of such registration decisions in practice.

Chapters V and VI, which analyze supply chains, document substance manufacturers' considerations of their registration strategy and any underlying, non-confidential portfolio analyses. In addition, registration costs are compared with anticipated net profits in calculations of payback periods based on general assumptions (concerning e. g. anticipated registration costs, margins, etc.). The relevant assumptions are explained in the empirical chapters. Payback periods that extend substantially beyond the normal periods set by companies indicate that purely economical reasons can hinder registration without risk-associated reasons necessarily playing a role. From the standpoint of economics, long payback periods are sometimes tolerable when they are oriented around the average life of a substance (SRU - Rat von Sachverständigen für Umweltfragen 2004). If the payback periods extend beyond this threshold, registration would only be economically justified if additional outside benefits were anticipated from recycling the substance that are not reflected in the company's anticipated profits.

Beyond the individual company's registration decision, the results of the registration decisions of all manufacturers of a substance influence the supply of this substance in the market. The requirement to register a substance can arrive at different times among competitors due to different production volumes, and this creates competitive problems between late-registering companies and early-registering companies (see Chapters III, VII and VIII). Possible supply-side effects are:

- Price increases11,
- The withdrawal of individual manufacturers from the market resulting in a concentration of remaining manufacturers (with the possibility that they will be able to expand production and increase prices),
- All manufacturers refuse to register the substance, and the substance is no longer available on the market,
- The worst-case scenario: the cessation of a functionality only offered by one substance on the market (see Fig. II-7).

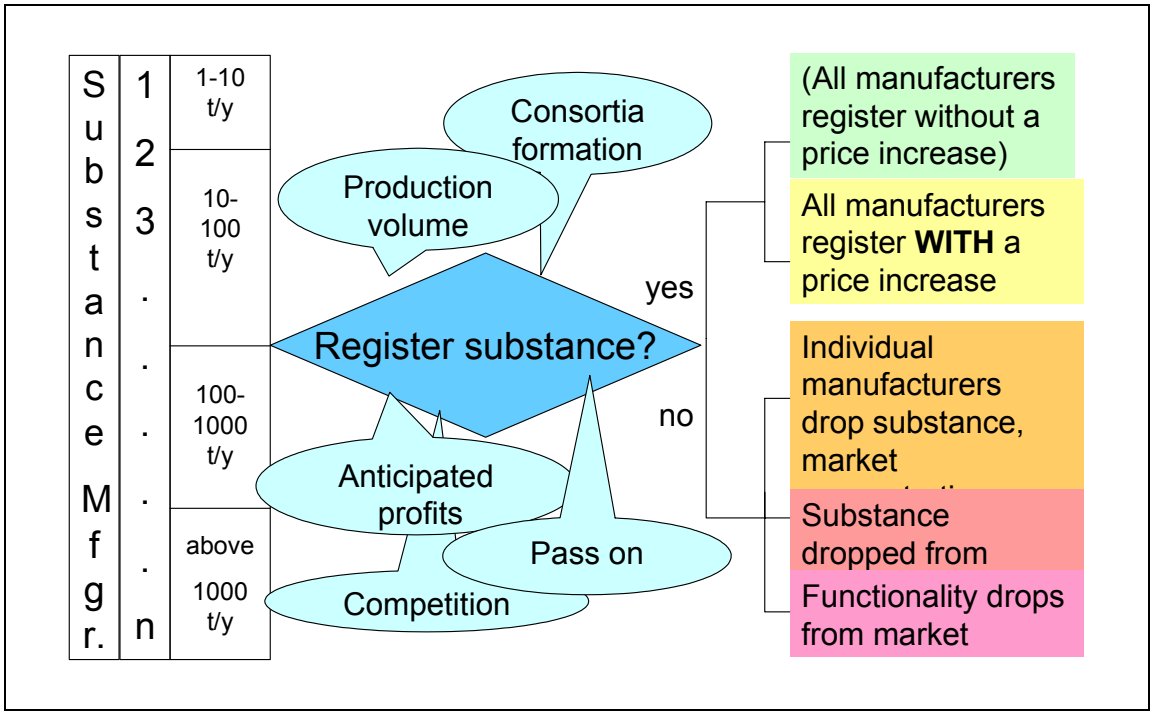
11 It is theoretically conceivable that every manufacturer will register the substance and not pass on the registration cost to their customers, but it is improbable in the opinion of the researchers and therefore not considered further.

The ability to understand a substance's effect on supply using the corporate case study methodology of this study is limited. Monopolies of a substance or functionality by a manufacturer[12] and their results on registration decisions were discussed in the interviews to gain insight into which of the above cases would arise if registration were refused.

II.4.2 Registration by importers

Substances by themselves or in preparations that come from outside Europe must be registered under the REACH system just like substances that are made in Europe. Importers, i. e., the company that directly imports the substance, are subject to the registration requirement if the non-EU manufacturer has no representatives in the EU who will register the substance. In this case the expense for registration is borne by the import trade or the importing substance manufacturer, formulator or user. One particular problem arises for the importation of preparations in general and the importing trade in particular as the party responsible for registering.

Figure II-4: Factors influencing registration decisions, and possible effects on the supply of substances



12 The competitive forces in a market economy generally ensure that manufacturers cover most special substance functions with multiple products.

When a non-European preparation manufacturer does not register its product itself (or through a representative in the EU), the non-EU manufacturer must disclose the formulation (and hence the related know-how) to import-ready buyers who want to register the product. Two alternatives are conceivable:

- The non-EU preparation manufacturer presents the formulation to the user. This is conceivable when the user (such as high-demand branches like the automobile industry) has corresponding negotiating power with the non-EU manufacturer.
- The preparation manufacturer does not disclose the formulation to any parties interested in registering. The corresponding preparation will then be unavailable in the European market after expiration of the registration deadline.

In the investigation, the importance of direct imports was determined on every level of the supply chain, i. e., imports by companies that are not involved in importation and use the product for their own production.

The chemical importing trade is subject to different market conditions than the manufacturers of substances and preparations. In comparison to chemical manufacturers, the volume at which they market a substance fluctuates much more, and their production portfolio is usually more extensive. Under REACH, this places special demands on this group of actors whose registration decision requires a separate evaluation. The following situations can result:

- The registration of a substance or preparation is not economically worthwhile for the import trade because registration costs are too high in comparison to expected sales. This holds true especially for substances and preparations that are imported once or irregularly depending on the market situation. For preparations, the importer must create a registration dossier according to the existing draft regulation for each substance in the imported preparations that exceed 1 t/y. The administrative expense to procure the necessary data (or rights to use the data) for all the components of the imported preparations would be high.
- The import trade cannot register substances in a formulation because non-EU manufacturers does not disclose the product formulation (and hence the related know-how) to the importer, and does not assign registration to his own representative.

If the non-EU manufacturer and import trade do not register the chemical and there is no European manufacturer, it is withdrawn from the European market. If there are competitive products of European origin, the import trade no longer acts as a “price throttle."

The outlined mechanisms were discussed several times in the advisory committee. The chemistry trade association also presented concrete examples. These are presented

in the box below. In two cases, it was illustrated that payback periods for registration costs of 5-6 years could arise and cause the product to be abandoned. In the third example, the price-controlled role of small import quantities is illustrated. In the supply chain analyses, only selective aspects of the problem could be illuminated since only one importer was surveyed due to limited resources, and the other surveyed actors generally did not know if the substances and preparations they purchased came from outside Europe.

Excursus: Registration decisions in the import trade

An importer with around 30 million EUR in sales per year increased his imports from non-EU countries to 30 % of his sales over the last five years. Of the 45 imported substances and preparations, 31 are between 1 t/y and 10 t/y. The remaining substances are imported at amounts between 10 and 1000 t/y. For a substance with a market volume of 100 t/y (1 manufacturer and 13 importers), the market share of the relevant importer is t/y (market price: 9 EUR/kg). Given assumed registration costs of 70,000 EUR and a profit margin of 13.5 %, the payback period is approximately six years. The importer would remove the substance from his portfolio. The situation is similar in a second example with a 600 t/y market share, assumed registration costs of 500,000 EUR and a margin of 10.8 %.

In a third example, the importer illustrates the price-controlling role of the import trade. In 1990, 3000 t/y of a certain esterification catalyst was marketed by a manufacturer in Europe. Market price: 3 EUR/kg. In 2003, 10 % of the market was covered by 1-2 importers. The market price is now 1.50 EUR/kg.

Source: Documentation from Goldmann, Bielefeld; made available through VCH in August 2003;

II.4.3 Registering based on the biocide ordinance model

In the advisory committee, the industrial representatives repeatedly noted that their experience with the notification system associated with the biocide ordinance clearly indicates the potential negative market consequences of REACH. In the following, the underlying conditions and market mechanisms of biocide notification and active substance authorization will be compared with the requirements of the REACH system. In both systems, existing substances are subject to a binding, multi-step reporting mechanism that ends with a risk evaluation and the generation of an obligatory set of test data. In addition, a failure to report or present data automatically leads to a marketing ban after a certain period.

The basic conclusion after a cursory comparison is that the mechanisms are indeed similar, but the market volumes, market prices and test requirements are quite different:

- Whereas the test data requirements in the REACH system are differentiated according to market volume, they are not in the biocide ordinance notification system. That is, even small volumes of biocides are subject to the full test program.
- The going market price of biocides in the 10-100 t/y range (e. g. BIT 10 – 30 EUR/kg) or the 100-1000 t/y range (Guanidine 3-8 EUR/kg)[13] is on the same scale as specialty industrial chemicals. In comparison, the test program up to the acceptance of an active substance is €1.5 to 4 million (ENDS Report 332, 2002) biocides, i. e., many times as expensive as the corresponding registration data required under REACH.

Given these facts, we can see that the market-adjusting and concentrating effect of the biocide ordinance is not as extensive as that of REACH. However, the mechanisms are comparable.

Side note: Biocide guideline

The market-adjusting effect of the biocide guideline can be illustrated by the following figures: Of an original 5000 notifications of 943 active substances in 2002, 565 notifications (from 216 companies) remain for only 345 substances. Of these 216 companies, approximately one-half reported only one substance. On the other hand, there is a concentration of notifications among 8 companies with more than 10 active substances each (ECB 2004).

When notification of an active substance is provided, a basic database is also provided with which the manufacturer notifies the EU Commission of its intention to continue marketing its product. As of 2003, all other substances may no longer be used as biocides.

Examples of the present level of biocide prices can be found in the following table (research by Ökopol). In particular, we can see that biocides were frequently secondary uses of widely-available industrial chemicals.

13 Own research by Ökopol

Side note: Biocide guideline

Substance	Production volume t/y	Market price €/kg
Benzalkonium chloride	10,000	0.90 – 1.50
Guanidine	600 – 700	3.00 – 8.00
Alcohols	10,000 – 20,000	0.20 - 1.00
BIT(1,2- Benzisothiazolinone))	10 – 100	10 – 30

As is the case with REACH, the authorization costs depend on the amount and quality of the available data. The present estimated costs for an average authorization dossier for an existing biocide range from €1.4 million to €4 million (Ends Report 332 2002). The cost for a notification dossier with a corresponding basic database is €200,000 to €300,000.

Sources: Hazardous Substances No 21, ENDS Report 332, September 2002 http://ecb.jrc.it/biocides

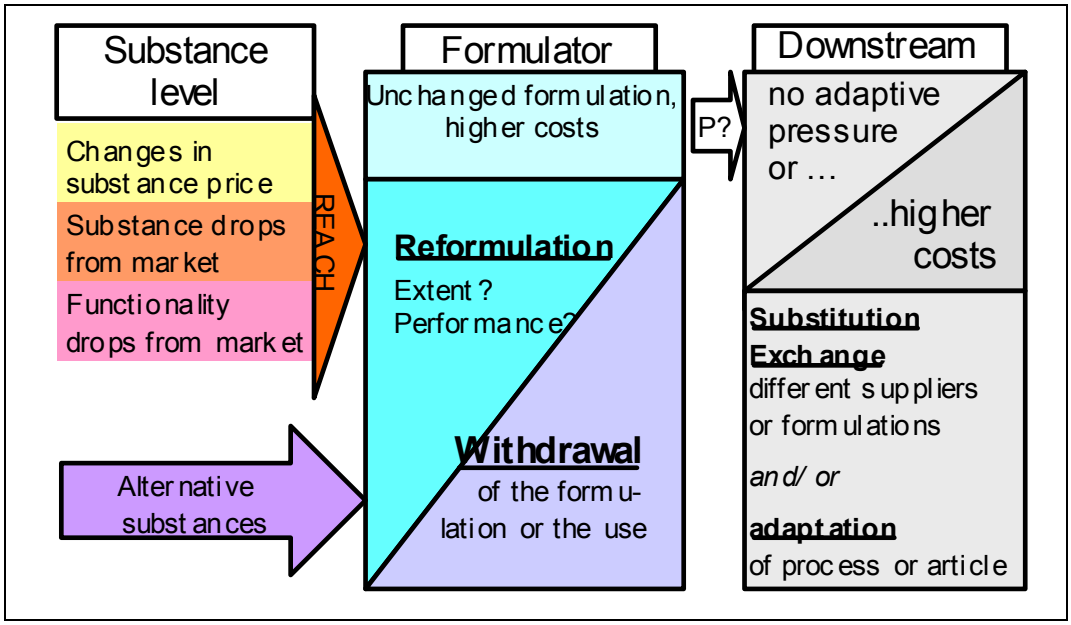
II.5 Hypotheses on mechanisms to adapt to REACH

REACH-induced changes in the price structure and availability of substances and functionalities can make adaptations necessary on downstream levels in the supply chain (see Fig. II-9). In terms of price formation, the question on each supply chain level is whether additional REACH-induced costs can be passed on to the customer. Hypotheses relating to this matter are dealt with in II.5.1. On the technical side, formulators are faced with the necessity of adapting their recipes to REACH-related changes in the raw material price structure and substance availability. Of relevance are the extent of required reformulation and potential functional losses. Alternately, a preparation may have to be completely abandoned. The approach used to analyze the formulator situation is further treated in II.5.2.

Depending on the formulator's reaction, users are faced with different modes of adaptation under REACH. In the best-case scenario from the user's vantage point, all raw materials of a preparation remain available, and the costs of registering are absorbed by the upstream levels in the supply chain. The user hence experiences no change. In another scenario, it is conceivable that only the price but not the preparation formula-

tion will change. Finally, the both price and composition can change. The user is then faced with the question of whether he should look for alternative preparations or suppliers. Independent of this, there is the issue of how much the production process (technical or organizational) or product will have to be adapted because of the altered preparation. The greater the integration between the chemicals and production process, the greater the necessary adaptations by the user. In an extreme case, it is conceivable that highly-specialized plants will have to discontinue operation when the formulations they use are no longer available. The required adaptations are elucidated further in the interviews.

Figure II-5: Mechanisms for adapting to REACH on downstream supply chain levels



II.5.1 Ability to pass on costs

Registering the substances generates one-time costs for the registering party. These can remain on the relevant level of the supply chain and reduce profit, or they are passed on to the next supply chain level. This reduces the possibility that registering will be neglected for economic reasons. The following level in the supply chain would suffer from correspondingly higher (raw) material prices.

The precise procedure for estimating the extent to which the substance manufacturer (and importer) will pass on the registration costs by raising the substance prices could be inferred by estimating the price elasticity in the demand for these substances. However, there are not data on this, especially on the value-chain-related demand for the

substances. The official product group statistics or comparable sources do not provide sufficient product detail in this regard.

As a substitute, this study used a series of comparisons. A first indication of the amount of pressure to pass on registration costs to downstream market participants is found by comparing registration costs, substance costs and market volume (see above). In addition, past price formation behavior is clarified on the different supply chain levels in regard to the feasibility of price increases and the factors that made price increases easier at an earlier period. In particular, this concerns if and how cost increases were passed on in the past by substance manufacturers, especially arising from the registration costs for new substances. On the subsequent levels of the supply chain, corresponding questions were asked concerning the transferability of increased (raw) materials costs (for formulators) and chemical costs (for users). The experience of formulators in replacing hazardous substances was also used as an analogy to reveal how much the resulting added costs could be passed on in the form of higher product prices, or if industrial and private customers demanded the additional product quality but would not pay a higher price for it. In addition, the different actors in the supply chain were asked if they were ready to pay for REACH-registered substances or preparations based on them. If so, it may indicate that the information on the substances is held to be robust, and risk management instructions are believed to be realistic (since they are application-specific). The described approach cannot however predict the reaction on the demand side and hence the trend of sales if prices are increased.

II.5.2 Hypotheses on the consequences of streamlining formulator substance portfolios

In the context of substance portfolio streamlining, hypotheses were also developed about the consequences of discontinuing substances on the supply chain level of the formulator. The interviews particularly illustrate the extent of and conditions for adapting and reformulating recipes. An initial indicator of the extent to which reformulations may be necessary is the **absolute size of the substance portfolio.** The more substances a formulator uses, the more substances (viewed in an absolute sense) can be affected by their discontinuation, making corresponding reformulations necessary. This indicator allows a comparison of the impact on supply chains without, however, quantifying the reformulation expense. The second indicator provides the following assistance: The interviewees were asked about **substitution costs for substances based on past examples.** Their relevance of these instances to the situation under REACH was also discussed.

An important comparative standard of the formulator's ability to adapt to the discontinuation of raw materials due to REACH is provided by the third indicator that measures prior fluctuation in the raw materials portfolio. A distinction was therefore made in the survey between "**forced exchange"** and **"self-determined discontinuation"** measured by the number of substances discontinued by the supplier and formulator to the overall formulator raw materials portfolio. Included under "forced exchange" are situations in which for example a supplier no longer offers a substance for economic reasons, or a substance is no longer marketable after additional hazardous properties are made known. In both cases, the formulator has no influence on which substances are affected. The situation is different with "self-determined discontinuation." This includes situations in which the supplier replaces a component of his preparation with an alternative substance in his continuous search for more economical or potent raw materials. High exchange rates in the development of a reference are interpreted in the study as a high ability to adapt to REACH. In particular, high rates or capacities for self-determined discontinuation are held to indicate that they can be used within a certain framework for adapting to an increased rate of forced exchange under REACH. However, these capacities would then no longer be available for reacting to customer desires, or for proactive market positioning by the supplier.

II.6 Hypotheses on the effects of REACH on international competitiveness

In analyzing the effects of REACH on corporate international competitiveness, a distinction must be drawn between the individual supply chains. First let us consider the competitive position of European manufacturers of substances and preparations. Since substances and preparations that are imported into the EU are also subject to REACH, substance manufacturers and formulators are on the same level as imported substances and preparations within the EU market. The requirements of the REACH system may ward off certain non-European suppliers from exporting further to the EU. The availability of (raw) materials is affected when they can only be supplied by importers outside of Europe (such as some raw materials for manufacturing surfactants). Against this background, the actors in the supply chain were asked if they use non-European imports, and what their expectations were regarding their availability under the REACH system. The expectations were discussed against the backdrop of the EU's importance in the world market for chemicals.

Another situation results when substance manufacturers or formulators in the EU market their products outside of Europe. They compete in these markets with substance and preparation suppliers who do not have to observe the stipulations of the REACH

system. These competitors do not incur any direct registration costs, and the formulators may have a broader substance portfolio at their disposal. In this instance, REACH can lead to a competitive disadvantage for European companies in the world market. The companies were therefore asked about the importance of non-European export markets to their business, and to estimate how this would be affected by REACH. It was also discussed whether better-documented product safety from the REACH system can be used as a competitive advantage in these markets.

If non-European markets are very important to the sales of substance manufacturers and formulators, moving production to locations outside of Europe may represent a relevant adaptation strategy for companies subject to REACH. As a reference, the companies were also asked about their past decisions regarding location (criteria, motive, and experiences). In addition, branch trends affecting the chemical industry in the relevant supply chain were factored in to create a wider context for the statements made in the interviews.

On the user level, i. e., manufacturers of “articles” as defined by REACH, a distinction is drawn between auxiliary agents in the process that do not remain in the product, and chemicals that remain in the product. In the first case, non-European industrial manufacturers of articles are free to use substances and preparations that are not registered under REACH even when the articles are for export to Europe. This can increase import pressure. If companies feel that the availability and cost are significantly better outside of the EU, REACH may stimulate manufacturers of articles to consider moving production and serving the European market from non-European production sites. Given this consideration, article manufacturers were asked about the existing import pressure from outside the EU facing their own products, their sources for components, factors influencing relocating, and changes in these matters anticipated under REACH. This served as a springboard to a discussion of REACH’s influence on relocation factors. Cost-related motives for relocation could be stimulated by REACH. This can increase import pressure.

For chemical substances that remain in the product and are properly released stipulations and therefore must be registered, or substances that are improperly released and require notification, Article 6 of the draft ordinance theoretically provides that articles which are produced inside and outside of the EU must be equivalent starting 2017. Therefore it would not be worthwhile over the long term to relocate production to serve the EU market. There are many questions regarding practical feasibility of Article 6 that could not be addressed in greater detail in this study. In the interviews, the companies were asked about their expectations regarding these competitive influences, and the plausibility of these expectations was critically evaluated by the researchers.

From a methodological viewpoint, the researchers note that the focus of the analysis on international competitiveness lies on the corporate level as is the case with other topics. The goal is to identify effects of the REACH system and possible adaptive mechanisms. An aggregate or quantitative analysis of foreign trade does not lie within the scope of the study. On the level of the article manufacturer, conclusions are made more difficult by the fact that each surveyed manufacturer belongs to a different branch, and branch-specific background analyses to determine reference scenarios did not fall within the scope of the project. In addition, the focus lay on the supply chain of selected chemicals; hence an overall picture of the impact on users under REACH cannot be achieved. For this reason, only very limited conclusions can be made regarding the extent to which REACH can influence user tendencies to relocate.

III Estimation of direct registration costs

The direct costs to companies of registering are among the major factors in the economic consequences of REACH. In this study, the registration costs are considered investment costs that entitle the substance manufacturer or importer to initially manufacture and market (new substances) or continue manufacturing and marketing (existing substances). If the costs of registration exceed the foreseeable economic benefit to the manufacturer or importer, the substance will not be registered. A factor in this equation is the manufacturer's estimation of the transferability of one-time registration costs to his customers.

The following chapter refers to the direct costs of registering on the corporate level. One goal is to outline the direct registration costs to allow a comparison with the present substance market price (an indicator of the economic sensitivity of substances). In addition, the cost-determining influences will be identified that directly result from the draft ordinance and its implementation. This will allow strategies to be derived that can be used for optimizing the cost efficiency of the REACH system. It is not the aim of the following discussion to forecast the overall cost of the REACH SYSTEM.

III.1 Underlying data

The costs for registering a substance under the REACH system depend on numerous factors:

- The absolute costs of registration per substance are determined by the required standard information on substance properties, the standard tests and availability of existing information, the desired information quality (see Annex IX), and the assignment of the individual requirements to the registration volume range (see Annex V to VIII of the draft ordinance).
- On the basis of the present draft ordinance, costs for evaluating exposure only accrue for hazardous substances (according to the criteria of Directive 67/548/EEC).
- The registration costs are also greatly influenced by the models and rules for forecasting potential exposure that may enable certain tests to be dropped because relevant exposure is improbable in the identified applications (see Appendices I, VI and IX of the draft ordinance).
- The level and distribution of market costs also depend on the company's cooperation in procuring the necessary information, the level of kg-specific costs of registering, and the time at which the information must be procured.
- In regard to implementing the requirements in the market, the costs also depend on whether a uniform IT-based standard has been introduced to convey information to the individual actors.

The cited factors differ from company to company and branch to branch. To estimate the effect of the registration costs, scenarios need to be defined and differentiated in regard to the volume ranges.

The studies by RPA (2003c) and JRC (2003) on the *Extended Impact Assessment* of the EU Commission (CEC 2003b) were used to this end since they represent the best-available assessment of the present status of the ordinance and inventory of existing substances in the European market:

- All the covered cost factors in the cost estimation by the Commission have been clearly documented and published.
- The estimation refers to the phase-in substances under the REACH system and is not based on extrapolating costs from the present new substance regime.
- It makes assumptions about the prices of standard tests and the necessity for the individual end-points to actually carry out these tests. Scenarios are developed concerning the availability of existing (or already approved[1]) data, and the future applicability of QSARs[2]. The draft of the REACH ordinance explicitly demands the that available data be evaluated before new tests are performed (see Annex V to VIII). This requirement refers to all tests and not just to vertebrate studies.
- The estimation assumes that there is one data set per substance because the ordinance anticipates that companies will be strongly motivated to share substance data.
- The estimations in the 1-10 t/y range do not correspond to the observations of the draft ordinance and had to be modified in this study[3].

The estimations by the VCI of the registration costs are higher than the estimations by the RPA and JRC. Whenever the authors of this study knew the references for the cost estimations, they were documented. The estimations by the Federal Institute for Occupational Safety and Occupational Medicine (BAuA 2004) confirm the estimations of the Commission of the 10-1000 t/y ranges (see Table III-5).

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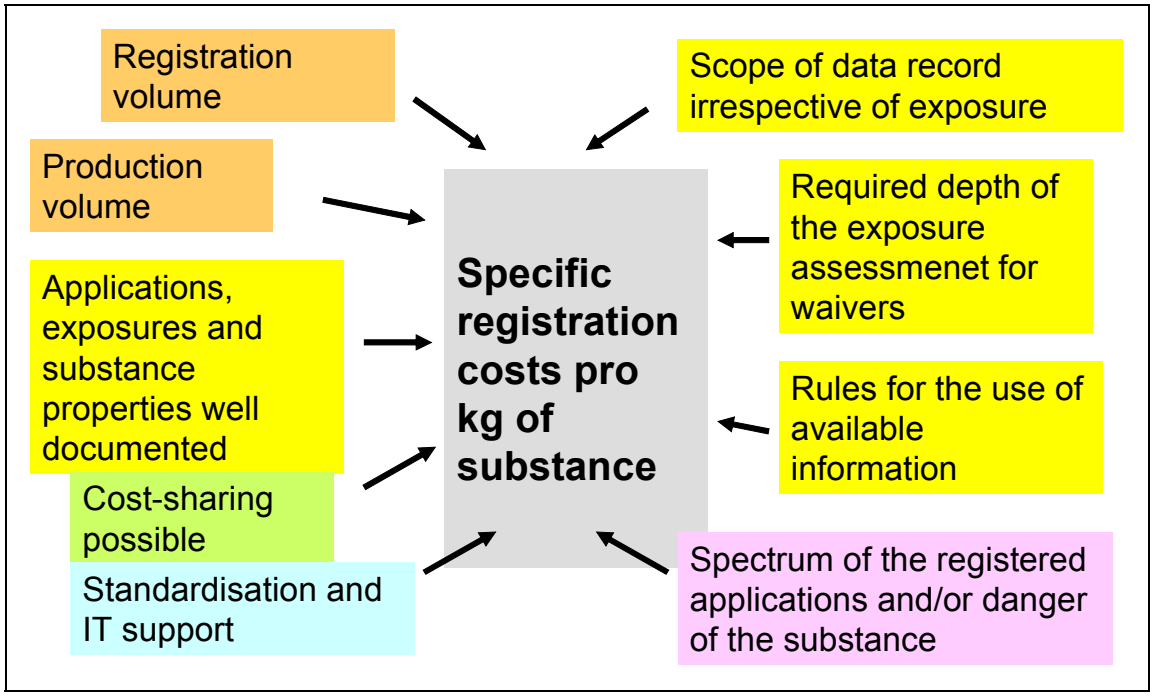
1 US HPV Challenge Program for 2150 high-volume substances, ICCA initiative for 1000 high-volume substances, and the VCI minimum data set for approximately 33 % of all substances in the EU > 1 t/y (JRC 2003)

2 Quantitative structure/activity relationship. Models for deriving information on the properties of a substance from its molecular structure.

3 Adaptation to the ordinance text with reference to the Excel spread sheets on which the Impact Assessment of the EU Commission is based (CEC 2003b).

Figure III-1: provides an overview of the factors that influence specific costs of registration.



In the cost analysis, a distinction is drawn between the test costs and costs to evaluate safety and create a dossier. In addition, the fees for registering and evaluating doses are included. Since only the exposure of hazardous materials needs to be evaluated according to the draft ordinance, an assumption had to be made about the percentage of substances from the respective volume range that will incur additional exposure evaluation costs. RPA (2003d) assumes a ratio of 40 % hazardous substances to 60 % non-hazardous substances based on experience from new substance notifications. In addition, the following cost information for each substance refers to phase-in substances that were not evaluated under international existing-substance programs in the EU and OECD.

III.2 Costs of testing substance properties

Table III-1 uses three scenarios to summarize the JRC's estimation (2003) of the average cost to test a substance in the different registration ranges. The data are taken from Table 9 of the JRC study and were modified for the 1-10 t range.

Table III-1: Test-related registration costs estimated by the JRC (2003), modified

	1-10 t/y*	**1-10 t/y**	**10-100 t/y**	**100-1,000 t/y**	**>1000 t/y**
Average scenario (Euro/Sub)	7,700	12,100	73,100	163,000	208,000
Minimum scenario (Euro/Sub)	6,700	8,600	40,500	128,000	185,000
Maximum scenario (Euro/Sub)	8,700	16,400	152,000	244,000	278,000

For the modified (*) information on the 1-10 t range in Table III-1, the JRC's calculations were adjusted by the costs for the algae test (average of 990 EUR per substance of all 19,200 substances[4] in the average scenario), for the test of easy biodegradability (average of 1,271 EUR per substance), and for the cytogenicity test (average of 2,151 EUR per substance). These tests were dropped from Annex V in the most recent draft ordinance negotiations; the studies by JRC and RPA were not correspondingly adapted, however. This means that the average costs per substance in the average scenario will fall approximately 4,400 EUR per substance to 7,700 EUR to meet the requirements in the draft ordinance. Average costs per substance are 7,740 EUR in the maximum scenario, and 1,930 EUR per substance for the minimum scenario.

The JRC's projections are based on the following important assumptions:

- Cost assumptions for implementing standard tests (see Table III-3).
- Assumptions on the availability and usefulness of existing information (see Table III-2 in regard to the requirements in Annex V and VI).
- Assumptions concerning the necessity of more extensive tests (for example concerning reproductive or developmental toxicity) when initial tests indicate (no) hazardous properties (see section III.7 in this chapter).
- Assumptions on the usefulness and acceptance of techniques to predict substance properties that are not based on new tests (drawing analogies, group evaluations, quantitative structure-activity relationships [QSAR]).

The two borderline scenarios of the JRC for the average test costs per substance differ substantially as a result of the following assumptions for the average scenario:

4 17,500 substances between 1-10 t/y, plus 1,700 substances that are transported intermediate products > 1000 t/y.

Table III-2: Scenario formation in the JRC (2003) study

	Minimum	**Maximum**
Studies on reproductive toxicity (according to 6.7.2 and 6.7.3 in REACH Appendices VI and VI)	Only additionally required for 10 % of substances without data	Only additionally required for 25 % of substances without data
Use of QSARs, group evaluation and drawing analogies	Optimum use according to i) US HPV Challenge Program and ii) estimation by the Danish Environmental Agency of the usefulness of other QSARs based on intensive research in the next few years.	Regulative acceptance of QSARs depending on the tonnage range and QSAR quality. Combination of professional evaluation by the Danish Environmental Agency and the RPA's estimation (2003d) of the acceptance of QSARs in the regulated area.

The test costs for a company that has all the required information about a substance is 0 EUR. The maximum costs for a substance about which there is no useful information is approximately 36,600 EUR according to Annex V (BAuA 2004), and an additional approx. 150,000 to 165,000 EUR according to Annex VI (see Table III-3). Initially, the information from the BAuA (2004) was used to estimate the maximum costs according to Annex VI. If no cost information could be found, information from the RPA/JRC (2003) was used. In contrast to the data in Table III-3, no assumptions were made about reproductive and developmental toxicity: a) A study on developmental toxicity is being done (Annex VI, item 6.7.2; OECD 414) that will cost approximately 80,000 according to in-house research. b) A study based on 6.7.1 (screening) is being done that will cost approximately 65,000 EUR according to in-house research.

There are two basic reasons for assuming that a data set (in German companies) already exists: (1) Such a data set is part of the VCI commitment of 1997 (VCI 1997) that states that the association will ensure the availability of a minimum data set at the site of handling for each substance of which > 1 t/y is handled. (2) The manufacturer must be aware of certain other properties of the substance for safety and quality reasons (technical behavior of the substance, flammability, explosivity, hazard to waterways arising from transportation and storage)

Table III-3: Test costs (EUR) for the obligatory end-points in Annex V and VI

	App.	RPA/JRC 2003	BAuA 2004	VCI 2003	Data exist
Chemical-physical properties					
Melting point, boiling point, density	V	no info	1918	2500	2
Vapor pressure	V	no info	2788	3000	2
Surface tension	V	no info	832	1000	
Water solubility	V	no info	4406	3500	
Octanol/water distribution	V	no info	3167	2500	1
Flashpoint, flammability, explosivity, oxidation effect, self-ignitability	V	no info	9700	5700	2
Particle size distribution	V	no info	no info	1300	
Humanotoxic properties					
Skin irritation in vitro Skin irritation in vivo	V VI	885 885	1185	800 900	1
Eye irritation in vitro Eye irritation in vivo	V VI	950 950	1105	800 900	1
Skin sensitization	V	3900	3210	4000	
Ames test for mutagenicity	V	2300	2928	3000	1
Cytogenicity to mammalian cells	VI	18000	15017	20000	
Genetic mutation of mammalian cells	VI	12000		15000	
Acute oral toxicity	V	1800	1423	1500	1
Subacute toxicity (28 day test)	V	41500	no info	50000	
Screening test for developmental and/or reproductive toxicity	VI	19612	no info	50000	
Test of developmental toxicity	VI	165000	no info	70000	
Environment-related properties					
Daphnia toxicity	V	3800	5374	4000	1*
Inhibition of algae growth	VI	5000	5649	5000	
Fish toxicity	VI	5000	5374	5000	1*
Activated sludge test	VI	1900	no info	2000	
Easily biodegradable	VI	12300	4837	3500	1
Hydrolysis	VI	6091	no info	6000	
Adsorption/desorption	VI	2600	no info	2500	

* alternative

III.3 Costs for registration and evaluating safety

In Working Paper 4 for the Commission, the RPA estimated the costs for evaluation steps up to registration and the administrative costs associated with registration (RPA 2003d, Table 5.6).

Table III-4: Categorization of non-test-related costs in euros per substance based on RPA 2003d

Work package	**1-10 t/y**	**10-100 t/y**	**100-1,000 t/y**	**>1000 t/y**
Administrative work to create a dossier	*5,000*	*5,000*	*10,000*	*10,000*
Evaluation of substance hazard	*not* relevant	*1,500*	*8,700*	*8,700*
Summary of relevant studies			*500**	*1,000**
Contact with users and evaluation of exposure		*6,200**	*19,200**	*34,500**
Characterization of risk		*800**	*3,500**	*3,500**
Safety report and safety datasheet		*1,000*	*2,000*	*2,000*
Overall costs per dossier for a non-hazardous substance and hazardous substance	5000 5000	7,470 *14,420**	20,650 *44,350**	20,650 *60,150**
Overall costs given a 40:60 ratio of hazardous to non-hazardous substances	5000	10,250	30,130	36,450
Fees**	400	400	8,000	8,000

* only for hazardous substances; as assumed by RPA 2003d, approx. 40 % of phase-In substances (extrapolation from new substance statistics); **oral information from DG Enterprise, 2004

According to the RPA, we can see that the categorization of a substance affects the costs of evaluating exposure and risk. If, as suggested by many parties, certain categorization-relevant tests were discarded in the 10-100 t/y range based on an evaluation of exposure, additional costs for exposure evaluation would correspondingly accrue. That means the savings from a case-specific abandonment of certain standard information requirements in Annex VI would be (at least partially) lost by the greater expense of evaluating exposure. This relationship has bearing on the discussion relating to the optimization of the cost-benefit ration of REACH.

III.4 Overall costs per substance

Table III-5 lists the above-discussed test-related and non-test-related costs.

Table III-5: Registration costs according to the RPA and JRC 2003 (modified[5])

	1-10 t/y	10-100 t/y	100-1,000 t/y	>1000 t/y
Medium scenario (Euro/Sub)	13,100	83,750	201,130	252,450
Minimum scenario (Euro/Sub)	12,100	51,150	166,130	229,450
Maximum scenario (Euro/Sub)	14,100	162,650	282,130	322,450

If these estimations are compared with the figures from the VCI (2003 und 2004) and BAuA (2004b), we obtain the following picture:

According to the **estimations of the VCI,** average costs of 20,000 EUR/substance[6] arise in the 101-t/y range; in the 10-100 t/y range, average costs are 240,000 EUR/substance; the 100-1000 t/y range, average costs are 400,000 EUR/substance; and in the range > 1000 t/y, costs are between 400,000 EUR and 1 Million Euro per substance (VCI 2003a, 2004a). This deviating estimation includes the following assumptions and types of costs:

- For the 1-10 t/y range, it is assumed that not all data are available on the chemical and physical properties of the substances for registration under REACH[7], and the test-related costs of registering are approximately 10,000 EUR/substance (administration, determining substance identity, description of production, use and quantity).
- The costs of screening for reproductive or developmental toxicity are set higher by the VCI at approx. 30,000 EUR/substance than the JRC study (see Table III-3).
- A more pessimistic view of the acceptance of QSAR data is generally taken.
- Non-test-related costs (administration, procurement of information on exposure and use, evaluation of chemical safety) in the 10-100 t/y range are estimated much higher by the VCI at 20,000 to 40,000 EUR/substance than in the RPA estimations.

In its opinion on the draft of the present study, the BAuA (2004) refers to its own estimations on the 10-100 t/y range and the 100-1000 t/y range based on concluded new

5 The costs for Annex V are lower that calculated in JRC 2003 due to a reduction in the test requirements The costs for evaluation are also reduced for substances between 1-10 tons since the exposure evaluation has been dropped. The costs include the notification fees.

6 If the information already possessed by the companies is recognized, and GLP data are not accepted.

7 JRC 2003 assumes 100 % data availability.

substance procedures (including administrative parts). Based on this, the BAuA feels that the estimations by the EU Commission are realistic (BAuA 2004b).

- Average of the basic dataset for 10 substances (similar to 10 t/y and 100 t/y in the REACH system): 120,000 EUR. This does not include any reproductive or developmental toxicity test. In addition, a relatively narrow application spectrum must be assumed for new substances.
- Range of additional costs for 10 stage 1 applications (similar to the 100-1000 t/y range in the REACH system): 36,000 EUR to 466,000 EUR per substance (with reproductive and developmental toxicity).

The estimations by the BAuA refer to substances that have not yet been marketed. That is, the availability of existing data should be less than is the case with existing substances, and the notification costs should therefore be higher. On the other hand, the BAuA information on the 10-100 t/y notification does not contain any information requirement on reproductive toxicity and are therefore not comparable with the REACH requirements (additional cost effect: 65,000 to 80,000 EUR). In addition, the evaluation of exposure for existing substances may be associated with higher costs than new substances in certain instances as the area of application increases over the years.

In the volume range between 100 and 1000 t/y, the BAuA evaluation shows the spread of costs for new materials in specific cases depending on whether tests are for specific substance properties or the test results can be used for similarly structured substances.

III.5 Distribution of costs over time

The distribution of the registration costs over time per substance influence corporate liquidity needs. Especially when a company must register many substances over a relatively short period, the required liquidity may be restrictive. However it must be noted that the costs for vertebrate tests according to Annex VII and VIII proposed in the registration dossier by the registering party might only be due after the date of registration as soon as the authorities have rendered a decision.

The work packets for registering can be spread along the timeline (Table III-6). It is assumed that the ordinance will take effect in 2006, and that companies are already doing certain tasks only required at the time of preregistration or registration to enable them to inform their customers. The anticipated market performance of the relevant substance after the registration deadline is central to decision of whether or not to register; however, this frequently lies in the distant future. Companies are faced with the dilemma of postponing the expense for registration as much as possible and maintain-

ing the prerequisites for registering as long as possible (such as by preregistering and other necessary preparations).

Table III-6: Distribution over time of registration tasks for substances < 1000 t/y

	CMR	**1-10**	**10-100**	**< 1000**
identifying the requirements in the draft ordinance	2004	2004	2004	2004
Portfolio analysis on a company level	⇩	⇩	⇩	⇩
Inventory taking and information gaps				
Strategy to deal with REACH				
Preregistration	2007	2010	2010	2010
Communication in SIEF and possible formation of consortia	⇩	⇩	⇩	⇩
Obligatory tests for registration				
Evaluation of hazards and PBTs				
Exposure analysis and contact with users				
Repeated safety evaluation				
Creation of the registration dossier, CSR, safety data-sheet, test suggestions	2009	2017	2017	2012
Communication with the authorities (tests or dossier)	⇩			⇩
Tests possibly carried out starting				

The stepwise evaluation process makes it possible to choose the most economically viable solution in creating a sufficient basis of information for continuing or discontinuing marketing the respective substance. For example, when preregistering high-volume substances starting 2007 or medium-volume substances starting 2010, the question arises manufacturers of smaller volumes of the same substance will participate in a SIEF and register their substance early. The relevant manufacturer will weigh the following advantages and disadvantages:

- If the substance manufacturers possessing non-vertebrate studies[8] also offer them to small competitors for use, it can be advantageous to participate in a joint registration even when the registration costs are due years earlier. Manufacturers who want to continue marketing an unregistered substance can avoid a potential competitive disadvantage when the same substance is also offered “registered” (see Chapter VII).
- If expensive studies must be carried out to continue marketing the substance, small manufacturers or importers can profit from their later registration requirement and

8 There is no requirement to offer the results of non-vertebrate studies to others for payment.

continue marketing the substance for years at lower prices or a higher profit and then stop, or use the data of the *early registrants* free of charge after 10 years (see Article 23 and 24 of the draft ordinance). The competitive disadvantage would then lie with *early registrants.*

For all small-volume substances > 10 t/y, the years before preregistration can be used to enhance information on exposure until it can be documented at the time of registration that certain tests are not required because a relevant exposure can be excluded[9].

III.6 Specific registration costs per kg substance

The specific costs per kilogram substance influence the relationship between registration costs and potential profit. The decision whether or not to register should be considered an investment decision in which the specific registration costs are compared as a single investment with recurring specific net profits from the substance (see Chapter II.3). This means that the specific registration costs result from prorating the per-substance registration costs against annual production. This information is then used in other value-chain-specific considerations (see Chapters V and VI). To determine the specific registration costs for the individual volume ranges, scenarios are developed that assume production volumes at the bottom and top limits of the respective volume range.

Table III-7: Specific registration costs[10]

	1-10 t/y	**10-100 t/y**	**100-1,000 t/y**	**>1000 t/y**
Average scenario (Euro/kg)	13.10 – 1.31	8.37 – 0.83	2.01 – 0.20	< 0.25
Minimum scenario (Euro/kg)	12.10 – 1.21	5.11 – 0.51	1.66 - 0.17	< 0.23
Maximum scenario (Euro/kg)	14.10 – 1.41	16.27 – 1.63	2.82 – 0.28	< 0.32

Based on these scenarios, specific, one-time registration costs between approximately 0.50 EUR/kg and 16.30 EUR/kg can be assumed in the 1-100 t/y range[11]. The jumps at the edges of the tonnage ranges illustrate that REACH provides a stimulus to register in the lower tonnage range, or expand production substantially beyond the bottom

9 The authors of this study interpret the instructions in column II of Annex VI to mean that waiving tests based on exposure also applies to subchronic toxicity and reproductive toxicity. The industrial representatives in the advisory committee are assuming based on Annex IX that the tests in Annex VI cannot be waived for reasons of exposure.

10 Based on the estimations of the EU Commission (rounded).

11 The corresponding figures are 2 to 24 EUR/kg for the “average scenario” following the VCI estimations.

edge of the next tonnage range. It is therefore improbable that the peaks will extend above 10 EUR/kg; however, registrations could split or coalesce from cooperation among market actors.

The corresponding figures for the average scenario in the estimation of the VCI would lead to a spread of 2 to 24 EUR/kg.

III.7 Influence of selected cost-determining factors

III.7.1 Test costs

Test costs under the REACH system arise wherever there is no or insufficient standard required information on the properties of a respective substance. Some of the test costs under the REACH system arise when existing or first-time screening tests indicate potentially hazardous properties (suspected hazardous properties according to the required information in Annex V and VI), and the manufacturer does not want to cease marketing the substance. In this case, the costs of the REACH system depend on the prior and future behavior of the registering party. This applies for example when:

- An in-vivo study is done when in-vitro tests have yielded corresponding suspicions. JRC assumes that this applies to 30 % of the substances.
- A two-generation study is done on reproductive toxicity when there are indicates of structural similarities with substances with known reproductive toxicity, or a 90-day study has produced corresponding results. JRC assumes that this applies to 15 % of the substances.
- A study is done on the developmental toxicity of substances <100 t/y when there are positive results from a corresponding screening study. JRC assumes that this applies to 15 % of the substances.
- A 90-day study is done when the frequency and duration of exposure requires a long-term study, and there are indications that the substance has active or enriching properties that cannot be investigated in a short-term study. JRC assumes that this applies to 25 % of the substances.

Another part of the test costs arise from the requirement to provide specific basic information on each substance largely independent of known properties or anticipate exposure. These suspicion-independent or risk-independent test costs can scarcely be influenced by the behavior of the registering parties. Among the cost-intensive end points of the REACH system in the 1-100 t/y range are the tests for subacute toxicity,

the screening test for reproductive toxicity[12], the cytogenicity study of mammalian cells, the skin sensitization test, and the hydrolyzability according to Annex V[13]. Essentially two factors contribute to the high cost: The anticipated usefulness of QSARs is relatively low (skin sensitization and hydrolysis), and/or the test is particularly expensive (subacute toxicity and screening for reproductive toxicity).

The risk-independent informational requirements in Annex V (including the use of non-test-based information) can yield specific registration costs > 10EUR/kg for a small-volume substance based on the present cost assumptions of the EU Commission.

According to column 2 in Annex VI, the informational requirements on toxicity (6.6.1 and 6.7.1) can be discarded for the range of 10-100 t/y in certain cases when it can be documented that no relevant exposure can occur. The JRC's cost projection has been based on the assumption that the corresponding information is required for 90 % of all substances (JRC 2003), but that QSARs and references to analogous cases will render the tests largely avoidable.

The JRC's cost estimation for minimum and average scenarios is based on the assumption that intensive research over the next few years will increase the availability of non-test-based techniques for predicting substance properties (JRC 2003, p.21).

III.7.2 Other cost-influencing factors

The **amount and availability of the required information** on substance properties (see Annex V to VIII) in companies determines the cost of the informational gaps to be closed. The information procurement costs (test costs and exposure analyses) will be lower for companies that have already procured sufficient information than companies that have invested little in information gathering. However, there is already so much data on many high-volume existing substances that it may be very expensive to select the right studies on which to base the registrant's safety evaluation and evaluate and summarize the studies. That is, the chemical safety evaluation for data-rich substances can be much more expensive than evaluating substances for which few informative studies exist (see also NRW simulation)[14].

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12 Only in 12th position in table 8 of the JRC study due to the very low test costs of 20,000 EUR.

13 Table 8 (JRC 2003) also lists easy biodegradability (9th position) and the algae test (11th position); however, these are only found in Annex VI of the draft ordinance. This reduces the number of tests and hence the cost burden by more than 50 %.

14 ARGE simulation (2003), page 25.

The **formation of consortia**, i. e., the joint financing and use of additional test data can reduce the cost burden of individual companies. However, additional interaction costs arise from the formation of consortia that must be taken into account. RPA (2003d) calculates additional costs of 9000 EUR per consortium for substances with a market volume < 1000 t/y and 30,000 EUR for HPVs (RPA 2003d, Table 5.7). In addition, there is no leeway for consortia formation in market segments where the substance is only marketed by one or two manufacturers or importers. Misgivings against consortia formation pertaining to know-how are dealt with in the chapters on supply chain analyses.The rules to determine **satisfactory data quality** (Annex IX) will decisively influence how many new studies or investigations must actually be done. The same holds true for non-test-based techniques: Group evaluations, drawing analogies and quantitative structure/activity relationships (**QSARs).**

Starting in Annex VI, REACH allows **specific test requirements to be waived** when it can be documented that a relevant exposure cannot occur. This possibility is listed in Appendix VI in column 2 for two specific tests. For the test requirements in Annex VII and VIII, Annex IX (No. 3) provides the **general** option of waiving. How the manufacturer will present such proof will largely determine the extent to which the registration costs will be influenced by this option. It must be also taken into account that the justification for waiving a test may generate user costs from providing a sufficiently thorough evaluation of exposure and corresponding risk management measures.

The description of the **exposure scenarios** and the probable exposure risk can be restricted or extensive and can calculate realistic exposure risks or use worst-case scenarios. Exposures can be modeled or measured. The draft ordinance does not specify the detail in which the exposure is to be described in individual cases, or the extent to which existing models can be used for evaluating exposure. The costs will also be proportionally lower if examples of usage and exposure can be summarized in a limited number of exposure types (such as standard exposure scenarios or usage and exposure categories).

In the context of worker protection, many exposure-related measurements have has been taken over the past decades, and models have been developed to estimate exposure. The same holds true for industrial substance-related environmental protection. To date, however, these troves of information have not been very accessible or useful to manufacturers wishing to evaluate substances. If these information sources can be evaluated and made available to substance manufacturers under the REACH system, the need for further exposure data can be limited. That is, the cooperativeness of companies, authorities, trade associations and scientific facilities in **mining existing data resources** will decisively influence the costs for introducing the REACH system.

It will be impossible to implement the REACH system without a **harmonized EDP standard** for all data elements and exchange processes of the REACH system. The same holds true for the required **instruments** for implementing and documenting the evaluation of chemical safety, and for defining exposure scenarios and creating safety datasheets. The ease with which the instruments are used will also influence company expenditures. The instruments are being developed in *REACH Implementation Projects* (RIP) and are being financed by EU funds.

III.8 Conclusions regarding the aim of investigation

The text of the ordinance and the available inventory of substances from the supply chain can be used to forecast the extent to which the cited factors will influence the costs of implementing REACH only within the above-cited ranges.

The costs will depend on the rules of implementation to be finalized by 2006 (REACH Implementation Projects [RIP] in the transition strategy of the Commission), and on the cooperativeness of market actors and authorities. In addition, the ordinance itself offers a few decisive factors for the cost-efficiency of the system:

- The extent of legal compulsion or the stimuli to provide substance data relating to health and the environment to other registrants against reimbursement will influence the overall cost of the system. At present, this requirement only extends to vertebrate studies (Article 23).
- The interaction of obligatory and flexible data requirements in Annexes I and V-IX will decisively influence how closely the relative registration costs correlate with the inability to forecast safety of use in individual cases. That is, registering substances for high-rise applications will generally be associated with higher test costs than registering substances for low-risk applications. The present approach of tying information requirements to market volume and tested substance hazards (exposure evaluation only for hazardous substances > 10 t/y) will contrastingly cause a sizeable jump in registration costs starting at 10 t/y with no correlation to risks from substances between 1-10 t/y and 10-100 t/y.
- The flexibility of the Annexes will also influence the extent to which the yet-to-be-developed techniques for non-test-based substance evaluation can be used as soon as they provide technically reliable results.

Practical, cost-reducing suggestions for designing the REACH implementation will be proposed in Chapter VIII (conclusions).

IV Potential benefits of REACH

The proposal of the EU Commission for a new European chemicals policy aims, among other things, at creating a better framework for protecting health and the environment. At the same time, it is intended to strengthen the competitiveness and innovativeness of the European chemicals industry. This also includes developing harmonized risk assessment and communication standards within the common marketplace (and implementing them) and more transparency with regard to the (eco)toxic properties of substances, as well as generating the conditions under which they can be safely used. These standards will apply to all substances, regardless of when they were first introduced to the market (*cf*. Chapter 1).

The following chapter illustrates the potential benefits of the REACH system. The focus here is on i) improvement of the existing regulatory instruments in chemicals legislation1 (reduction of the implementation deficit and eradication of instrument loopholes) and ii) prevention of the costs of chemicals-related harm.

IV.1 Methods and emphasis

IV.1.1 Deficits of current chemicals legislation

One of the potential benefits of REACH is the eradication of certain systematic flaws in current European chemicals legislation. These were analyzed in diverse investigations during the run up to the drafting of the white paper[2]. They include:

- the unavailability of data on the properties of old substances on the market
- the lack of obligation for formulators and substance users to disclose information on uses and exposures
- the strict testing demands placed on new substances in comparison to old substances, even for small market volumes
- the very slow risk assessment process for old substances within the authorities' area of responsibility and, as a result, the laborious process of restricting the marketing of substances.

These analyses do not need to be repeated during the course of this study.

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1 A comprehensive analysis of all substance-relevant regulatory instruments, for example in connection with riparian legislation, immission control legislation, construction products legislation, foodstuffs and commodities legislation, did not form part of the R&D project.

2 A report on the four main Community legal instruments was completed in November 1998, SEC (1998) 1986 (CEC 2001).

IV.1.2 Excursus: interfaces to existing legislative requirements in environmental and health protection

One field that has previously been almost completely ignored is the interaction of chemicals legislation, on the one hand, with the numerous, historically developed regulations for substance-oriented risk management in diverse areas of product and plant legislation, as well as occupational safety, on the other. A systematic analysis of the various fields is necessary in order to develop an efficient holistic system for substance-oriented environmental and health protection leading up to the incremental introduction of the REACH system until 2017. Such an analysis, however, did not form part of the R&D project. Nevertheless, some aspects of the process necessary for the integration of the various regulatory areas should be noted, in particular because they were continuous topics in the working group accompanying this study:

- Previously, the official old substance program strictly differentiated between risk assessment and risk management. That is, the instruments previously available for risk assessment are only of very limited suitability for integrating the existing or additionally necessary risk management measures in the assessment process. Under REACH, however, this is precisely what is envisaged for the Chemicals Safety Assessment. That is, for every Chemicals Safety Assessment for a given field of use, the existing legislative risk management requirements, together with their actual implementation, must be taken into consideration if they are substance-specific. Due to the numerous national peculiarities in plant-related environmental protection and industrial safety, the requirement for harmonization and standardization is substantial, if REACH is to improve efficiency.
- The REACH system is risk-oriented, that is, the conditions for safe use are derived from the substance properties and the expected exposures. On the other hand, substance-specific emission caps are generally derived from the state-of the-art of the technology involved and are not risk-oriented. This means that the existing risk management requirements, for example pursuant to the technical directive on air, or sewage regulations, and the "safe use conditions" derived from REACH, will often not be identical for the same substance. Here, it will be necessary to eliminate substance-specific "double requirements", while simultaneously retaining the group parameter approach used in environmental protection. After all, only the impact risks of defined feedstock can be assessed within the scope of the REACH system, but not the impact risks of biochemical conversion products or, for example, the ozone-forming action of volatile organic components (VOCs).
- For certain product areas, such as washing and cleaning agents, toys, foodstuffs packaging or construction products, requirements for substance-oriented product safety exist or are being developed. Similar requirements apply to products for which there is a Europe-wide take-back obligation (scrap vehicles, packaging, scrap electronic equipment). Many of these product-oriented regulations also play an important role in the two investigated supply chains. In some areas, systems for the

assessment and documentation of substance risks already exist; here, REACH will only provide additional benefits to a limited extent; for washing and cleaning agents or the substance documentation systems of the automobile industry, for example. In these areas, much depends on using the existing systems as envisaged by REACH and on designing REACH with the flexibility to make this possible. In other areas, for instance when implementing the Construction Products Directive, the REACH system can play a role in generating and documenting the information required for the construction product assessment.

These illustrations demonstrate that any efficiency improvements caused by REACH are not achievable merely by consolidation of European chemicals legislation. In particular, the integration of chemicals legislation and substance-oriented risk management with environmental and health protection is necessary. There is a requirement here for further research.

IV.1.3 Emphasis of this study

This study concentrates on three aspects with regard to the potential benefits of REACH.

- To what extent can REACH improve the existing foundation for assessment and communication of substance-oriented risks in the supply chain? This relates principally to the German implementation of the EU Safety Data Sheet Directive by means of the TRGS (*Technical Regulations for Hazardous Substances*) 220.
- By what means can REACH contribute to improved knowledge management with regard to assessing old substances?
- To what extent can the hypothesis that REACH contributes to the prevention of chemicals-related harm costs and thus recuperates part of the investment by preventing harm be demonstrated by concrete case histories?

Forming the foundation for these three aspects of the investigation, the possible theoretical causes for errors arising with regard to the management of chemicals in the supply chain are first characterized (Section IV.2).

IV.2 What causes chemicals-related damage?

The reasons for undesired, harmful effects of chemicals in the course of the product lifecycle can generally be assigned to one or more shortcomings in chemicals management. In particular, the belated and unsystematic assessment of existing information on dangerous substance properties with regard to risk management can be seen as a decisive factor for the extent of subsequent harm (*cf*. the conclusions in RPA 2003a).

The following factors can lead to errors in the risk management of chemicals at the level of actors and to the associated follow-up costs:

- The user of chemical substances (manufacturer or user of preparations) does not have information on the type and amount of dangerous substances in the raw materials. A lack of factual information or insufficient communication between or within enterprises may contribute to this.
- The user of chemical substances (manufacturer or user of preparations) does not have information on the ways and means of safe handling. A lack of factual information or insufficient communication may contribute to this.
- The user does not have the qualifications and/or the management system to convert the information given to measures.
- The user does not have the motivation (for whatever reason) to utilize the available information.

All of the reasons given above are related, despite the goodwill of the actors, in as much as often a common "risk language" does not exist in the supply chain and all actors tend to be overstretched by the multitude of existing individual case rulings. For example, one of the experiences made in the simulation carried out in North-Rhine Westphalia was that the actors in the textile chain were not, at first, capable of communicating in a language understandable to both parties on the environmental risks of a textile additive selected as an example for the simulation (Bunke et al. 2004).

With regard to the potential benefits of REACH pertinent to communication in the supply chain, the following questions arise:

- Does the provision of basic information for each substance, such as an (e-co)toxicologically-based upper exposure limit, or the systematic and standardized correlation of substance properties, exposure and risk management lead to more product and use safety? This question must also be answered taking into consideration that the current Safety Data Sheet Directive envisages precisely this link, at least as far as industrial safety is concerned.
- Which elements of REACH can lead to deterioration of the initial situation, for example by shifting too much assessment responsibility to SME users or by an imbalance between data generation and evaluation capacity (key word: data cemetery)?
- Where can REACH **alone** not alter anything relating to the causes of the existing deficits, for example with regard to a lack of expertise, management capacity or even motivation within the enterprises?

IV.3 TRGS 220 and the Preparations Directive

IV.3.1 Scope of the TRGS 220 and instrument loopholes

The German TRGS 220, which is derived from the EU Safety Data Sheet Directive (91/155/EEC, 93/112/EU and 2001/58/EU) and the EU Preparations Directive (88/379/EEC and 1999/45/EU), already contains substantial sections of the requirements intended to be anchored Europe-wide as part of the REACH system. As an instrument type, it should form the basis for communication in the supply chain for industrial safety and environmental protection. The question posed, then, is: Is it possible that an instrument such as the TRGS 220 is sufficient to achieve the same goals as those associated with the REACH system?

The results of a systematic comparison of the TRGS 220 (including relevant elements of the TRGS 230 and 240) to Annex 1 of the REACH regulations are given in Table IV-1. It is obvious that current industrial safety information requirements are comparable to large portions of the REACH draft.

Table IV-1: Comparison of requirements in the appendices of the REACH regulations and the TRGS 220

	REACH	**TRGS 220**
Evaluation and consolidation of available substance data	IV – Stages 1-3	4 (3) 6.11 (6)
Provision of additional information upon request by the user	Article 34.2	4 (14)
Definition of foreseen and/or known uses	I (5) + IV (3)	6.1.2 6.7.3
Use of available information on user workplace burdens	I (5)	6.8.2 (2)
Specific information on safe use in the workplace	IV (5)	6.8.2.1
Necessary information for restricting and monitoring environmental exposure	I (5)	6.8.2.2
Exposure scenarios	I (5)	Element in TRGS 430 TRGS 420
Process and substance-specific criteria for working area monitoring		

The exposure scenario instrument used for systematic classification of use areas, exposure patterns *(= exposure stages,* consisting of *exposure path* and *exposure probability*) and necessary or suitable protective measures is already utilized in the TRGS via isocyanates (TRGS 430). Viewed from this angle, the question arises whether the TRGS 220 contains loopholes and whether REACH contributes anything to closing these loopholes. Because the TRGS 220 was developed principally from the perspective of industrial safety and is an instrument for risk management at the workplace, it cannot cover certain aspects of a Chemicals Safety Assessment after REACH:

- The TRGS 220 and the corresponding regulations in other TRGSs only deal marginally with environmental protection questions and not at all with consumer protection. Here, REACH creates a harmonized instrument for Chemicals Safety Assessments (including deriving the necessary measures for safe handling) with regard to all three areas of protection. This does not make the existing regulations for consumer and environmental protection superfluous. But a system is introduced in which the respective upstream supplier must consider substance properties, exposure assessment and risk management. And this is not only with regard to workplace burdens, but also to environmental burdens and consumer exposure.
- Substances for which the substance manufacturer considers classification to be unnecessary, based on the information available to him, do not require a safety data sheet. This means the substance user does not know whether the substance is classified as not dangerous on the basis of adequate information or on the basis of poor information. Here, REACH makes it obligatory to create for all substances brought into circulation a dataset on substance properties and generic use in the registration dossier. Indicators for any environmentally dangerous substance properties can be derived from the data in Annex VI of the REACH regulations draft (substances > 10 t/a)3 or, for German companies, from the existing minimum dataset in accordance with the VCI voluntary agreements. As far as health dangers are concerned, corrosive, irritating and sensitizing properties, as well as possible mutagenic properties, can be derived from the data in Annex V. Indicators for subacute and chronic effects can be derived from the datasets in Annex VI. According to the current draft regulation, every manufacturer of substances > 10 t/a can decide, on the basis of the obligatory dataset, whether he is dealing with a dangerous substance or not.
- Complementing the *EU Technical Guidance Document on Risk Assessment* (TGD), which harmonizes principles and methods of risk assessment, REACH integrates the measures required for risk management within the Chemicals Safety Assessment (CSA) framework. The Chemicals Safety Assessment (CSA) thus represents the previously missing legislative bridge between substance-oriented risk assessment within the scope of the old substance regulations and deriving the necessary protective measures (including transparent communication of these measures along the chain). However, this makes it necessary to adapt the previously used instruments for exposure assessment to the conditions under REACH and to develop them further: simplification, development and standardization of exposure models, where these are still missing.
- Currently, the safety data sheet only contains information on safe use by the initial user of the substance or preparation. Possible risks to the users at subsequent levels of the supply chain are usually not taken into consideration in the safety data

3 In the current Annex V, no information on biodegradability is envisaged, either based an OECD screening test or based on the available QSAR models.

sheet. Here, REACH makes it obligatory to define possible exposures and the necessary risk management measures for all relevant levels of the supply chain in exposure scenarios. This allows the integration of industrial safety, environmental and consumer protection, and product safety, in one information document. This extended safety data sheet is intended to help the industrial and commercial users of substances and preparations to play a role in the safe use of substances.

- The question of who needs what information at which level of the supply chain in order to facilitate the safe use of the respective substance, varies from case to case and cannot be unequivocally specified for all use situations and substances within the scope of regulations. For this reason, the EU Safety Data Sheet Directive contains obligatory headings, but no obligatory data catalogue. This results, in parts, in grievous differences of interpretation between market participants and the authorities, and among the authorities themselves (*cf*. ECLIPS results, for example, in Section IV.3.3). What is still missing is a **standard procedure** to determine which information for risk management is gathered, transparently assessed and translated into the conditions necessary for safe use. Likewise, a clear delineation of reviewing responsibilities is absent. Annex I of the proposed REACH regulations presents such a standard procedure in conjunction with Articles 29-36. In particular, the systematic review of upstream supplier information to Article 34 by the user and the resulting a) feedback or b) acceptance of own responsibility are new elements.

In summary, the REACH system closes some of the existing instrument loopholes in the current interaction between old substance regulations and TRGS 220. In the long-term, this can result in an improvement in the information situation for the market participants, more efficient information management, a reliable delineation of responsibility, and certain protection from unpleasant "contaminant surprises".

In this way, REACH can contribute to removing current deficits as identified by the chemicals industry (Barker 2004):

- The current requirements are aimed at the dangerousness of substances and too little at supporting risk management.
- Information flows predominantly from the substance manufacturers to the downstream users, but not in the opposite direction.
- The information is only harmonized for substances listed in Annex I of EU Directive 67/548. For other substances, the information from different manufacturers is contradictory.

IV.3.2 Information on dangerous substances in preparations

The information requirements for classified, dangerous substances in preparations will not be significantly altered by REACH, because the EU Preparations Directive and the

Safety Data Sheet Directive are adopted as is. They call for the publication of the following information:

- The envisaged or proposed uses of a dangerous substance or a preparation containing dangerous substances, and the general technical function of the substance or the preparation, for example flame protection agents (point 6.1.2).
- The identity and the concentration range (EINECS or ELINCS, where necessary also CAS and IUPAC) of those dangerous substances in the preparation that lead to a classification as dangerous in accordance with the regulations in Article 3 (3) of the EU Preparations Directive (point 6.2.3).
- The identities of substances dangerous to health and the environment in preparations not classified as dangerous if they do not exceed 1 % (point 6.2.4). For substances classified exclusively as irritants or dangerous to health, a more general designation than the chemical identity can be selected (for instance, in accordance with Annex 6 of the Preparations Directive), if the marketer can demonstrate expertise protection problems. This also applies if a substance that is irritant or acutely dangerous to health is also inflammable, explosive or dangerous to the environment (point 6.2.4)
- The identity of substances in a preparation for which there are EU exposure limits at the workplace if the concentration in the preparation exceeds 1 % (point 6.2.3).

The authorities in the various EU countries may interpret these requirements very differently, however (see also ECLIPS 2004). Even in the marketplace, the flow of information often depends on the negotiating power of certain enterprises (such as the automotive industry) and less on the letter of the Directive. The draft regulation uses the cut-off criteria of the current Preparations Directive (with the exception of substances with PBT and vPvB properties) and thus pragmatically limits, as was previously the case, the obligation for performing an exposure assessment.

That is, REACH will not bring about any additional benefit or detriment with regard to the notification of dangerous recipe constituents.

IV.3.3 Empirical studies on the implementation deficit

In the past 8 years, both German and European authorities level have carried out a number of studies on the implementation of existing instruments.

They dealt with implementation of the notification obligations for new substances (NONS and SENSE projects), registration obligations for old substances between 1993 and 1998 (EUREX project), classification and declaration of dangerous substances (NONS), classification and declaration of preparations (ECLIPS), and safety data

sheets for preparations (ECLIPS and BAuA, 2002). Table IV-2 gives a summary of the results.

The proportion of reviewed products (substances or preparations) for which shortcomings were determined is given. Only ECLIPS makes any statements on the severity of these shortcomings, although the authorities of the member states obviously rate them very differently for the products reviewed by them. The German authorities consider 23 % of the deficiencies recorded to be severe and 60 % to be minor. The Swedish authorities classify 12 % of the deficiencies as severe and 25 % as minor.

The ECLIPS study, in particular, is important as a background for an empirical investigation of the paint and varnish supply chain and the washing and cleaning agent chain. The total number of reviewed products was 1,579, 31 % of which were reviewed in Germany. There were 109 chemicals manufacturers and 21 retail enterprises in the random sample. Of the reviewed products, 68 % formed part of the supply chains also empirically investigated for the present project (38 % paints and coatings, 18 % cleaning agents, 12 % washing agents).

Table IV-2: Implementation deficits in the existing instruments

Non-notification of *new substances*: 37 % [NONS 95/96]
Non-registration of old substances: 34 % [EUREX 97-99]
Insufficient specification of substance identity: 31 % [NONS], 6 % [SENSE 96/97]
Deficiencies in classification and declaration of dangerous substances: 50 % [NONS]
Deficiencies in classification and declaration of Annex 1 substances: 25 % [paints 10 %] and 42 % [paints 31 %] [SENSE 96/97]
Deficiencies in classification of preparations: 62 % [CLEEN 03];
Deficiencies in the safety data sheets of preparations: 75 % [CLEEN 03], 66 % [BauA 2002]
Flaws in the internal documentation system: 57 % [NONS]
Documentation does not correspond to the requirements of Directive 92/32/EEC: 32 % [SENSE]
Deficiencies in classification/declaration [60 %] and safety data sheets [69 %] of preparations [ECLIPS 2004]
Incorrect classification of preparations with regard to sensitizing substances and/or CMR: 40 - 50 % [ECLIPS 2004]

The various studies also make statements on the principal causes of the implementation deficits:

- The legal requirements are not known or not understood (EUREX, NONS, ECLIPS).
- Information and defined responsibilities are lost through company restructuring (EUREX).
- Internal documentation of substance inventories and the respective, relevant customer groups is absent in the enterprises (NONS).
- There is a minor dependency on company size and experience, but the decisive factor is the enterprise-specific management system and management practice (BAuA 2002).
- ECLIPS determined a clear correlation between the deficiency rate and the size of the enterprise, and the existence of a management system certified to ISO or EMAS. What is conspicuous in the ECLIPS results is the difference between ISO 9000 systems (quality management) and ISO 14000 systems (environmental management). The environmental management systems obviously contribute much more to correct safety data sheets than a quality management system (ECLIPS).
- Enterprises organized in associations have a slightly lower deficiency rate than non-organized enterprises. But even in enterprises with sufficient knowledge of the legal requirements and membership in an association, the deficiency rate is still around 20 – 40 % with regard to the reviewed end points (ECLIPS).
- Legislative coercion and customer wishes are seen as the stronger engine in comparison to the *Responsible Care* voluntary agreement and an acknowledgement of product responsibility (BAuA 2002).

Two conclusions for the possible benefits of REACH can be drawn from this summary factor analysis:

- Without changes in the management systems and management practice within enterprises, without the authorities implementing suitable inspection strategies and without clearly articulated enquiries for REACH information from the market, the implementation deficits will hardly be reduced.
- If REACH is understood as an obligatory instruction to improve current management routines with regard to product safety in supply chains, the system addresses one of the central sources of the implementation deficits.

IV.4 Knowledge management in the REACH system

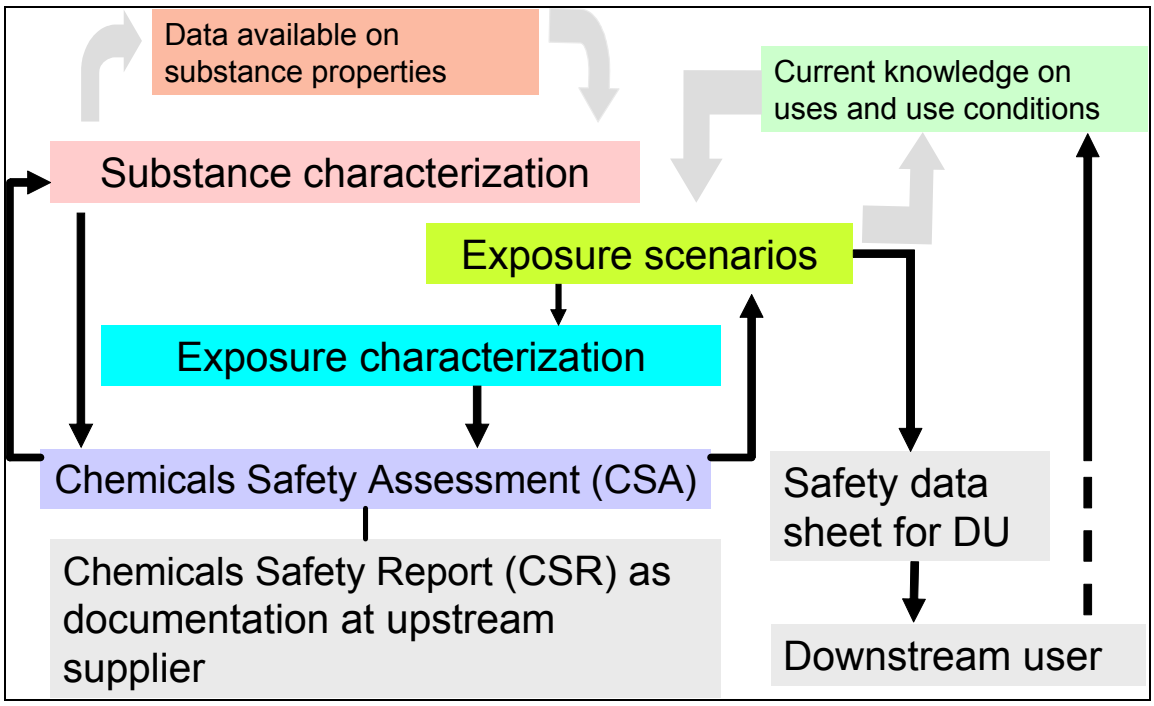
REACH introduces a common system for the systematic and staged evaluation of existing databases and for generating additional information on environment- and health-

relevant substance properties and exposure patterns. The draft regulations contain five principal components:

1. Evaluation process

The multi-stage, iterative evaluation process in accordance with Annex I is the basis for step-by-step refining of the information situation by substance manufacturers. They thus put themselves in a position to specify the conditions for safe use by their customers. This process is rendered in Figure IV-1 with the corresponding terminology from the draft regulations.

Figure IV-1: CSA as systematic evaluation process



2. Documentation

The result of this evaluation process is two information documents if a dangerous substance with a market volume > 10 t/a is being dealt with:

- In the safety data sheet, the manufacturer describes the conditions suitable to guarantee use that is safe for employees, the environment and consumers. This description is such that the manufacturer can recognize a preparation, its uses and usage conditions for which the substance is suitable.
- In the Chemical Safety Report, the manufacturer documents its assessment for itself and for the registration authority.

3. Utilizing existing substance knowledge

In order to produce uniform information requirements for all substances on the market not subject to special regulations (pharmaceuticals, biocides, pesticides), the draft regulations contain standard information requirements in Annex V to Annex VIII, differentiated according to market volume. To save on both animal testing and costs, the draft regulations focus requirements on the evaluation of existing information (compare introductions to the 4 Annexes). In Annex IX, the information types, which may be used for characterization of substance properties, are named. This includes non-GLP test data, and non-test-based forecast techniques such as structure-activity relationships, group assessments and analogies. Annex IX will prompt industry and the authorities to agree on generally accepted rules for utilizing the existing knowledge base. This offers the potential for substantial efficiency gains during substance assessment.

4. Stronger consideration of exposure

Certain information requirements for substances between 10 and 100 t/a and all information requirements in Annexes VI and VIII need not be complied with if the substance manufacturer can document, through his exposure assessment, that no relevant exposure can occur. The relevance of an exposure is according to Annex I determined by the location, duration, frequency, input path to the environment, human exposure path, and concentration. Here, too, the development of regulations on how comprehensive an exposure assessment must be in order to exclude relevant exposure must be dealt with. Compared to the current requirements for old substances, REACH places a much stronger emphasis on the exposure assessment. This presents a chance to overcome the present hazard-weighting4 in the handling of old substances. However, three aspects must be considered, which limit the potential benefits brought by the REACH approach:

- Exposure forecast models have previously been much less standardized than testing regulations. This means that the use of exposure models for regulative purposes will only develop in the course of the next few years.
- Exposure forecasts always assume knowledge of uses and use conditions. This means that the expertise protection interests of the formulators tend to restrict information.
- The present draft regulations envisage an exposure assessment for dangerous substances only. Whether or not a substance is dangerous can often only be decided,

4 Substance handling is currently determined predominantly by which dangerous properties of the respective substance are known.

however, when the appropriate tests have been carried out. That is, the simultaneous reduction of test requirements and the restriction of the risk assessment to dangerous substances have substantially restricted the potential benefits of REACH with regard to the low-tonnage substances (< 100 t/a).

5. Utilizing existing knowledge on uses and exposures

The manufacturers often do not have the necessary information on the uses and conditions of use of their substances. On the one hand, this leads to possible substance effects having to be tested in advance; on the other hand, the options for offering practical risk management support to the substance users remain restricted. Simultaneously, some of the formulators and industrial users of the formulations have the detailed knowledge to address just these questions. The chemical-toxicological know-how, in contrast, is often restricted. By systematic combination of these two fields of knowledge the following effects can be achieved:

- Exposure- and substance-oriented information is systematically combined and form the foundation for a targeted identification of risks and additional risk management requirements in the supply chain itself.
- The remarks of the substance manufacturers on risk management can be formulated in a more practice-oriented and actor-specific manner.
- The determination of substance properties can be better aimed at which exposures are relevant.

IV.5 Preventing damage costs with REACH

IV.5.1 Method

One of the hypotheses on the benefits of REACH is that REACH prevents costs caused by harm to health and the environment and thus returns part of the investment. An examination of this hypothesis is difficult for a number of reasons:

- Many of the damage costs associated with chemicals are not wholly due to the effects of substances, but only in part. The chemistry-related contribution is often difficult to quantify. This is true for contact allergies, for example.
- The costs for averting damage (drinking water treatment, sewage treatment) can often not be correlated to a specific substance and its handling, the corresponding cleaning technology has a broad spectrum effect.
- Damage is usually only quantifiable after the fact, that is, at a time when the cause of the damage has already been suppressed or at least reduced. When evaluating historical cases, the constellation of possible causes must therefore be analyzed far into the past in order to allow forecasts for the future to be derived.

- If the conclusion is reached that the constellation of possible causes is still relevant today, the REACH mechanisms can be examined for their influence.

Information is only available in the literature in very few cases, in particular with regard to the environmental and consumer areas. Documentation systems such as those for industrial safety do not exist here. There are also almost no studies on the importance of behavioral contributions to damage causes. Some case studies could not be performed within the scope of this project. Only easily accessible documents were therefore evaluated: studies by the Federal Environment Agency and the European Environment Agency, cost studies by British and Dutch water utilities, evaluations of industrial disease statistics issued by professional associations, and a study by the BAuA on the costs of work-related illnesses. Only in two cases were data collected in our own predominantly telephone research.

The aim of the following case histories, then, is not to quantify the damage prevention potential of REACH and thus to prove or disprove the hypothesis formulated above. Rather, the magnitude of selected, chemicals-related damage cases (including chronic pollution of aquatic systems) are quantified and the causes characterized. The modes of action of REACH then suggest whether REACH would have been able to prevent the causes or would be able to in the future.

In order to facilitate damage cost comparability from case to case, the damage costs are converted, where this makes sense, to "per capita" or "per capita/year" costs.

IV.5.2 PCB remediation in public buildings

Into the nineteen-seventies, paints, sealants and plastics containing PCBs were used in construction industry products. The main purpose of the PCB was as a (flame resistant) plasticizer. In the course of remediation measures in public institutions, in particular schools and kindergartens, costs arise which can be quantified at a local authority level: the remediation costs arise once per building and amount to between 2 and 56 euros/resident in the 6 selected west German local authorities. The average is **25 euros/resident** (see bibliography for sources).

One methodological difficulty consists of isolating the PCB-related costs from the costs of general modernization work, which is almost always carried out at the same time as PCB remediation. According to the ECO Institute (Dr. Zwiener), in Cologne, Germany, a 10 % - 15 % cost component can be assumed if no specific information is available.

Table IV-3: PCB remediation costs in 6 west German local authorities

	Costs in euros per resident	Determined
Bremen	22	Determined separately
Bonn	32	Determined separately
Gummersbach	26	Global factor 10 %
Cologne	2	Global factor 10 %
Monheim	56	Global factor 10 %
Münster	12	Determined separately

The principal information on the behavior and effects of PCBs harmful to the environment and to health was available by the end of the nineteen-sixties. In Sweden, all exposed uses were banned in 1972, and the OECD and other countries followed this lead. However, the bans were often restricted to "new" uses at first (EEA 2001). For years, PCBs were used at various locations in the supply chain (generally unintentionally) in preparations and products.

Would REACH have lead to the potential effects of PCBs being recognized earlier? No, persistence and bioaccumulability were not standard end points in dangerous substance classification at the end of the nineteen-sixties.

Would REACH have lead to a more effective restriction of the fields of use based on the recognized potential effects? Yes, if, at the time, a Chemicals Safety Assessment according to REACH had taken place, its use in paints and other construction materials could have been communicated to the market by the manufacturer as "use advised against". Responsibility for possible subsequent harm would then have been that of the party using the substance in their product despite this notice.

IV.5.3 Cleaning of raw water for drinking water purposes

When extracting drinking water from river and groundwater, the water utilities must remove the active ingredients of pesticides, biocides, pharmaceuticals, industrial chemicals and decomposition/combustion products (traffic, industry, households) from the raw water.

Cost estimates are available for the removal of pesticides; as far as we are aware, no specific cost estimates exist for other substances. However, it can be assumed that the technology employed to remove pesticides from raw water are also effective for chemicals with more general industrial uses. In principle, pesticides do not differ from industrial chemicals with regard to their spectrum of water solubility and distribution behav-

ior. According to the Netherlands Water Associations (2004), not only pesticides, but also "unknown" chemicals in the raw water play a major role for the water utilities. Three different sources of information were drawn on, using different calculation methods, for the cost estimate. The costs were converted to per capita costs.

Table IV-4: Costs of pollution of water with pesticides

	Costs in € millions/a	**Euros per capital and year**	**Investigation**
Costs for the removal of pesticides from drinking water (including monitoring)	162	2.75	UK Water Industry Research (2003); costs survey
	240 in 10a	1.6	Netherlands Water Association (2004), costs survey
Costs for removal of pesticides from drinking water (including monitoring) and costs of preventive measures	65 - 95	0.78 – 1.16	Hanover University (1998), calculation model

Would the REACH system prevent the occurrence of pesticides in the raw water of water utilities? No, the REACH system only deals with substances whose environmental behavior is not already examined by existing authorization procedures in present legislation; i. e. neither the active ingredients of pesticides nor biocides and pharmaceutical products.

Would the REACH system prevent the occurrence in raw water of substances emanating diffusely from products, private households or industrial plant? Yes, because the manufacturer must examine the degradability, solubility and distribution behavior in the environment at least for every substance explicitly included in preparations or products before registration. Based on just these three pieces of information, and in conjunction with the market volume and the exposure scenario, the extent to which a substance can occur in the raw water of the water utilities can be projected. Suitable additional measures for environment-oriented risk management can be formulated on the basis of this assessment, or the sale can be terminated in certain uses.

Would REACH be able to prevent the occurrence of "unknown" substances in raw water? Yes, if they are defined substances in preparations and products registered in Europe. No, if they are metabolites and decomposition products from industrial plant or if they are substances from imported products (e. g.: textiles).

IV.5.4 Chemicals-related industrial diseases

The statistics of professional associations can provide information on the costs of recognized chemicals-related industrial diseases. They record only compensation costs. Not included in these costs are the treatment costs of the (for legal reasons) non-recognized cases. The proportion of recognized cases in relation to the number of reported cases is sometimes very low; for serious skin diseases (Industrial Disease No. 5105), for example, a mere 8 %. This is because, among other things, compensation is only paid if the applicant relinquishes the employment leading to the disease. Generally, before recognition, a long-term medical history also exists, the treatment of which is financed by the health insurance.

In addition, illness-related manpower costs can be calculated from the case numbers.

Information on the costs of recognized, industrial, dangerous substance-related diseases can be taken from the statistics of blue-collar associations. For the reasons outlined above, these figures mark the absolute lower boundary of the actual costs of harm.

Substance-**specific** diseases can be differentiated from those for which exposure to industrial substances is only one of the possible causes.

Table IV-5: Costs to blue-collar trade associations from some industrial, dangerous substance-related diseases in millions of euros (HVBG 2004)

Substance	2002	2001	2000
Aromatic amines	15.1	15.4	12.5
Benzene	12.8	13.0	11.8
Halogenated hydrocarbons	7.6	6.7	6.6
Wood dust	5.4	5.9	5.0
Chromium	4.7	4.5	4.3
Isocyanates	4.9	4.1	3.3
Alkyl, aryloxides and sulfides	2.3	2.3	2.1
Nickel (excluding allergies)	1.7	1.9	1.5
Organic solvents	0.8	0.8	0.6
Total 2002 (excluding wood dust)	49.9		

Table IV-6: Costs to blue-collar trade associations from industrial asbestos, skin and asthmatic diseases (HVBG 2004)

Disease	2002	2001	2000
Asbestos diseases	295.1	291.2	236.8
Skin diseases	157.5	131.4	131.1
Asthma	119.6	107.2	104.9

Beside the compensation paid by the professional associations themselves, costs accrue for the employer due to loss of manpower. The Bau BG (construction trades association) assumes manpower loss costs at the same magnitude as the compensation payments (Rühl 2004).

If these costs are distributed to the total population of Germany, the following costs result:

- **1.30 euros per capita and year** for substance-specific compensation payments by the professional association and illness-related manpower loss costs for the companies (50 % of the sum is for manpower loss costs, 50 % for compensation).
- A further **4.70 euros per capita and year** for industrial chemicals-related skin and respiratory diseases not related to a specific substance. Calculation: non-substance-specific skin diseases 4 euros and asthma-diseases 3 euros per capita and year (50 % again manpower loss costs). According to RPA estimates, 88 % and 40 % of this, respectively, is due to chemicals. However, RPA arrives at generally substantially lower costs of harm in their study, because here they calculate with only 640 to 1,180 euros treatment costs per case (excluding compensation) (RPA 2003a).

In a study carried out by the Federal Agency for Industrial Safety and Industrial Medicine (BAuA 2002), the costs of industrial disease were derived from the usual risk factors used in epidemiology and based on empirical investigations in two branches. This includes diseases due to dangerous substances.

Dangerous substances contribute some 7 % to the unfitness to work in Germany and generate approximately 3 billion euros in direct (illness treatment) and 2.7 billion in indirect (disability) costs per year. A total, then, of 5.7 billion euros. Approximately 30 % of this sum are due to high, preventable workplace burdens. For the total population, this results in **21 euros per capita and year** in preventable costs from work-related encounters with dangerous substances (BAuA 2002).

Can REACH contribute to recognizing the dangerous properties of substances? Yes, the appropriate information is required at the time of registration. A harm prevention effect is expected by REACH for skin diseases due to the systematic check for sensitizing properties at registration. It is obvious from the substance-**specific** disease

costs that unknown substance properties cannot be the cause of a part of the costs. The dangers are known and are expressed in the declarations of these substances.

Does REACH do anything new for industrial safety? Yes**,** although REACH will not alter any of the material requirements for industrial safety. A danger assessment at the workplace and appropriate protective measures are legal requirements. But what REACH can do is ensure that the information provided by the chemicals manufacturer is more practical and thus more effective for the user**.** Because the creation of practically functional exposure scenarios is a prerequisite of the right to market the substance, REACH will exercise a greater motivating force than the TRGS 220. In addition, REACH improves the enterprises' information base and more effectively implements the minimization and substitution of dangerous substances decree.

Can REACH contribute to changing user behavior? *No,* REACH will hardly be able to prevent diseases caused by deficient industrial safety management (e. g. absent instruction and training, insufficient participation of employees in danger assessments). REACH acts where an insufficient information flow or an unclear allocation of responsibilities **between** enterprises exists in the supply chain.

IV.5.5 Allergy diseases in the general public

Approximately 7 % of the general public in mid-European societies is affected by contact eczema, that is, over 5 million people in Germany. Around 10 to 20 % of the population is sensitized (SCHNUCH et. al. 2004). Schnuch suspects that the high number of illnesses is due to the ubiquitous distribution of allergens. Here, they emphasize that if privately acquired sensitization exists, subsequent, work-related diseases are excluded from compensation. That is, there is a potential liability loophole.

About 3000 substances are known to initiate allergic contact eczema (UBA 2004). They include synthetic industrial chemicals, industrially utilized natural substances and non-industrially utilized natural substances. Detailed figures are available on the frequency in epicutaneous tests in Germany of the 30 most common contact allergens, from which priorities for preventive measures can be derived. At the forefront are: nickel sulfate, fragrance mix, Peru balsam, cobalt chloride, p-phenylendiamine (hair coloring agent and textiles), wool wax alcohols, colophonium, potassium chromate (e. g. cement, corrosion protection, leather), the antibiotic neomycin, the preservatives methylbromoglutaronitril, phenoxyethanol and chlormethylisothiazolinone, thiuram mix (in rubber), formaldehyde, benzocain (local anesthetic), parabenes, epoxy resin, turpentine (UBA 2004)

The specific contribution of industrial chemicals to the occurrence of contact allergies among the general public cannot be quantified. However, the list of the commonest allergens makes it clear that industrial chemicals play no small part here.

With the aid of case-specific treatment costs, a disease rate of 7 % can be extrapolated to total annual costs. Based on a study by the Danish Environment Ministry (Serup-Jansen et al. 2004), the annual costs for a sick person are around 840 euros. With 5 million sick persons, this results in 52 euros per capita per year for the total German population for diagnosis costs, public treatment costs, private treatment costs and man-power loss at the workplace.

It is not possible to make a reliable estimate of the contribution to this sum of contact allergens in chemical products. But even if only 1 % to 10 % of these costs were due to contact with allergens in chemical products, the costs would be **0.5 to 5.2 euros per capita and year.**

Can REACH contribute to recognizing the allergenic potential of substances? Yes, a test for skin allergy effects is envisaged at registration.

Does REACH apply to the uses of known allergens? Yes, but with limitations. The potential effects of REACH are restricted to health-oriented effects; cosmetics are not impinged upon. This means that routine testing of sensitizing properties for all registered substances will only provide additional benefits with regard to industrial chemicals, but not for cosmetics.

Can REACH contribute to a more effective restriction of the fields of use based on the recognized potential effects? Yes, in addition to the identification of allergens, determination of exposures is a major requirement in the fight against contact allergies (UBA 2004). This reveals a second principal effect of the REACH system: the substance manufacturer defines the field of use of his substances and examines which exposures may occur within the life cycle and how they may be prevented. Theoretically, exposure to allergens in clothing, footwear, paints and coatings, construction materials, adhesives and plastics can thus be prevented. However, this only applies to products with a supply chain located predominantly within Europe. For contact allergens in imported products, REACH will only show a direct effect as of 2017 (coming into force of Article 6 of the REACH regulations). From that time, importers of products containing individual substances with volumes > 1 t/a that can be inadvertently released in risk-relevant amounts must inform the chemicals agency of this. Nevertheless, considering the volume threshold and the release criterion, it is not certain whether this mechanism will be effective for allergens in products.

IV.5.6 Skin cancer in the general public

The increase in skin cancer in the last few decades is due to intentional exposure, as a result of beauty ideals and other behavioral factors. At the same time, the UV filtering effect of the atmosphere has been reduced by release of CFCs and the ensuing depletion of stratospheric ozone. This effect has contributed to the increase in skin cancer among the general public. The associated costs can be estimated.

UNEP estimates give a figure of around 8000 additional skin cancer cases per year to be expected in Germany due to stratospheric ozone depletion (UNEP 1998). Based on the global estimates of the WHO for all cancer cases, the result is, on average, approximately 10 % "black" skin cancer (melanoma) and 90 % lighter ("non-melanoma") skin cancer (of which 10 % severe cases). If the AOK Saxony/Dresden University Clinic cost estimates of 50,000 euros for each severe case of skin cancer not detected early enough are accepted, this results in treatment costs of **0.5 euros per capita and year.**

The methodic difficulty involved in calculating these costs is that no official, diagnosis-specific costs are available. The figures given are for curative worst-case costs. It is possible to reduce costs by the prevention of severe cases by early diagnosis. Taking other factors into consideration, such as loss of quality of life and manpower losses for less severe cases, would increase the calculated costs.

A major technical benefit of CFCs was that they are neither flammable nor explosive. That is, in the first half of the last century, CFCs were viewed as a safe substitute for refrigeration systems, textile cleaners and metal cleaning systems. Initial hypotheses on the possible effects on the ozone layer were formulated in 1974. Only 13 years later was the Montreal Protocol signed, signaling the end of the widespread use of CFCs (CEC 2003b).

Would REACH have lead to the potential effects of CFCs being recognized earlier? No, ozone-depleting effects were not standard end points in substance classification at the end of the nineteen-sixties. Once the potential effects were recognized and understood, this substance group was abandoned relatively quickly. The existence of REACH would probably not have lead to acceleration of this process.

Would REACH have lead to a more effective restriction of the fields of use based on the recognized potential effects? Yes, the responsibility for integrating of recent knowledge in the formulation of risk management measures for the maintained marketing period would have been with the substance manufacturer and not with the authorities. This would have lead to substitution efforts by the users being initiated several years earlier*:* The substance could have only been sold if the manufacturer had noted

that CFCs may only be utilized in closed systems (i. e. not in foam rubbers) and if documentation of the old substances was guaranteed.

IV.6 Summary of the potential benefits of REACH

The safe use of substances and preparations in products and processes depends on the following requirements, among others:

- The existence and availability of sufficient information relating to the substance identity (including impurities) and the dangerous properties of the respective substance, where the data themselves are not as important as a systematic evaluation.
- The availability of a suitable standard instrument for use and exposure-related evaluation of the substance properties and defining the respective safe (user-oriented) conditions for use.
- The availability of a suitable standard instrument to communicate this information within the supply chains (including user-oriented information preparation).
- The availability of the required technical knowledge and necessary management capacity in enterprises to generate the necessary information and to understand and to convert into measures.
- Unequivocal definition of responsibility boundaries and responsibility transfer (and thus liability risks) between the actors within the supply chains, which includes suitable documentation standards.
- The existence of a motivating background with regard to the regulative and market-oriented framework.

From this standpoint, the potential benefits of REACH can be summarized as follows on the basis of this analysis:

The REACH system will significantly improve the information basis for the health and environmental properties of substances not previously judged to be dangerous as a legally binding catalogue of information requirements will be introduced to the market. Formulators and downstream users can thus better assess the properties of the raw materials they use and document the safety of these substances.

The substance manufacturer’s estimation of exposures for the application of substances and the description of the practically safe application conditions is a prerequisite for the marketing of a substance. This creates a stronger incentive at the manufacturer level to actually take exposure into consideration, in contrast to the current requirements of the TRGS 220.

The risk-relevant properties of raw materials are comparable thanks to the obligatory set of basic information in the REACH system. REACH would mean that companies would not longer be able to enjoy a market advantage from not having to label dangers because no information is available or was gathered (as in the current system). At the same time, the authorities will have to enforce this system in the traditional manner.

REACH will introduce a common system for the systematic, incremental evaluation of existing data stock and the generation of additional information needed on substance properties and exposure patterns. The current information gaps for existing substances can thus be closed in a cost-effective, harmonized manner. However, some of the instruments needed for the implementation of the concept are lacking.

In addition, a mechanism is installed that forces substance users to decide whether they want to talk to the substance manufacturer about the condition for safe application or whether they want to assume responsibility for the exposure and risk assessment themselves. This mechanism clearly demarcates responsibilities. The system thus creates incentives for information transfer from the substance user to the substance manufacturer.

The interaction of chemicals law and health and environmental protection for specific substances has already become so complex that small- and medium-sized enterprises often cannot cope. The implementation deficits in the standard instruments of chemicals legislation that have been repeatedly noticed for many years (safety data sheets, classification, declaration, etc.) can also be explained by this inability to cope. If the information and evaluation processes cannot be simplified in the course of the implementation of REACH, the already existing implementation deficit will only grow.

Based on a variety of historic and current case histories, it can be illustrated whether and how the REACH system can contribute to preventing chemicals-related harm costs. The analysis has lead to the following insights:

- The recognition of new substance effects is not supported by REACH, because the information requirements to Annexes V to VIII only contain standard end points. In other words, even after the REACH system has been introduced, there will be “surprises” in terms of the effects of substances. The ozone depleting effect of CFCs, for example, was a new realization at the beginning of the nineteen-seventies.
- REACH will not be able to reduce health and environmental damage caused when available information is ignored and laws are not enforced any more than current legal requirements could. For example, skin protection is not always used sufficiently when chemicals are used at the workplace.

- The systematic identification of skin sensitizing substances can be promoted by REACH and thus contribute to the prevention of skin diseases at work and in private life.
- The stronger weighting of the exposure assessment in the REACH system and the definition of safe areas and conditions of use improves environmental and health protection with regard to substances with known harmful properties.
- The **estimated** value of the per capita costs of harm for documented cases is predominantly around 0.5 to 5 euros per year. Considering that local authority PCB remediation programs on buildings can extend over periods of 10 years, these costs are of a magnitude similar to the given range. To what extent REACH can prevent costs cannot be quantified, because REACH can only influence a part of the background in **current** cases of harm. In the known cases with **historical** causes of harm (PCBs, CFCs), REACH can make no contribution to cost reduction.

V The effects of REACH on the supply chain of washing and cleaning agents

V.1 Analysis of the structure of the supply chain of washing and cleaning agents

This case history considers reportable products within the scope of the German Washing and Cleaning Agents Act (WRMG - *Wasch- und Reinigungs-mittelgesetz*). The products concerned are defined in Article 2, Para. 1 WRMG: "Washing and cleaning agents ... are products intended for cleaning purposes ... and which experience indicates may enter aquatic systems after use.“ They include textile washing agents, and household, commercial and industrial detergents. Organic solvents (hydrocarbons), such as those used to remove greasy deposits, are not included if they do not enter aquatic systems but are disposed of as waste after use.

The products affected by the WRMG can be divided into two sectors according to their scope of use:

(a) Washing and cleaning agents for household and similar uses. This includes, for example, textile washing agents, dishwashing agents, household cleaners for the kitchen, bathroom and restroom, and for glass.

(b) Cleaning agents for industrial and commercial applications, including public facilities (e. g. public health service) and in agriculture. They include metal degreasing, vehicle washing facilities, janitorial services, gastronomy and the food industry, commercial laundries, hospitals and agricultural producers.

With a turnover of around 3.9 billion euros, household washing and cleaning agents represent by far the most important market sector (IKW 2004a)[39]. In 2002, the washing and cleaning agent turnover for industrial and commercial applications was 595 million euros (IHO 2003)1[34]. However, this also includes products based on organic solvent formulations. Turnover of water-based washing and cleaning agents for industrial and commercial use is somewhat more than 300 million euros. More precise figures and information on the distribution of sales to various uses or product groups are not made available by the IHO.

1 The turnover figures are with reference to member enterprises of the IHO.

V.1.1 Ingredients of washing and cleaning agents

V.1.1.1 Surfactants

The central active ingredient group in washing and cleaning agents for aqueous environments are the surfactants. This applies equally to washing and cleaning agents for uses in the household and for industrial and commercial applications. Surfactants are surface active agents; they always consist of one hydrophobic and one hydrophilic molecule component. This structure allows them to reduce the surface tension of water, penetrate adhesive oily and greasy soiling of fibers and surfaces, loosen off the dirt and hinder its redeposition by keeping it in aqueous solution (soiling carrying capacity). Surfactants represent the largest group in the manufacture of detergent raw materials. In 2002, around 2.5 million tons of surfactants were manufactured in western Europe (CESIO 2002)[38], of which, according to TEGEWA, approximately 400,000 tons annually are used in Germany2 [36]. Surfactants also have a wide range of uses outside of the field of washing and cleaning agents. They range from additives in concrete to paints and ice cream. The German Federal Statistical Office (Statistisches Bundesamt) gives the total production of surfactants for 2002 at 1.28 million tons (Statistische Bundesamt, 2003)[44]3.

Because of their ability to reduce the surface tension of water, surfactants are toxic in higher concentrations to fish and other aquatic animals. Their concentration in surface aquatic systems is limited by the demand for rapid biodegradability. No critical metabolites should occur as a result of their reduction. With a final biodegradability of more than 90 %, the substances used on a large scale today as surfactants easily fulfill these requirements. After prolonged contact, surfactants can cause skin irritation in humans. Many surfactants are classified as dangerous substances, in line with Directive 67/548/EEC.

Surfactants are divided into anionic, cationic, non-ionic and amphoteric surfactants. The oldest and best known surfactant is soap. Soap manufacture can be traced back to the 3rd century B.C. It is therefore one of the oldest consumer chemicals known to man. Soap is an anionic surfactant and is used in large quantities in personal hygiene products. It is also present in small quantities in modern washing agents as a foam inhibitor. Further anionic surfactants of great economic importance are linear alkylbenzene sulfonate (LAS), fatty alcohol ether sulfate (FES) and fatty alcohol sulfate (FAS). Tetra-

2 TEGEWA interview on 02/25/2004

3 TEGEWA considers this figure to be too large and assumes that it also includes preparations containing surfactants.

propylene benzene sulfonate (TPS) only biodegrades with difficulty and is of no economic importance today. During the fifties it was responsible for causing the extensive foaming seen on water bodies. In the anionic surfactants the hydrophilic component is negatively charged. They can be manufactured cheaply and are used in large-scale applications.

With regard to quantity, the non-ionic surfactants form the second most important surfactant group. They do not form ions in aqueous solution. The hydrophilic component of the molecule consists of highly polar bonds. The most significant non-ionic surfactants are fatty alcohol ethoxylate (FEAO) and fatty acid ethanolamide (FAA). The alkyl phenolethoxylates (APEO) previously used, including nonyl phenolethoxylate (NPEO), are inexpensive surfactants with excellent technical properties. However, upon degradation, metabolites result which are toxic to aquatic life. For this reason they are now very rarely used in Germany. Since 1987, industry has voluntarily foregone their use in household washing and cleaning agents, as well as in detergents for commercial laundries. In the EU, their use was limited in 2003 by Directive 2003/53/EC. Figure V-1 shows the successful substitution of APEO in industrial washing and cleaning agents since the middle of the eighties.

In the cationic surfactants, the hydrophilic component carries a positive charge. They occur primarily as washing agent additives, in fabric softeners, for example. Due to their positive charge they can attach to textile fibers and surfaces, hydrophobize them and thus hinder electrostatic charges. Some cationic surfactants are microbiocidal, making them suitable as disinfectants and preservatives. Dodecyl dimethylbenzyl ammonium chloride is one of them.

The hydrophilic component of amphoteric surfactants consists of a negatively charged and a positively charged group. The principle representatives are the alkyl betaines (betaine). They possess very good washing properties, can be combined with other surfactants, are insensitive to hard water, possess only low toxicity, and are hypoallergenic. They are used sparingly in washing and cleaning agents due to their price. They are employed primarily in personal hygiene products.

Figure V-1: Substitution of APEO in industrial washing and cleaning agents in Germany (source: IHO)

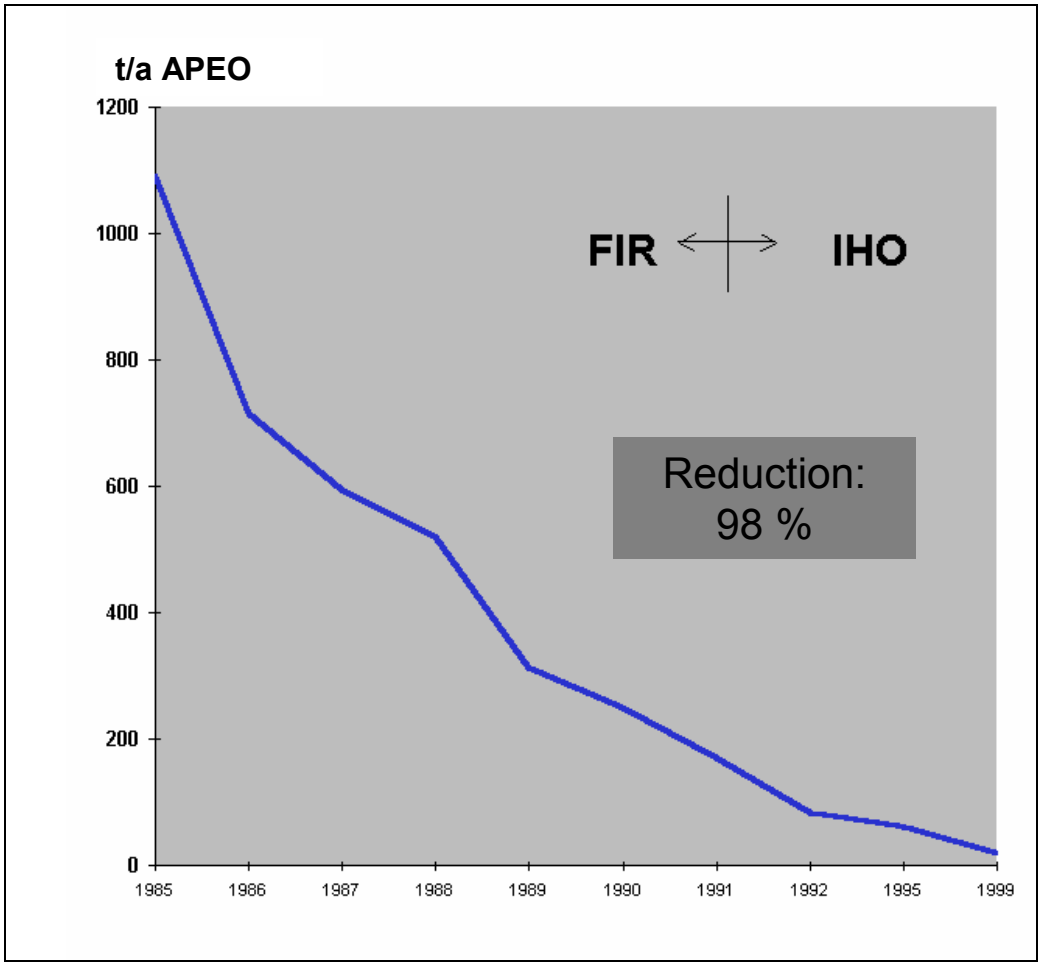
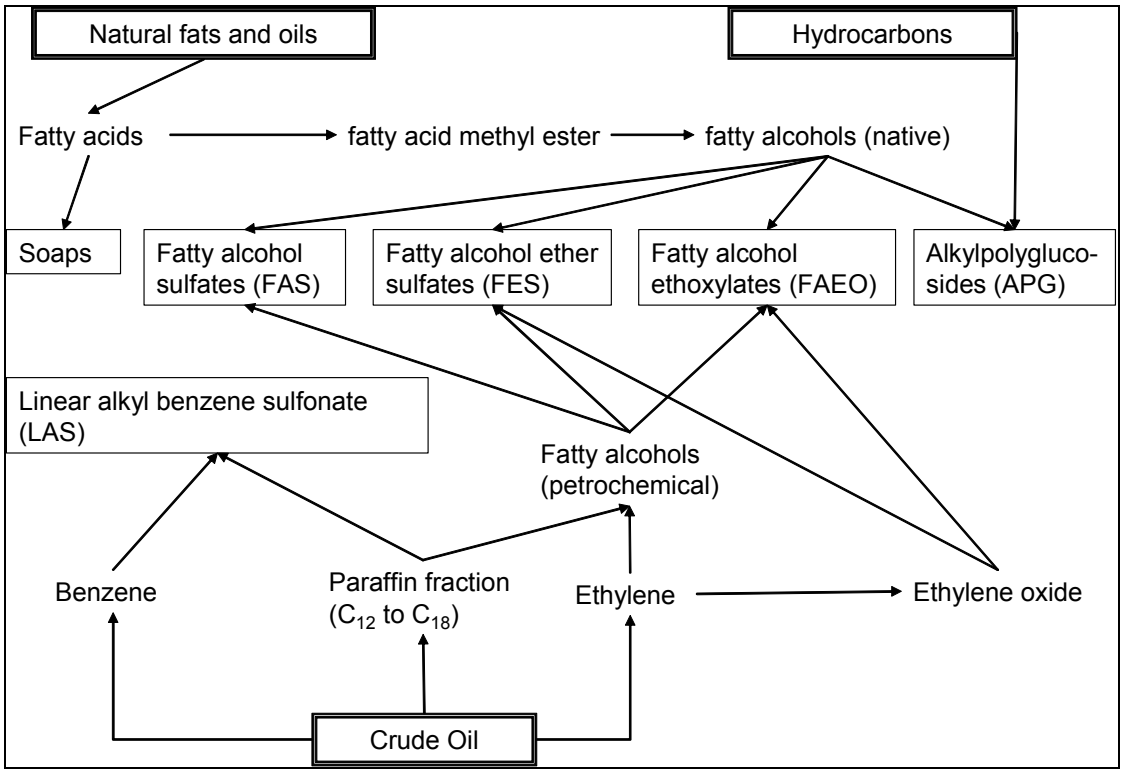


Table V-1 Use of surfactants in household washing and cleaning agents in Germany in 2002 in tons (source: IKW)

	2002	**2000**	**1995**
Anionic surfactants	101,262	101,200	86,000
Non-ionic surfactants	49,936	53,600	48,000
Cationic surfactants	32,108	35,200	23,400
Amphoteric surfactants	3,256	2,700	1,600
Total	**186,562**	**192,700**	**159,000**

Soap is extracted from biogenic fats and oils. The principal raw materials are beef tallow, lard, coconut oil, palm oil and palm kernel oil. LAS is synthesized from petrochemical-based raw materials such as crude oil. Surfactants based on fatty alcohols such as FAS, FES and FAEO use petrochemical-based raw materials, as well as animal or vegetable fats and oils.

Figure V-2: Raw material base for the manufacture of anionic and non-ionic surfactants (Wagner 1993)



V.1.1.2 Further ingredients

The following summary describes the function of the principal ingredients of washing and cleaning agents (Hauthal et al. 2003)[33]4:

Acids and alkalis — Acids sustain the eradication of mineral soiling such as lime stains, cement residue, rust, etc. Hydrochloric acid, sodium bisulfate (NaHSO4), acetic acid, citric acid and others are employed. Greasy and oily soiling are best re-

4 A comprehensive list of substances, ordered according to active ingredient groups and substance designation, is available from the German Federal Environmental Agency (http://www.umweltdaten.de/daten/wasch/inhalt.pdf). The list is the result of the evaluation of registered washing and cleaning agents.

	moved in an alkaline environment. Soda, sodium silicates and sodium hydroxide are employed here, for example.
Bleaching system	Removes colored soiling by using oxidizing agents, such as hydrogen peroxide or sodium percarbonate. In order to lower the treatment temperature, bleaching activators such as TAED are employed.
Enzymes	Are used mainly in washing agents and dishwashing agents to remove soiling containing proteins. Today, they are genetically manufactured and lower the treatment temperature (energy-saving).
Biocides	Kill microorganisms on the surfaces being cleaned and stabilize the aqueous cleaner recipe (preservative).
Solvents	Water-soluble solvents support the action of the surfactants and help to achieve a residue-free surface. Important solvents are alcohols, glycols and glycol ethers such as ethyl alcohol, propyl alcohol, glycerin and butyl glycol.
Hydrotropes	Hydrotropes are solubilizers that can influence the viscosity of liquid cleaning formulations.
Abrasives	They facilitate removal of solid soiling by mechanical abrasion. Extremely fine-grained quartz, garnet and corundum sands are used.
Complexing agents	In cleaning agents they support bonding of iron, manganese, copper or other heavy metal ions, which would otherwise cause colored marks. Today, sodium phosphonates are used as complexing agents.
Dispersing agents	It is their task to keep the pigment soiling from the cleaned surfaces in the cleaning solution and to hinder its redeposition if the soiling-carrying properties of the surfactants are insufficient. Polycarboxylates are used here, for example.
Thickeners	They increase the viscosity of liquid cleaning agents, for example, in order to extend the duration of action of cleaning agents on vertical surfaces. Pectines, starch, polysilicic acid and other substances are used.
Fragrances	They are intended to mask the often unpleasant odor of cleaning formulations or to provide a pleasant odor to the cleansed objects or areas.
Dyes	In certain care products, they refresh colors (leather, shoes, furniture).

Care components	Ingredients of care products for floor coverings, furniture, leather, shoes, textiles, automobiles, cooking tops, tiles, metals, etc. are wax emulsions, silicons and polymer dispersions, including polyacrylates.
Sundry additives	Corrosion inhibitors, foam inhibitors, etc.

V.1.2 Household washing and cleaning agents

The market for household washing and cleaning agents and similar commercial uses has been stagnating for years (Table V-2). Half of the turnover of about 3.9 billion euros in 2003 was achieved by textile washing agents. Over 90 % of the total turnover is achieved through households [37], less than 10 % for commercial uses similar to households, such as, for example, dishwashing agents in company kitchens. The manufacturers of household washing and cleaning agents and similar uses are organized in the German Cosmetic, Toiletry, Perfumery and Detergent Association (IKW).

Table V-2: Sales of household washing and cleaning agents in Germany in €m (source: IKW)

	1999	2000	2001	2002	2003
All-purpose washing agent	1,204	1,150	1,165	1,145	1,111
Specialized washing agent	243	240	256	248	240
Washing agent additives[5]	577	606	581	560	578
Dishwashing agents	515	516	520	534	546
Household cleaning agents	600	599	603	619	625
Furniture care products	103	142	137	140	153
Leather care products	112	99	95	85	77
Car care products	245	240	235	235	245
Specialized cleaning / care products	247	258	265	292	313
Total market	**3,846**	**3,850**	**3,857**	**3,858**	**3,888**

5 Fabric softener, washing additives, pretreatment, washing care and special treatment products.

V.1.2.1 Ingredients

Despite the impressive chemical properties of the surfactants, they alone cannot constitute a powerful detergent. Further active ingredient groups are required, depending on the specific use, for water softening, foam regulation, bleaching, as corrosion inhibitors and complexing agents (cf. Table V-4).

According to the IKW, around 200 principal ingredients are handled within the industry in active recipes. To this must be added 200 fragrances and 200 dyes. In surfactants, builders, and the substances of the bleaching system, manufacturers of detergent raw materials probably all reach the production tonnage range of over 1000 t/y[6] [37]. Raw material in the tonnage ranges below 1000 t/y, on the other hand, plays a greater role for specialized cleaning agents for the private household and for minor ingredients in general (e. g. dyes). The same applies to cleaning agents for commerce and industry.

Depending on the use, the industry differentiates between the washing agent types in the table below (cf. Table V-3). As can be seen in Table V-5, their formulations can differ greatly. There are manifold further cleaning and care tasks in the household, corresponding to a large range of products. Table V-6 gives a summary of example uses. The final column indicates whether the products for the specific use are registered pursuant to WRMG, i. e. that experience shows they will enter the sewage system.

Table V-3: Household washing agent types

Universal washing agent	**Specialized washing agent**
1. Universal washing powder 2. Universal washing liquid 3. Modular systems (washing agent components)	4. Mild washing agent 5. Coloreds washing agent 6. Wool washing agent 7. Curtain washing agent 8. Hand wash agent

Source: Wagner 1993

6 IKW interview on 02/26/04

Table V-4: Raw material use for formulation of washing, cleaning, polishing and care products for households in Germany, 2002 (Source: IKW)

Substance	t	Proportion	Function
Surfactants	186,562	32.0 %	Dissolving greasy and oily soiling
Zeolites	94,234	16.2 %	Builders for water softening in washing agents
Sodium carbonate (soda)	75,491	13.0 %	Adjustment of alkalinity (pH) of the washing lye when using zeolites
Sodium sulfate (Glauber's salt)	63,013	10.8 %	Filler for powder recipes
Sodium perborate tetrahydrate	30,527	5.2 %	Stain remover. Phytotoxic, thus decreasing in use
Sodium percarbonate	26,216	4.5 %	Stain remover. Substitute for sodium perborate tetrahydrate
Phosphates	20,745	3.6 %	No longer used in washing agents. Cannot yet be adopted as softener in dishwashing agents
Alcohol-based solvents	20,801	3.6 %	Solubilizer in liquid washing agents
Silicates	13,630	2.3 %	Corrosion inhibitor, creates protective coating on aluminum surfaces
Polycarboxylates	11,575	2.0 %	Co-builder for optimizing the action of zeolites
Sodium citrate	11,679	2.0 %	Co-builder for optimizing the action of zeolites
TAED	9,349	1.6 %	Bleach activator
Fragrances	5,866	1.0 %	Approx. 200 individual substances
Enzymes	3,851	0.7 %	Dissolving starch and protein soiling, stain removal. Lowers washing temperature
Phosphonates	2,850	0.5 %	Complexation Substitute for ETDA
Carboxymethylcellulose (CMC)	2,223	0.4 %	Graying inhibitor for cellulose fibers (e. g. cotton)
Paraffins	1,996	0.3 %	Foam inhibitor
Soil repellents	954	0.2 %	Polymers, are absorbed onto the fiber and reduce adhesion of soiling
Discoloration inhibitors	439	0.1 %	Improve the sludge carrying capacity of the surfactants in the washing lye
Optical brighteners	438	0.1 %	Brighten yellowish taints in white laundry
NTA	276	0.05 %	Complexation Substitute for ETDA.
Dyes	99	0.02 %	Approx. 200 individual substances
Sum	**582,814**	**100.0 %**	

Table V-5: Mass proportion of washing agent ingredients in percent (Wagner 1993).

Substance group	**Examples**	**Universal washing powder**	**Compact universal washing powder**	**Universal washing liquid**	**Coloreds washing agent**	**Specialized washing powder**	**Compact specialized washing powder**	**Specialized washing liquid**
Anionic surfactants	LAS, SAS, soap	5-10	15-25	25-40	8-13	13-18	19-24	3-40
Non-ionic surfactants	FAEO, FAA	2-7	4-9	8-15	6-11	1-6	4-9	10-25
Builders	Zeolite A, polycarboxylates, sodium citrate	20-40	15-55	1-4	20-55	10-40	30-70	1-8
Alkalis	Soda	5-15	5-20	0	5-25	0	0	0
Alcohols	Ethyl alcohol, glycerin	0	-	8-12	0	0	0	5-15
Bleaching agent	Sodium perborate, sodium percarbonate	10-25	10-20	0	0	0	0	0
Bleach activator	TAED	1-3	3-8	0	0	0	0	0
Corrosion inhibitors	Sodium silicate	2-6	2-6	0	1-5	0	0	0
Stabilizers	Phosphonates	0-1	0-1	0-+	0-1	0	0	0-+
Foam inhibitors	Soap, silicon oil, paraffins	0.1-4	0.1-2	0	1-3	1-5	1-5	0
Enzymes	Amylases, cellulases, lipases, proteases	01-0.8	0.5-2	0.3-1	0.5-2	0.1-0.8	0.4-1.5	0-2
Graying inhibitors	CMC	0-1	0-1	0	0-1	0-1	0-1	0
Discoloration inhibitors	Polyvinyl pyrrolidon derivatives	0	0	0	0-2	0-0.2	0-1.2	0
Fillers	Sodium sulfate	0-20	0	0	0	0	0	0
Fragrances	Musk compounds	+	0-+	+	+	+	+	+
Optical brighteners	Stilbene derivatives, biphenyl derivatives	0.1-0.3	0.1-0.4	0-0.3	0	0	0	0
Water		Rest	Rest	Rest	Rest	Rest	Rest	Rest

+ ... present in minor quantities

Table V-6: Supply structure for household cleaning and care products (Hauthal et al. 2003)

Cleaning task	Product group	WRMG?
Dishwashing	Hand dishwashing agent. Machine dishwashing agent: Cleaner, rinser, regenerating salt, fragrant rinse, machine care.	Yes Yes
Surface cleaning	All-purpose cleaner, abrasives, cleaning cloths.	Yes
Kitchen cleaning and care	Kitchen cleaner, hob cleaner, ceramic glass hob cleaner, descaler, oven cleaner. Metal cleaners.	Yes Yes/no
Bathroom cleaning and care	Bathroom cleaner, tub and shower cabin cleaner, toilet cleaner, fragrant rinse, flush cleaners, hygienic cleaner, drain cleaner.	Yes
Glass and window cleaning	Glass cleaner, anti-fogging agent	Yes
Floor cleaning and care	Heavy duty floor cleaner, soft soap, all-purpose soap, mopping care products, dry-bright emulsions, carpet cleaner, stone flooring cleaner.	Yes
Furniture care	Furniture polish. Plastic cleaners, plastic care products, upholstery shampoos.	No Yes
Leather care	Shoe care products, leather cleaning and care products for clothing and furniture	No
Car cleaning	Car shampoos, wheel cleaner, windscreen cleaner, paint care products, plastic cleaner.	Yes
Stain removal	Stain remover, stain soaps	Yes
Fragrance improvement	Air freshener, odor absorbers. Textile freshener	No Yes

V.1.2.2 Structure of the supply chain

The supply chain for household washing and cleaning agents is comparatively short. Surfactants and a number of other detergent raw materials are acquired mainly from TEGEWA enterprises. Around 100 enterprises are organized in TEGEWA; of these, some 90 are SMEs. 17 enterprises manufacture surfactants. Among these are 10 large enterprises such as BASF, Bayer, Clariant GmbH, Cognis Deutschland GmbH & Co. KG, Sasol Germany GmbH, Degussa, Dow, Shell Chemicals etc. They make up 93 – 95 % of surfactant sales. The rest is attained by 7 SMEs, including Leuna-Surfactant

GmbH, Wall Chemie GmbH, Kao Chemicals GmbH. 40 % of the turnover of TEGEWA enterprises is achieved with surfactants. There are 50 surfactant manufacturers in total in Europe. They are organized in CESIO, a sub-committee of the European Chemical Industry Council, CEFIC.

According to an internal survey, around 3,000 products are marketed by TEGEWA enterprises, including (pure) substances, preparations and an unknown number of polymers. Surfactants are sold as raw surfactants and as mixtures of substances. Small enterprises primarily draw on substance mixtures, whilst for large enterprises raw surfactants predominate. An average price of 1 euro/kg for surfactants can be calculated from the production statistics of the Federal Statistical Office[7]. The average surfactant component for all supplies is 70 %. Surfactant mixtures are preparations within the scope of REACH. Primarily the surfactant manufacturers themselves produce the upstream products, such as ethylene oxide, propylene oxide and alcohols, for example. Foreign trade of such upstream products with countries outside Europe is negligible.

The washing agent market in Germany is dominated by the three large enterprises Henkel KGaA, Procter & Gamble and Lever Fabergé. They make up 85 % of sales; the rest falls to about 90 SMEs. The SME market sector is disproportionately higher for the cleaning agent market[8].

Retailers are the direct customers of the IKW enterprises. The manufacturers sell their products under their brand names, such as Henkel (Persil), Procter & Gamble (Ariel), Lever Fabergé (Sunil), Fit (Rei), Domal-Wittol (domal), for example. Contract manufacturers produce trade names for retail discounters such as ALDI (Tandil), for example. Discounters (e. g. Aldi, Lidl) and drug store chains (e. g. Schlecker, dm, Rossmann) play a decisive role in market pricing. Foreign trade of washing and cleaning agents with regions outside Europe is negligible. However, the importance of EU-internal trade is increasing. For example, of the three large washing agent manufacturers, only Henkel still produces washing agents in Germany.

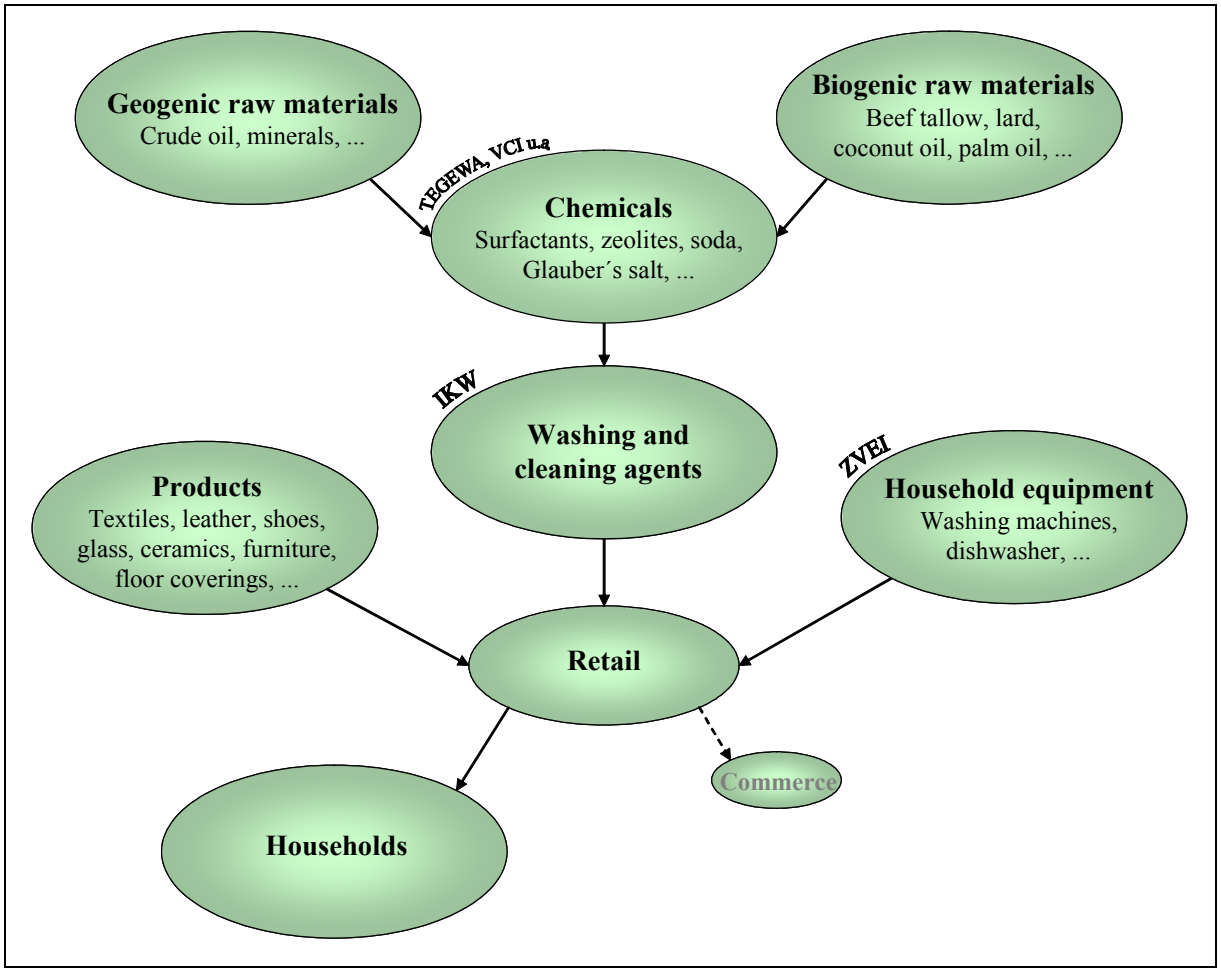
Development of washing and cleaning agents is not possible without the cooperation of the manufacturers of products such as textiles, shoes, ceramic-glass hobs, etc. As far as washing or cleaning is carried out using machines, a certain amount of coordination with the manufacturers of washing machines, dishwashers, etc. is also necessary. This results in the supply chain structure shown in Figure V-3. The arrows indicate product flows. The substances and products mentioned are for illustration only. Where

7 TEGEWA interview on 02/25/2004

8 IKW interview on 02/26/04

they are of interest, the associations of the enterprises active at the respective level in the supply chain are named.

Figure V-3: Supply chain in the household washing and cleaning agent sector



V.1.3 Cleaning agents for commerce and industry

The manufacturers of cleaning agents, washing agents, care products, disinfection agents and preservatives for industrial, commercial, institutional and agricultural applications are organized in the Hygiene and Surface Treatments Association (IHO)[9]. The industry structure represented by the IHO consists principally of medium-sized enterprises. About 40 member enterprises achieve approx. 80 – 85 % of the total industry

9 The manufacturers of solvents and additives for chemical textile cleaners do not form part of the IHO. Nor are special cleaning agents for the manufacture of electronic components supplied by IHO enterprises.

sales. Among the large enterprises are Henkel Surface Technologies, Henkel Ecolab GmbH & Co OHG, JohnsonDiversey GmbH & Co. OHG, Chemetall GmbH und Castrol Industrie GmbH.

On average, 500 – 1000 raw materials[10] per company are processed to around 500 formulations; large enterprises may have 1000 – 2000 products in their portfolio. On average, relations are maintained to 2.5 raw material manufacturers per raw material. Preparations contain 5 to 25 components, among them dangerous substances within the scope of Directive 67/548/EEC, for example surfactants. CMR, PBT or vPvB are not present in the formulations.

The average price of a formulation is given at 2.00 €/kg[11] [35]. Competition between suppliers is strong, and it is difficult to pass increased costs on to the customer.

V.1.3.1 Applications

The application sectors served are extremely wide-ranging. Table V-7 summarizes applications and examples for the sectors of the economy served[12]. The association structures these products' uses into five fields:

- Metal industry and technical cleaning
- Janitorial services and canteen kitchen hygiene
- Foodstuffs manufacturing and processing
- Public health
- Laundry technology

10 Generally not individual substances with a CAS or EINECS number but formulations of several substances.

11 IHO interview on January 21, 2004

12 A classification of the applications for washing and cleaning agents, originating in the Federal Environment Agency's registration practice for washing and cleaning agents is available from their website at http://www.umweltdaten.de/daten/wasch/standard.pdf.

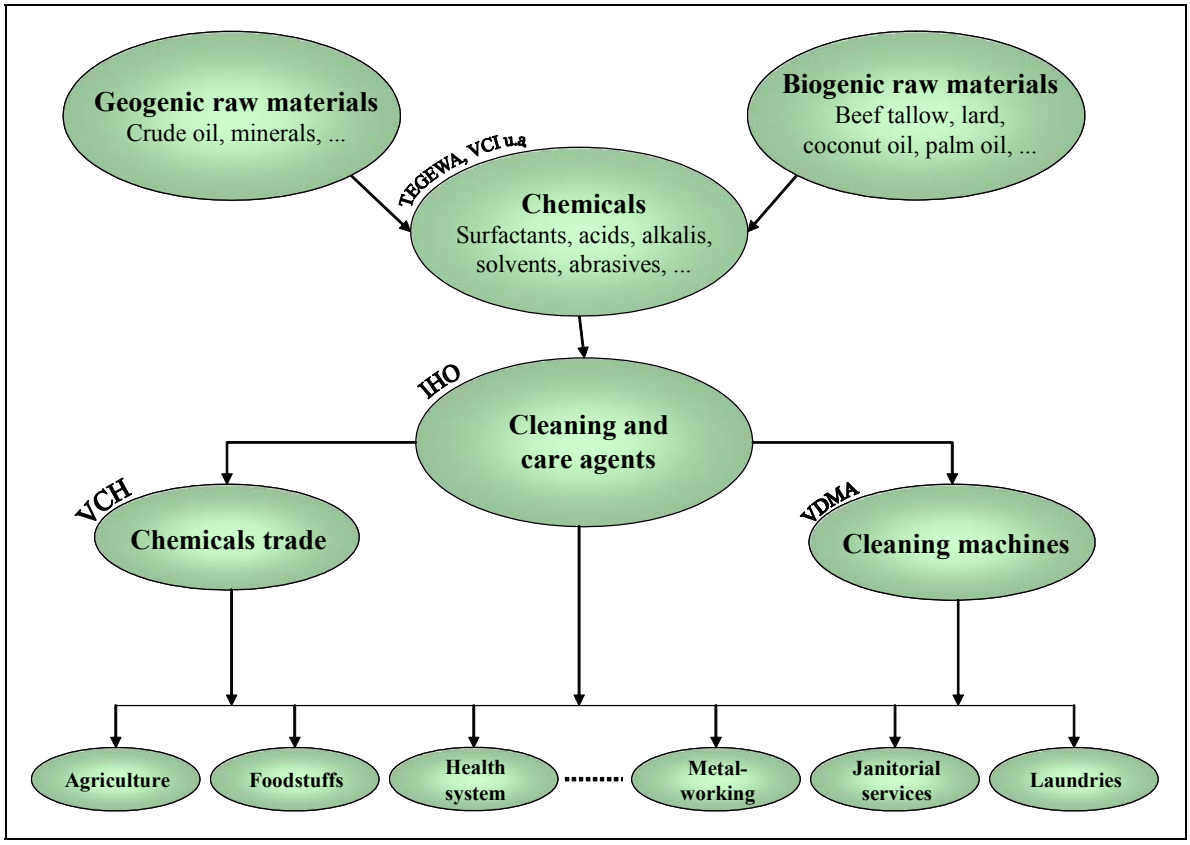
Table V-7: Classification of uses for industrial and commercial cleaning agents

Cleaning in the services industry	
Janitorial services	Floor coverings, windows, tiling, etc.
Workshop cleaning	Floor coverings, windows, tiling, etc.
Vehicle cleaning	Trams, busses, cars, trucks, aircraft
Commercial laundries	Workwear, towels, cloths, etc.
Industrial metal degreasing	
Machine cleaning of metallic parts	Mass-produced parts, assembly parts
Manual parts cleaning in workshops	Appurtenances, brake drums, etc.
Manual cleaning of capital equipment	Lathes, punches and milling machines, etc.
Specialized cleaning	
Printing drum cleaning	Printers
Plastics casting machines	PUR, epoxy, silicon, etc
Product finishing	Electronic equipment, cameras, etc.
Depreservation of cars	Removal of paraffin wax
Fine cleaning	
Electronics	Circuit boards, etc.
Optical lenses and glasses	Objectives, binoculars, etc.
Precision engineering	Watches, clocks, etc.
Cleaning in the public health industry	
Hospitals	Cleaning, disinfecting, surfaces, instruments
Doctor's practices	Cleaning, disinfecting, surfaces, instruments
Cleaning in agriculture	
Capital equipment	Milking machines, etc.
Stables	Cleaning, disinfection
Cleaning in foodstuffs processing	
Capital equipment	Vats, juice presses, agitators, etc.
Slaughter houses and production sheds	Tools, floor coverings, tiling, etc.
Sundry uses	

V.1.3.2 Structure of the supply chain

For commercial cleaning and care products the supply chain is also comparatively short, but branches quite strongly at the applications level. The metalworking industry, janitorial services and foodstuffs processing represent particularly important market sectors. The surfactant raw materials are provided by TEGEWA enterprises, similar to household washing and cleaning agents. About 50 % of the surfactants for washing and cleaning agents are utilized in the commercial and industrial fields; the rest, in household washing and cleaning agents.

Figure V-4: Supply chain in the industrial and commercial cleaning and care products sector



In addition to the direct business relationships between enterprises, the chemicals trade also plays a role in the supply of chemicals. Medium-sized formulators and the applications industry in particular take advantage of the services of the chemicals trade. The cooperation between manufacturers of cleaning machines is predominantly bilateral, either between formulators and engineering or between the chemicals trade

and engineering. Enterprises devote up to 50 % of their personnel costs to the sales department[13] [35].

The interlocking trading links within the EU have increased in importance. The import and export of raw materials and preparations from and to countries outside of Europe plays only a minor role.

Figure V-4 shows the supply chain for commercial washing, cleaning and care products. The arrows characterize product flows. The names are given for the associations of the principal actors in the respective level of the supply chain. The interlinking shows the chemicals trade as the central pivot in this sector.

V.1.4 Basis of the empirical investigation

V.1.4.1 Overview of surveyed enterprises

Thirteen enterprises at various levels of the supply chain were surveyed for the purpose of this investigation. These included one substance manufacturer, one importer, seven formulators and four downstream users. The selection of enterprises was based in part on proposals or on the mediation of the associations, in part on proposals of other members of the advisory committee, and in part from research carried out by the authors. The survey covers a wide range of enterprise sizes. Of the 13 enterprises questioned, two are small enterprises according to the EU definition (fewer than than 50 employees and less than €10m turnover) and 3 are medium-sized enterprises (less than 250 employees and less than €50m turnover). The distribution of the companies with regard to turnover and employment is given in Table V-8. The letters are used in the following depiction of the empirical analysis to provide a relationship between the interview data, on the one hand, and the field of activity and the enterprise size, on the other, and thus to put the statements of the enterprises better into context.

Enterprises k, l, and p on the downstream user level were also analyzed within the analysis of the supply chain for paint and coatings (*cf*. Chap. I.5). They are anonymized there using the following letters

- Company k in Chap. V corresponds to Company K in Chap. VI;
- Company l in Chap. V corresponds to Company L in Chap. VI;
- Co*mpany p* in Chap. V corresponds to *Company P* in Chap. VI;

13 IHO interview on January 21, 2004

Table V-8: Structure of surveyed enterprises

	Position of the enterprise in the chain	Employees	Turnover in €m
0	Importer	780[1)]	1,000
a	Substance manufacturer (surfactants)	2,000	1,500
b	Washing and cleaning agent manufacturer (janitorial services, industrial metal degreasing)	25	5
c	Washing and cleaning agent manufacturer (commercial laundries, janitorial services)	48	9
d	Washing and cleaning agent manufacturer (commercial janitorial services)	170	26
e	Washing and cleaning agent manufacturer (household washing and dishwashing agents)	98	31
f	Washing and cleaning agent manufacturer (household washing and cleaning agents)	132	45
g	Washing and cleaning agent manufacturer (surface engineering, automobile chemistry, chemicals trade)	150	60
h	Washing and cleaning agent manufacturer (industrial metal degreasing)	250	65
i	Washing and cleaning agent manufacturer (janitorial services)	23,500	328
k	Washing and cleaning agent downstream user (automobile chassis)	31,800	14,000
l	Washing and cleaning agent downstream user (agricultural machines)	2,200	520
p	Washing and cleaning agent downstream user (forklift trucks)	3,500	1,200

1) including branches

V.1.4.2 Represented market sectors

A series of selection principles were used to define the section of the supply chain for the washing and cleaning agents to be investigated in more detail. On the one hand, solvent-based washing and cleaning agents were excluded and the focus placed on the industrial-commercial cleaning of surfaces, because the metal surface cleaning field uses water-based preparations for 60 % of its cleaning processes. A mere 10 % of cleaners were based on high-temperature hydrocarbons and 20 % on CHC solvents. The latter are also a special case in Germany because of their use in predominantly closed systems and in leasing models, although they are certainly of interest in the context of REACH with regard to the controlled use of dangerous substances.

Moreover, market sectors that strongly overlap with other areas of regulation were ignored, because an analysis of the meeting points involved would not have been possible within the scope of this project. For example, it is against this backdrop that disin-

fection agents and washing and cleaning agents in foodstuffs-related fields (e. g. canteen kitchens), were excluded[14]. However, the question of the meeting point between REACH and other regulators is a very high priority for the enterprises concerned, and the screening of the various legislative areas for overlap was formulated very clearly in the interviews as a brief for politicians. For the purpose of this project, the meeting point problem is illustrated using the example of the selected market sectors.

Finally, areas were explored that simplify the comparison of household and industrial uses. These factors finally led to the selection of the industrial metal cleaning, car washes, janitorial services, commercial laundries and household washing and cleaning market sectors. The industrial uses are described briefly below.

V.1.4.2.1 Machine cleaning of metallic components

Metal parts are often contaminated with oil and grease during working. For instance, during machining with oil-based lubricants, parts are submerged or may be purposefully coated with bending and drawing greases during forming processes. Before further processing, painting or galvanic coating, the parts must be free of oil and grease contamination. Cleaning machines are used for this purpose; in addition to organic solvents, they employ aqueous cleaning systems as the washing solution.

Aqueous cleaning methods cannot be as universally adopted as organic solvents (UBA 1998). The cleaning agent and the dosage in the machine are therefore attuned very specifically to the cleaning agent and the particular soiling. For example, alkaline cleaning agents attack aluminum in particular, while acid cleaning agents attack non-ferrous metals such as copper. Generally, if the cleaning agent recipe is altered the machine must be correspondingly adjusted. Here, close cooperation between the machine manufacturer and the manufacturer of the cleaning agent is both necessary and common.

V.1.4.2.2 Janitorial services

The tasks performed by commercial janitorial services are, in part, similar to cleaning tasks in the household. However, the cleaning tasks are more diverse. For instance, escalators, clean rooms in the electronics industry, machines in production sheds, ducting in air-conditioning systems, etc. must all be kept clean. In the commercial field,

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14 Some participants in the working group proposed a limitation to industrial disinfection agents due to their high health and environmental relevance. However, the advisory committee reached a consensus that this was a special case.

cleaning machines are used to increase efficiency. A distinction is made between sweepers and suction sweepers, scrubbing machines, vacuum washers, vacuum cleaners, steam cleaners and high-pressure cleaners. Specialized machines with the corresponding cleaning and care agent system are used for each cleaning task. The machine manufacturers, such as Alfred Kärcher Vertriebs-GmbH, see themselves as system suppliers, offering the machine and the chemicals system together. Large machine manufacturers offer a range of almost one hundred cleaning and care products. Janitorial services constitute a subset of facility management, and they are provided by specialized service enterprises.

V.1.4.2.3 Vehicle cleaning

Cleaning systems for cars, trucks, busses, trams and subways, trains or aircraft are implemented as gantry or drive-in systems with automated sequences of several treatment stages. In the commercial field, manual cleaning plays a subordinate role only. It is useful for construction machinery, for example, which is less maneuverable and possesses complicated exterior geometry. In order to support the mechanical cleaning effect of the brushes, a number of chemicals are added to the washing water, depending on the cleaning stage. Surfactant-based cleaning agents are utilized to dissolve soiling and soften the water. After cleaning, the objects are rinsed, preserved and dried. Waxes are employed for paint care and preservation.

V.1.4.2.4 Commercial laundries

The drum washing machines used in commercial laundries are similar to those used in households. However, for economic reasons, the machines are substantially larger. The typical volume is 100 to 150 kg, but machines are also available which accept up to 400 kg of washing. The machines are steam-heated.

Large batches of sorted washing are washed in multi-stage washing lines. The washing is transported automatically from washing station to washing station. They are therefore known as batch washers. Washing lines and large drum washing machines operate with modular system washing agents, in which the water softener, surfactants, bleaching agent, enzymes, etc. are separately and individually tuned and dosed to the washing and its soiling (modular washing).

V.2 Substances requiring registration and direct costs in the supply chain

V.2.1 Number and structure of handled substances and preparations

Research question: How large is the substance inventory in the supply chain of the washing and cleaning agents affected by REACH, and how is it structured? How large is the proportion of products for which an exposure and risk assessment is to be performed?

(1) The proportion of small-volume surfactants (< 100 t/y) for washing and cleaning agents represents around 35 % of the surveyed manufacturer's surfactant portfolio for washing and cleaning agents.

Comments: This runs contrary to the common belief that surfactants for household washing and cleaning agents are all manufactured in large volume production[15].

(2) A registration duty also arises for the surfactant manufacturer from the direct import of raw materials such as palm kernel oil from outside of the EU, for example.

Comments: This increases the number of substances in need of registration.

(3) The number of substances utilized at the formulator level cannot be determined from their statements on the number of raw materials.

Comments: The addition of substances to the supply chain could not be demonstrated to date or determined within the scope of this project.

(4) At the formulator level, between 60 % and 100 % of raw materials are classified as dangerous.

Comments: The definition of exposure scenarios and the implementation of a risk assessment is therefore necessary for a large part of the current raw material inventory.

(5) None of the surveyed formulators or downstream users import raw materials or preparations themselves from countries outside of the EU 25.

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15 Sections marked in italics represent interpretations of the data by the contracted researchers; normal text summarizes the data from the interviews.

Comments: This means that these actors are themselves not subject to a registration duty for substance imports under REACH.

At the level of the substance manufacturer, the washing and cleaning agent supply chain analyses focus on the central surfactant active ingredient group, due to limited capacity, particularly since a great many aspects of REACH can be illuminated by this substance group. Generally, in the discussions centered around REACH, surfactants are rated as unproblematic, because they fall predominantly in the high-tonnage range with regard to washing and cleaning agents. In our case study, this could not be completely confirmed. A significant volume of low-tonnage surfactants (approx. 35 % below 100 t/y) was indicated for the surveyed manufacturer, measured against the number of washing and cleaning agent-relevant surfactants (23 in a portfolio of approx. 400 – 450 substances, excluding polymers). However, the contribution of these low-tonnage surfactants to the total production volume and to sales is extremely small.

In addition to the substances manufactured in self-controlled synthesis, a duty of registration also arises for the surveyed surfactant manufacturer for the direct import of raw materials required for the manufacture of surfactants from countries outside of Europe. For example, this concerns fatty acids and fatty acid methyl esters from coconut oil or palm kernel oil.

The interviewed formulators of washing and cleaning agents process between 90 (companies e and g) and 300 raw materials (enterprise h) to 40 – 1,200 traded recipes (cf. Table V-12). They are thus somewhat below the figures given by the IHO (*cf.* Chap. V.1.3). Only in exceptional cases are the raw materials used pure substances with CAS or EINECS numbers. The substance manufacturers market their substances predominantly with additives, for in-can stabilization for example. Within the scope of REACH, such substance mixtures are regarded as preparations.

The durations of the supply contracts between the manufacturers of preparations and raw materials vary greatly. The ranges vary between bi-annual contracts at fixed prices to spontaneous orders of single batches. The majority of formulators attempt, where possible, to maintain business relationships with a number of suppliers for each raw material. Of course, smaller enterprises cannot sustain this strategy for securing the supply of raw materials as easily as larger ones, as this reduces the supplied volume to the detriment of any discounts, and because there is often not enough or any space and silos for storage.

The proportion of dangerous raw materials in the formulator's raw material portfolio is very high. In many active ingredient groups, it is almost 100 %. Surfactants, for instance, are for the most part classified as irritants (Xi) and dangerous for the environ-

ment (N) due to their surface activity. Quantitative data on the proportion of dangerous substances in the total portfolio vary between 60 % and almost 100 %. According to REACH (Article 13, Para. 4) an exposure assessment and risk characterization must be performed by the registrant for any dangerous substances. This, then, is necessary for a large proportion of the current raw material inventory. This element is viewed with some reservation by the chemicals industry due to the effort involved and will be further illuminated in the following chapters.

The surveyed formulators acquire their raw materials exclusively from chemical trading enterprises or substance manufacturers with headquarters within the EU. Direct raw material import by these formulators from outside of the EU does not take place. The direct import of preparations from outside of the EU 25 by downstream users outside of the chemicals industry is negligible. This means that none of these actors would have a duty to register as substance importers under REACH in a normal case.

The proportion of preparations declared as dangerous in the product portfolios of the surveyed formulators fluctuates greatly. The surveyed formulators with household customers have very little to no preparations with a declaration obligation (cf.Table V-11, enterprises e and f). This can be achieved by diluting to below the limits specified in Directive 1999/45/EC - Classification, packaging and labeling of dangerous preparations. In addition, exceptions to the irritant declaration are possible for household washing agents if sufficiently similar recipes exist, test results prove that they do not act as irritants, and an external expert confirms that the test results can be transferred to the recipe of the household washing agent in question. Among the surveyed formulators with industry customers, the proportion of dangerous preparations to the total marketed preparations is between 40 % and 100 % (in three cases over 90 %).

The marketing prices given for preparations range between €/kg 0.80 and 8.60. The majority of the marketed volume is probably between €/kg 1 – 2.

V.2.2 Registration costs

Research question: What is the magnitude of the specific registration costs in contrast to the range of market prices for the substances? Which factors are decisive?

(1) Surfactants are relatively low-priced substances.

Comments: In the lower tonnage ranges below 1000 t/y, the specific registration costs can, in unfavorable constellations, lead to extremely long payback times or may not even be realized over the usual marketing duration.

(2) Consortiums are seen as a possible option for cost reduction by both the surveyed surfactant manufacturers and the surveyed importers.

Surfactants are rather low-priced substances. The average price for the surfactant portfolio of a large manufacturer was given as €/kg 0.82. However, the range of market prices varies according to the production volume of the substance (see Table V-9). These ranges can now be compared to the specific registration costs. To facilitate comparability between the two supply chains, we must first turn to the specific registration costs described in Chapter III. The specific registration costs are summarized in Table V-9 for the EU Commission's minimum and maximum scenario for all tonnage ranges. Depending on the cost scenario and tonnage range, spans can be calculated for the specific registration costs of between €/kg 0.17 substance (minimum scenario, upper limit of the 100 – 1000 t/y range)[16] and 16.80 euro/kg substance (maximum scenario, lower limit of the 10 – 100 t/y range).

For this calculation the cumulated registration costs per substance were correlated to annual production. The respective limit values of the tonnage ranges are assumed for the annual production bandwidth. The correlation to a single annual production indicates that these are one-off costs[17]. They can be interpreted as capital costs (see Chap. II.4). The investment in registration allows resale of the substance after the registration date. In the context of an investment assessment, the specific registration costs must therefore be compared to the periodic net yields (also per kg substance) from resale of the substance after the registration date. These net yields will be estimated below, based on the span of market prices for surfactants determined in the surveys. It is assumed for this purpose that the profit margin is 10 %, i. e. the net yield per kg of surfactant is 10 % of the market price. This figure is repeated in a number of studies (among others BASF 2004; MERCER, NERA 2004) and was also given by substance manufacturers in the paint and coatings supply chain (see Chap. VI). Arthur D. Little (2002) assumes a margin of 8 %, but this is with regard to the average for the whole of the processing industry. The span of market prices for surfactants is also relatively low for the low tonnage ranges described here. Some surfactants are thus examples of "low volume / low value" substances. This aggravates the economic impact of the registration costs.

16 Even lower costs are possible above 1000 t/y.

17 That fact that the registration costs are one-off costs does not eliminate the possibility of various elements of the registration costs being due at various times (see Chap. III).

By comparing the specific registration costs and the net yields, the payback time spans can be calculated (Table V-9)[18]. For high-tonnage surfactants (above 1000 t/y), enterprises generally accept in the region of 3 – 5 years or less. In the tonnage ranges below this, the payback times for favorable constellations (production at the upper limit of a tonnage range, upper end of the market price span, minimum scenario) also lie in this region. However, for production between 1 t/y and 1000 t/y, the payback times for unfavorable constellations (production at the lower limit of a tonnage range, lower end of the market price span, maximum scenario) are not only far longer than the usual enterprise cut-off criteria, they are also beyond that which would be appropriate from an economics point of view, i. e. the average expected life-cycle of a substance (see SRU - Council of Experts on Environmental Questions 2004). These figures show that an enterprise's choice of production quantity becomes a strategic parameter under REACH (e. g. avoiding a minor infringement of the 10 t/y threshold). From the point of view of production and expansion planning, this is a new challenge. For the policy maker, the figures underline the urgency of creating the necessary prerequisites for adhering to the minimum scenario.

Table V-9: Importance of specific registration costs compared to possible yields

	1 - 10 t/y	**10 - 100 t/y**
Specific registration costs		
Minimum scenario (euro / kg)*)	12.10 - 1.21	5.11 - 0.51
Maximum scenario (euro / kg)*)	14.10 - 1.41	16.27 - 1.63
Market price spans for surfactants (euro / kg)	1 - 3	1 - 2
Margin (assumed)	10 %	10 %
Payback time (years)	**4.0 - 141.0**	**2.6 - 162.7**

	100 - 1000 t/y	**> 1000 t/y**
Specific registration costs		
Minimum scenario (euro / kg)*)	1.66 – 0.17	<0.23
Maximum scenario (euro / kg)*)	2.82 – 0.28	<0.32
Market price spans for surfactant (euro / kg)	0.8 – 1.6	0.7 – 1.2
Margin (assumed)	10 %	10 %
Payback time (years)	**1.1 – 35.3**	**1.9 - 4.6**

*) EU Commission estimate

18 Alternatively, the capital value can be calculated. Here, though, an assumption would need to be made on the appropriate basic interest rate and, where necessary, calculations carried out for the scenario. This is ignored here for reasons of clarity; the static view of payback times is preferred. A dynamic view of the registration cost decision and a discussion of the interest effects follows in Chapter III.

As was readily demonstrated in Chapter III, the VCI (*Verband der Chemischen Industrie* – Chemicals Industry Association) registration cost estimates are higher than those of the EU Commission's maximum scenario. Moreover, the surveyed surfactant manufacturer has carried out his own registration cost estimates on the basis of the substance data already available to him. The estimates are based on the pure test or investigation costs[19]. They partially consider toxicity data already available in the company, but do not specifically relate to surfactants. Instead, they are relate to the situation for the company's total portfolio[20]. The estimated bandwidths generally fluctuate around the VCI estimate. Uncertainty about the magnitude can also arise, for example, because it only becomes clear which data are available after the consortiums are formed. In the tonnage range above 1000 t/y, the range is displaced upwards compared to the VCI. This is explained by the substances being predominantly used as direct end-consumer products in the form of preparations. Where, according to the draft regulation, the outstanding studies for volumes > 1,000 t/y may be negotiated with the authorities, the enterprise assumed that the authorities will require more stringent, advanced investigations to accommodate better consumer protection.

Based on these company-specific registration cost expectations, the number of WCA-relevant surfactants and their production volumes in the respective tonnage range, the specific registration costs for the concrete case of the surveyed surfactant manufacturer can be estimated (see Table V-10). According to the surfactant manufacturer, the margins in this market are lower than assumed above and vary at around 5 % to 7 %. With specific reference to the same market price spans as above, and assuming the more conservative value for the margin, the payback times can be derived[21]. They show that the registration costs can be realized in a very short period for the high-tonnage range above 1000 t/y. In the tonnage ranges below this, and between 10 and 100 t/y in particular, payback times, even in the favorable constellations (lower limit of

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19 Moreover, the enterprise expects an additional total expenditure of 5 person-years (corresponding to €500,000) to create the CSRs and new safety data sheets for their portfolio. For the internal administrative accompaniment of the registration (inner-enterprise amalgamation of data, etc.), they expect a further 3 - 5 person-years. The company's portfolio currently encompasses 400 – 450 substances (excluding polymers), whereby only approx. 60% of these are to be registered. The estimated, non-test related costs are thus probably below the RPA estimates.

20 The assumption of the researchers that the data situation for surfactants over 1000 t/y must be of above average quality because of the HERA project, and the registration costs thus be lower compared to the total portfolio, could not be confirmed by the interviewees.

21 Due to the confidential nature of the data, the number of substances and their production volumes in the individual tonnage ranges cannot be reproduced individually here. For production volumes and prices, current figures used in this calculation were extrapolated into the future.

the registration cost estimate, market price at the upper limit of the span), are in some cases substantially above usual enterprise cut-off criteria - in unfavorable constellations, as much as 131 years. More than 40 % of the surveyed surfactant manufacturer's washing and cleaning agent surfactants fall into the tonnage range below 1000 t/y. This has implications for the number of substances for which he does not envisage registration (see Section V.5.2 for substance withdrawal).

One way of reducing the substance manufacturer's registration costs envisaged in the draft regulation is the option to create consortiums and to split registration costs between the consortium partners. In his registration cost estimate, the surveyed surfactant manufacturer assumes that the registration costs per substance can be reduced by one third (regardless of tonnage range) using this option[22]. The surveyed importer is aiming for a cost-sharing consortium with the suppliers of commodities. For substances with relatively few customers (e. g. defoamers), sharing the registration costs with other distributors is also imaginable for him. Further prerequisites for creating consortiums are discussed in Chapter V.4.7.2.

Table V-10: The importance of specific registration costs compared to possible yields based on the expectations of the surveyed surfactant manufacturer

	1 - 10 t/y	**10 - 100 t/y**
Registration costs per substance (thousands of euros)	7 – 18.5	195 - 270
Specific registration costs		
Minimum / maximum estimate (euro / kg)	2.00 – 5.29	4.74 – 6.56
Market price spans for surfactant (euro / kg)	1 - 3	1 - 2
Margin (assumption for the surfactant market)	5 %	5 %
Payback time (years)	**13.3 – 105.7**	**47.4 - 131.2**

	100 - 1000 t/y	**< 1000 t/y**
Registration costs per substance (thousands of euros)	385 - 525	735 - 1575
Specific registration costs		
Minimum / maximum estimate (euro / kg)	1.48 – 2.02	0.05 – 0.11
Market price spans for surfactant (euro / kg)	0.8 – 1.6	0.7 – 1.2
Margin (assumption for the surfactant market)	5 %	5 %
Payback time (years)	**18.5 - 50.5**	**0.9 - 3.3**

22 Administration costs for consortiums have not been taken into consideration.

V.3 Current information situation and management capacity for product safety

Research question: On which personnel capacity, information and instruments is the implementation of the current requirements of the hazardous substances legislation based? How does this influence the capacity for implementing REACH?

(1) At the formulator level, one employee is responsible for 40 to 600 safety data sheets or recipes.

(2) All actors receive the safety data sheets from their upstream suppliers and rely on the information contained in them. The VCI minimum dataset is available to the substance manufacturers as a template for creating the safety data sheets.

(3) Based on the national registration procedures for washing and cleaning agents, some states (e. g. Finland, Czech Republic) demand that this information also be contained in the safety data sheets. That is, recipes must be partially revealed or certain information be contained in the declarations. This entails a great deal of updating effort and workload within the enterprise.

(4) The washing and cleaning agent manufacturers are generally aware of the uses and application conditions of their customers. However, this information has not yet been systematically evaluated according to the TRGS (*Technical Regulations for Hazardous Substances*) 220 – e. g. for defining use-oriented risk management instructions.

(5) According to the formulators, no information requirement exceeding that given on the labels or the safety data sheet exists on the customer's side.

(6) The manufacturers of washing and cleaning agents are subject to a series of further legal regulations. If REACH induces a large amount of recipe changes, they lead to additional expenditure.

(7) Formulators already exceed their legal information requirements on the basis of voluntary agreements.

The largest manpower requirement for the current chemicals legislation is for the creation of the safety data sheets. According to the surveyed companies, the safety data sheets are "practically renewed" every two years. The companies give a range of 0.5 to 2 person-years for the creation and maintenance of the safety data sheets. This corre-

sponds to 3 to 20 h per recipe[23]. In contrast, one employee is responsible for 40 to 600 safety data sheets (see Table V-12, but generally calls on the laboratory and IT for support.« This chemicals safety management capacity is in contrast to the formulators' high proportion of dangerous raw materials and dangerous preparations (with the exception of the companies active in the household sector, e and f). Then there are new raw materials, which are added to the portfolio and must be appropriately examined. The ratio of new raw materials per year to the total portfolio of raw materials is between 1.7 % and 5.6 % for formulators, with one outlier (company g) at 45 %.

Because of the very different registration procedures for the national chemical registers and the tendency of the registration authorities to include relevant information from notification as completely as possible in the safety data sheet, the regulations can only be adhered to with great effort (e. g. Finland: the quantity of all dangerous ingredients must be given in the safety data sheet, Czech Republic: VOCs must be declared) and changes to safety data sheets and declarations can only be followed with difficulty[24]. In a few cases it is impossible for the companies to accurately implement the national requirements. In some countries this has no consequences; in others, such as Austria, which requires declaration of the waste code to Austrian standards in the SDS up to the end of 2004, fines of 5,000 to 10,000 euros are threatened for inadequate safety data sheets. Additional costs thus also result from lower label quantities, which vary from country to country and regulations can change rapidly.

Exposure information from the formulators and substance manufacturers is not available. For marketing reasons they have very good information on application engineering, but no information on the emission situation at the customer end. These concentrations are partially monitored by the trade inspectorate (e. g. for occupational safety) but are currently not easily available to washing and cleaning agent manufacturers and therefore do not make their way into the safety data sheet[25], i. e. they are not used to

23 A company that also imports gives this as substantially lower at 0.2 h per recipe.

24 To what extent such national safety data sheet requirements act as inadmissible barriers to trade or are permissible use of national leeway in the implementation of the SDS (safety data sheet) directive could not be clarified in the context of this project. The surveyed companies prefer to comply with the demands in order to ensure access to the market.

25 According to TRGS 220 "Safety data sheet", Section 6.8.2: Limiting and monitoring exposure, Para. (2): If information is available on workplace loads, it should be given; e.g., information can be taken from the recommendations of professional occupational safety associations (BG/BIA Recommendations), product codes and industry regulations or be asked for at the occupational safety agencies of the German states, the professional associations, the guilds, etc.

define measures for safe handling. In order for this to happen under REACH, practical implementation instruments must be developed.

According to information provided by the formulator, the VCI minimum dataset is available to their raw material supplier. Formulators can access this when required; this is agreed with the delivery in individual cases ("Letter of access"). For the formulators, the decisive information is generally that derived from the data in the safety data sheet.

Operational substance inventories exist for all washing and cleaning agent manufacturers, which are either continuously updated, or once annually, with the newest safety data sheet. However, these inventories are generally not classified according to substance identities (CAS or EINECS numbers). This means that a vital condition for facilitating purposeful querying of the substance suppliers may be absent due to missing information pertaining to the environment and health-relevant properties of the dangerous and non-dangerous substances supplied. Almost all formulators maintain internal forbidden-substance lists. Automatic subscription to the latest safety data sheets and selling restrictions are standard. These last are important because extremely irritant substances, such as hydrofluoric acid for example, are also used in special cleaning agents for commercial applications. In the opinion of the contracted researchers, the established procedures for managing forbidden substance lists and selling restrictions provide a starting point for examining their own use for consistency with the registered uses and exposure scenarios, as anticipated in the new REACH requirements.

Application advice and product information in excess of that given in the safety data sheets is provided by application engineering, which is very prominent within the washing and cleaning agent manufacturers. According to the formulators, customers have no information requirement exceeding that given on the labels or the safety data sheets. Enquiries arise almost solely from misunderstood information in the safety data sheets. According to the observations of the surveyed manufacturer (company a), the quality of hazardous substance management at an operational level is increasing because there are more detailed enquiries for German safety data sheets.

In addition to the Chemicals Act, the manufacturers of washing and cleaning agents are affected by a number of further regulations relating to washing and cleaning agents. REACH-induced modifications, for example to recipes, will lead to some extent to subsequent expenditure in order to adhere to this legislation. In particular, the following are noteworthy:

- Washing and Cleaning Agents Act (WRMG), Surfactant Regulations

- Foodstuffs and Commodities Act (FCA), Commodities Regulations[26].

Whilst the Washing and Cleaning Agents Act and the Chemicals Act are only relevant to certain cleaning and care agents, the Foodstuffs and Commodities Act applies to all products in this group (Hauthal et al. 2003). It prohibits the manufacture or bringing into circulation of cleaning and care agents[27], which

- may be mistaken for foodstuffs due to their smell or design or
- may damage the health of the consumer during intended or foreseeable use.

The Commodities Regulations prescribes warning notices for certain cleaning and care agents. For example, products containing more than 0.1 % formaldehyde must be labeled with "Contains formaldehyde". This is intended to hinder foreseeable misuse.

The Washing and Cleaning Agents Act is an environmental law that serves in particular to protect aquatic systems. It therefore applies exclusively to products that enter the sewage system during intended use. Beside textile washing agents this includes, for example, dishwashing agents, WC and bath cleaning agents, flooring or all-purpose cleaning agents. The Act prescribes, among other things, that the recipes of these products be declared to the UBA (*Umweltbundesamt* – Federal Environment Agency). Among other things, the packaging must contain dosage recommendations, taking water conservation issues into consideration. It must be easily readable, in German and permanent (for further compulsory information to WRMG see Table V-11). Anionic and non-ionic surfactants in cleaning and care agents that enter the sewage system must adhere to the requirements of the Surfactant Regulations, i. e. they must have an average biodegradability of at least 90 %.

Beside the legal requirements, more than 20 voluntary agreements have now been entered into by the German industry, which influence washing and cleaning agents, including:

- Forwarding of framework recipes to health agencies (1975/1993)
- Limitation of the use of NTA in washing agents (1984)
- Dispensing with the use of APEO in washing agents (1986)

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26 In addition, the Calibrations Act is relevant. It is intended to protect the consumer when purchasing measurable goods and guarantee measurement security in health, occupational and environmental protection. The Consumer Packaging Regulations, which prescribes labeling according to volume or mass, was also enacted on the basis of the Calibrations Act.

27 Bringing into circulation is defined in the Act as "supplying, storing for sale or otherwise providing, offering for sale and any form of making available to others".

- Dispensing with the use of EDTA (1991)
- Information on the enzyme type on the packaging (1996)
- Creation of a UBA database for washing agent enzymes (1997)

Based on these agreements, information is provided over and above the legal requirements and a number of substances have been substituted in the past. This "voluntary" provision of additional information was partly due to market pressure from customers. The surveyed downstream user in the automobile industry (company k) expects his preparation suppliers to reveal the complete recipe (according to CAS numbers and for proportions > 0.1 %). Only then can the formulation, in conjunction with the safety data sheet, be internally cleared for the respective use. The downstream user stated that enquiries then arise for 10 to 15 % of formulations, because his information requirement is greater than the legal requirement. The surveyed downstream user expects an improvement in the data situation through REACH: it allows an improved hazard analysis and will bring advantages to the enterprise in the long term.

Table V-11: Principles of the prescribed declaration elements for washing and cleaning agents

	Washing and Cleaning Agents Act	Chemicals Act	Commodities Regulations
Product trade name	X	X	
Name and location of manufacturer or importer	X	X	
UBA registration number	X		
Dosage recommendations	X		
Ingredients to EU recommendation	X		
Hazard symbol(s)		X	
R and S classes (risk and safety)		X	
For irritants: Name of hazard trigger		X	
Note as of 0.1 % formaldehyde			X

Source: Hauthal et al., 2003

Table V-12: Management capacity indicators for chemicals safety at importers, substance manufacturers and formulators

	Im-porter	**Sub-stance manu-fac-turer**	**Washing and cleaning agent formulator**						
Company	**0**	**a**	**b**	**c**	**d**	**e**	**f**	**g**	**h**
Employees	780	2,000	25	48	170	98	132	150	250
Raw materials	-	-	180	187	270	90	207	90	300
Proportion of dangerous raw materials	-	-	58 %	very high	80 %	al-most 100 %	high	very high	80 %
Proportion of new raw materials p. a.	-	-	5.6 %	1.6 %	3.7 %	n.a.	n.a.	45 %	1.7 %
Products (substances, recipes)	10,000	1,700 (1)	135	141	180	40	100	1,200	400
% dangerous products	n.a.	n.a.	38 %	90 %	99 %	20 %	0	60 – 80 %[2)]	100 %
Employees responsible for SDS	3	3	1	0.5	2[3)]	1[4)]	0[5)]	2	1
Products per SDS employee	3,300	600	135	282	90	40	n.a.	600	400

1) whole "surfactants" field including polymers; 2) depending on field of use; 3) updating only, without creating; 4) not to 100%; 5) outsourced

V.4 The innovation effects of REACH

V.4.1 The term “innovation” in the detergent / cleaning agent chain

The companies and associations surveyed understand “innovation” as a quite broad set of developments. IKW sees 10 basic innovations in household detergents in the past 100 years (IKW, 2004):

1907 Fritz Henkel markets “Persil”, the first independent detergent.

1958 A measurement method for the biodegradation of surfactant is developed.

1960 The first surfactants that are quickly biodegradable are used.

1968 Enzymes are used to remove spots.

1977 Bleach activators reduce washing temperatures for whites to 60 %.

1986 The first phosphate-free detergent comes to market after five years of development.

1987 The first fluid detergent is sold.

1994 The first concentrated detergent is sold.

1997 The first highly concentrated detergent tablets are sold.

2001 The first highly concentrated fluid detergent tablets are sold.

Substance manufacturers listed innovations in process engineering and new applications in the interviews. One concrete example was the development of raw materials for detergents at low washing temperatures due to shorter chain lengths in surfactants.

The formulators surveyed focused on developments that customers perceive as innovations. They include new recipes, such as special detergents for black textiles, and new applications (such as cleaning agents for vitrified clay tiles) and changes in the shape of products (such as tablets or integrated rinsers in dishwashing detergents) or packaging. From the perspective of those surveyed and the IKW, pioneering basic innovations are quite rare; rather, one finds a tradition of incremental improvements.

Users mentioned innovations related to detergents and cleaning agents mostly when they were related to dosing techniques. The switch to closed cleaning systems / closed cleaning fleets was also mentioned.

In the interviews, the interviewee’s particular understanding of innovation always served as a basis for the answers to the questions. Some of the questions concerned the substitution of raw materials in formulations, even when they did not necessarily fit the customer-oriented definition of the company’s innovation activities.

V.4.2 Indicators of the innovation capacity and strategy of substance manufacturers and formulators[28]

Research question: How much R&D does the company invest to generate its long-term revenue? What role does the variety of raw materials and the customer-oriented diversification of the product portfolio play for formulators?

(1) The share of R&D expenditures in revenue is between << 1 % and 3 % for the substance manufacturers and formulators surveyed in the detergent and cleaning agent chain.

Comment: These figures are clearly lower than the average for the chemicals industry. The below-average research intensity indicates that the adaptation capacity for REACH will also be below average. This has to be remembered when we discusses the pressure to adapt.

(2) The breadth of the range of raw materials as an innovation base is much more unified and less crucial for detergents and cleaning agents than for paints.

Comment: This sector will thus be less affected by REACH.

(3) The number of recipes per million euros of revenue is between 1 and 28.

Comment: This indicates that the companies pursue different market strategies, with a high number reflecting the strategy of product differentiation.

(4) Product differentiation is greater for formulators who serve industrial customers than for formulators whose serve households, and slightly greater for small companies than for large ones.

Comment: An increase in product differentiation goes hand in hand with a large number of recipes and raw materials in the portfolio, which means that product differentiation also makes a company more sensitive to REACH.

(5) Quality management (laboratory) and field representatives are closely involved in the internal innovation management of formulators.

The survey of substance manufacturers and formulators revealed that the share of R&D in revenue ranges from far below 1 % to just below 3 % (see Table V-15).

28 The indicators and their background are derived and discussed in Chapter II.

In comparison, the figures for the chemicals industry (without pharmaceuticals) were between 5 % and 6 % in the past few years (Grenzmann et al. 2004; VCI 2003).[29] The formulators surveyed were thus far below the average in the chemicals industry. The indicator does not seem to depend on the size of the company. The surfactant manufacturers surveyed justified their low R&D budget with the argument that it was difficult or impossible to develop further new innovative surfactants for large volumes that fulfill the current, strict environmental regulations.

This indicator allows conclusions to be drawn about the extent to which manufacturers of detergents and cleaning agents will be affected. The low research intensity lead to low innovation capacity and hence a lower capacity to adapt to REACH than the average for the chemicals industry. This aspect relates to the pressure on specific supply chains to adapt discussed below.

Many formulators had trouble determining their R&D budget due to structural aspects in internal innovation management. Starting with the content of R&D work, they generally counted part of laboratory work, which is otherwise devoted to quality assurance, and part of field service / application technology, which is generally responsible for making preparations work on site, as the R&D budget. In contrast, the survey of the Association of German Foundations (Grenzmann et al. 2004)[30] was based on budgets for organizationally separate R&D units. The different ways of attaining the figures given in the interviews probably make them slightly artificially higher than the statistical benchmark for the overall chemicals industry as activities outside of reported R&D departments are included. The discrepancy between the figures in the case study and the benchmark cannot therefore be attributed to the measurement concept.

Formulators also use the absolute size of their (raw) material portfolio as an indicator of their innovation and marketing strategy. The raw materials base of formulators does not fluctuate much (from 90 to 300 raw materials), especially in comparison to the paint chain (see Ch. VI), and is much smaller than for paint manufacturers. When the two chains are compared, the breadth of the palette of raw materials is thus narrower here and plays a less important role as a basis for innovation. Possible limitations of the raw materials base under REACH will thus not affect the detergent and cleaning agent chain as negatively as a basis for innovation. The size of the raw material portfolio does not seem to correlate to the size of the company. Small companies (such as b

29 The entire processing industry was just below 5 % (Grenzmann et al. 2004).

30 The survey was conducted regularly every two years and is the decisive reference for statistical R&D figures in Germany.

and c) have portfolios with almost 200 raw materials, while the second largest formulator surveyed (g) makes do with 90 raw materials.

The number of recipes was also used as an indicator of the innovation and marketing strategy of formulators relative to revenue. This indicator makes a distinction between the companies' different market strategies. A high value indicates a great degree of product differentiation, while a low value reflects an attempt to have a streamlined product portfolio and maximum revenue per recipe. The number of recipes per million euros of revenue is between 1 and 28 for the companies surveyed. Preparations for private households (companies e and f) are clearly at the bottom of this considerable spectrum. Product differentiation is thus much lower than in industry. If formulators with industrial consumers are deducted, product differentiation seems to be more of a strategy of small companies (see companies b and c).

For the assessment of the extent to which REACH will affect a company, it must be kept in mind that product differentiation entails a relatively large number of active recipes, which also indicates a relatively large portfolio of substances used (see Section V.5.1). This increases the likelihood that a formulator will have to withdraw substances under REACH. In addition, a large number of recipes makes the need for reformulation more probable if even one substance is withdrawn ("snowball effect"). Therefore, REACH will affect industrial customers more than households if product differentiation is an indicator; in particular, small companies seem to have built on this market strategy that is sensitive to REACH.

V.4.3 Innovation drivers

Research question: Which factors determine the direction of innovation? What effect does REACH have on the order of innovation drivers?

(1) Among formulators, customer wishes are always the first or second priority as innovation drivers. Formulators often visit customers to solve problems.

Comment: In other words, the effect of greater customer retention from REACH will not have many additional innovation effects on formulators.

(2) Adaptations to application technology and cost reductions were mentioned less often but were also a high priority. Internal R&D and product improvements were ranked differently, while legal requirements and voluntary industry guidelines were mentioned less often.

(3) For internal occupational safety and marketing reasons, preventing CMRs and labels of environmentally hazardous materials is a great priority. Past cases of substitution also demonstrate great commitment to replace substances that are publicly known to be problematic. In comparison, the general prevention of a label or a change in labeling currently only plays a minor role overall, at least for formulators with industrial customers as innovation drivers. Formulators said this was due to current competitive distortions in the correct labeling of products due to a lack of enforcement.

(4) Formulators expect the priorities for innovation drivers to shift somewhat under REACH. Adaptations to new price relations would mostly be a burden on internal R&D.

Comment: This is to be seen as a temporary process during the introduction phase of REACH.

(5) REACH will hardly affect the innovation drivers for the users surveyed outside the chemicals industry. Preventing dangerous materials could become more important in certain applications where it has always played a role (such as in cleaning buildings).

Formulators and users were able to provide data on the question of current drivers for innovations. The interviewees were to rank the drivers mentioned and name any other drivers, whose importance was also to be ranked. The results are given in Table V-13. It is clear that both formulators and users find customer wishes to be the first or second most important driver in all cases. In addition, formulators work closely with their customers on R&D and often visit them to solve problems. This indicates that the challenge of bringing together knowledge about substances and applications under REACH will meet with fertile ground in these two stages of the supply chain. In turn, any intensification of customer relations due to REACH will be largely redundant in the case of formulators and thus fail to provide many additional innovation incentives. This may not be the case for substance manufacturers (see Ch. V.4.8).

Cost aspects were mentioned less often, but still as a great priority (b and k). This includes switching to less expensive raw materials, the in-house manufacture of recipes that used to be purchased, and the pooling of raw materials for rationalization reasons. Adaptation to the application technology of customers was mentioned even less often but then was still usually considered an important driver. This includes, for example, the development of new detergents for car washes that have rags instead of brushes (company g).

Table V-13: Ranking of innovation drivers in the interviews

	Formulators							Users		
	b	**c**	**d**	**e**	**f**	**g**	**h**	**i**	**k**	**l**
Costs	1								1	
Customer wishes	2		2	1	1	1	1	1	2	2
Internal R&D / product improvement	3	1	1	2	2	4	2	2	3	1
Preventing dangerous substances / (changing) labels	4	2	3	4	2	3		1-2	3	0[(1)]
Adaptation to application technology			2		3	2	1	2	3	
Legal requirements and voluntary duties									3	

1) is not a task of R&D, but rather the production department.

The answers on the importance of internal R&D for product improvement are somewhat difficult to interpret. Only a minority of those surveyed (3 of 10) ranked this as the most important driver of innovation. The same number found that it played a minor role. These companies all have a quite wide spectrum of innovation drivers, which means that R&D is one factor among many. Only one company (k) named legal requirements and voluntary obligations that private entrepreneurs take upon themselves as a driver.

Preventing the use of dangerous substances and preparations as a driver for innovation, a distinction can be made between several aspects discussed further in Ch. V.2 and V.3. There, it was shown that the share of dangerous raw materials is very large among the components in detergents and cleaning agents and that formulators with industrial customers have a very large share of preparations that must be labeled, while formulators with household customers get around labeling based on certain exceptions and low concentrations of dangerous substances. This suggests that doing without labels for household products represents an innovation driver.

The interviews also clearly show that companies make a distinction between various types of dangers in their assessments of this driver. For instance, the label “irritant” is so common for raw materials and preparations in industry that it is not longer taken to mean “dangerous” on the market and hence no efforts are taken to prevent the use of these substances. Another reason why two of the formulators surveyed (b and g) find preventing the use of dangerous preparation components to be relatively unimportant is their experience in competition with “small garage enterprises” that do not fulfill their duty to label their products. The current lack of enforcement makes the playing field uneven and weakens this innovation driver.

The same does not hold true for the label “harmful to the environment”. Formulators find it absolutely essential to make sure this new label is not on their products. Formu-

lators with industrial customers find preventing CMRs[31] to have a similar high priority due to the resulting great efforts required for occupational safety. The sometimes great expenditures for the substitution of substances that have become a topic of public discussion (see Section V.4.5) and the sometimes explicit fear of bad press from the use of such substances also show that dangerous raw materials have been taken out of portfolios in the past. This also explains why this motive is no longer such a high priority.

Based on information gathered on current innovation drivers, formulators were asked about the effects of REACH on their ranking. Formulators expect cost aspects and the adaptation to the price relations of raw materials due to REACH to drive their innovation more. Customer wishes were seen to be less decisive as the capacity and ability to react is restricted due to other adaptations to REACH (such as expenses for in-house application notification and smaller substance portfolios). In-house R&D is found to be (even) less important, in some cases even completely overshadowed by other REACH priorities (companies b, d, and g). Company c finds this to be a general trend since these products are mature.

Companies b and e believe REACH will promote the driver “preventing the use of dangerous substances / labeling”. In one case, the reason explicitly given was that under REACH the duty to generate data could lead to an undesired labeling of raw materials not previously labeled. Company d also feels that REACH will clearly increase the number of substances that have to be labeled but concludes that there will then no longer be a way of getting around labeling and that this driver will then be weakened under REACH. Finally, in one case (company c) mentions a certain general trend to prevent the use of dangerous substances that REACH will not decisively affect additionally.

For most users, REACH did not seem to have any or only a very slight effect on drivers of innovation. The reason given was that product development and the need for chemicals are not closely related. In particular, technical requirements - such as threshing performance and cubic capacity - are primary in agricultural machines and utility vehicles (companies l and p). Changes to products thus have little effect on the downstream detergents and cleaning agents. Sometimes, the launch of a new design series necessitates the expansion of series process stages, which in turn leads to a change in the process with the concomitant adaptations in chemicals (such as a switch to cathodic dip painting as the final coating process in company p with the concomitant

31 The chemicals ban regulation specifies the CMRs cannot be passed on in preparations to private consumers.

changes in detergents and cleaning agents). In one specific example, however, no connection was seen between the motives for the change of process and possible incentives from REACH. For one user, a building cleaner (company i), preventing the use of dangerous preparations is already a great priority; this user expects REACH to increase this priority. This effect from REACH would be desirable.

V.4.4 New substances in detergents and cleaning agents and relevance for manufacturers

Research question: What role do new substances play for substance manufacturers, and how can the supply chain benefit from the facilitation of the development of new substances under REACH?

(1) The development of new substances plays a very minor role in the manufacture of detergents and cleaning agents. These companies have very little management capacity for registration procedures. From the perspective of formulators, new substances are not identified as such in Directive 67/548/EEC.

(2) Based on the statistics for new substances, a certain importance can be shown for new substances in the detergent/cleaning agent chain in Germany for the new substances notified by some 4 % of German companies between 1994-2002 with certain methodological provisos. The absolute number of these new substances is around 20.

Comment: If the development of new substances is to compensate, to some extent, for any withdrawal of raw materials under REACH, it will have to become more important under REACH.

(3) The rule for the exemption of substances in research and development projects (PPORD) met mostly with approval but is not possible for household customers.

The relevance of new substances for the supply chain of detergents and cleaning agents is hard to determine empirically. Two parallel methodological procedures were chosen for the assessment of the research issues concerning new substances as in Directive 67/548/EEC. In addition to interviews with substance manufacturers and formulators in which questions were asked about the relevance of new substances, the UBA's database was evaluated for the notifications of new substances made in Germany.

According to statements made by the substance manufacturer and importer surveyed (companies 0 and a), the development of new substances plays a very minor role in

their innovation work. The importer (company 0) has notified 2-3 new substances in the past 10 years, while the surfactant manufacturer (company a) has notified two new substances but generally avoids this area. One reason given was that the currently high notification costs represent a great investment risk. For the effects of REACH, this means that management capacities for the registration of existing substances under REACH can only be set up to a limited extent. Interviews with formulators of detergents and cleaning agents did not provide any additional information about new substances as these formulators usually do not have an inventory of their raw materials for specific substances and do not seem interested in separately itemizing new substances.

The substance manufacturer surveyed did not feel that REACH would make it essentially easier to develop new substances. The reduced test requirements for the tonnage range up to 10 t/y and the reduction in R&D for products and processes in REACH compared to Directive 67/548/EEC is thus not seen as decisive in practice[32].

Most of the actors surveyed reacted positively to the PPORD rule, which facilitates the parallelism between the product development of users and the fulfillment of REACH requirements. As one user put it, the use of a new substance under PPORD and the related development work for users only make sense if the conditions under which the substance can be registered after the PPORD phase are clear. Otherwise, users might face a situation in which they base their product development on a new substance that will not be available in the long term. For formulators that serve private households, PPORD is not practicable due to the breadth and multitude of users.

A second methodological way of determining the relevance of new substances in the supply chain of detergents and cleaning agents is to evaluate the database for registrations of new substances in Germany according to the categories of use and industry in accordance with the Technical Guidance Document (European Chemicals Bureau 1997).

The starting point is the figures for new substance notifications[33] in Germany from 1994 (when the new-substance directive for risk assessment was adopted) to 2002; the European Chemicals Bureau has also made evaluations available in the Internet for this purpose[34]. First, the industry categories (ICs) and use categories (UCs) that seem relevant to detergents and cleaning agents and have to be indicated for notification

32 This project was not able to investigate the reasons for this.

33 Without notifications for R&D.

34 See http://ecb.jrc.it/new-chemicals/… (viewed on 07/28/04).

were identified[35]. At the level of industry categories, the connection to detergents and cleaning agents is very hard to detect. Based on the Technical Guidance Document, only the following, very broad industry categories come into question:

- IC 5: personal/domestic
- IC 6: public domain

In addition, the use categories relevant to detergents and cleaning agents were also identified on the basis of their description in the Technical Guidance Document. The intersections thus calculated are shown in Table V-14. The use categories relevant to detergents and cleaning agents that had an intersection with IC 5 and 6 as shown in the Table comprise:

- UC 8: Bleaching agents
- UC 9: Cleaning / washing agents and additives
- UC 11: Complexing agents
- UC 14: Corrosion inhibitors
- UC 36: Odour agents
- UC 49: Stabilisers
- UC 50: Surface-active agents
- UC 98: Others

In total, 32 notifications relevant for detergents and cleaning agents in the personal/domestic field and 5 notifications relevant for detergents and cleaning agents in the public domain were made between 1994 and 2002 (Table V-14). The extent to which the intersections between IC 5 and the use categories overlap with the intersections of IC 6 and the use categories is not clear, in other words whether the substance in the intersection between IC 5 and UC 9 is the same one notified under IC 5. Depending on what one assumes, a total of 37 or - if there is complete overlapping - 32 notifications were relevant for detergents and cleaning agents.

These figures were corrected in two respects. The first correction concerns the estimation of notifications by German manufacturers (“origin of substance”) based on the notifications *in* Germany. Here, the figures in Chapter II from the European Chemicals Bureau were used. According to these figures, Germany has 25 % of the notifications per member states and 19 % in terms of the origin of the substances. Hence, the correction

35 This information was provided by the manufacturer. The extent to which applications are put into practice is not clear.

factor is 76 % if we want to approximate the notifications in Germany to those by German manufacturers.

The second correction concerns the removal of multiple mentions in use categories[36]. In the end, 21 or - if there is complete overlapping - 18 new substances relevant to detergents and cleaning agents notified by German manufacturers from 1994 to 2002 were counted. The share of all new substances[37] notified by German manufacturers in this period was this 4 % (see Table V-14).

It must be kept in mind, however, that some of the new substances may not have developed any market relevance after their notification but rather may have remained at a negligible level. In a initial step, this problem was reduced by taking the figures for R&D out of the data. No exact information on production quantities specific to Germany were determined. It can plausibly be assumed that the notifications of new substances by German manufacturers are spread across the tonnage ranges in the new substance regime for all of Europe. If so, then some 30 % of the notifications were below 1 t/y and thus not relevant to the market at this point. The tonnage range that VCI believes will be most affected by withdrawals - 10-100 t/y - makes up 8.5 % of previous notifications of new substances. As discussed in Chapter II, however, the contracted researchers find the comparison at the level of tonnage ranges to fall short. After all, when a new substance can replace an existing substance that is not registered, the development of its volume may be affected considerably. For instance, new substances in small tonnage ranges may also be considered as possible substitutes if they fulfill the registration requirements for the next volume threshold higher up.

As the explanations show, the classification and count of new substance notifications is subject to methodological difficulties that make estimates rather rough. Nonetheless, the new substances can be classified in this manner for the supply chain of detergents and cleaning agents. This classification shows that the relevance of new substances for detergents and cleaning agents is not absent, but has been very low up to now. It would be interesting to compare this number of new substances relevant to the supply chains with the number of existing substances relevant to the supply chain. As Chapter V.2 already made clear, however, there are no such estimates for existing substances. The size of a formulator’s raw materials portfolio does not tell us much about the number of chemical substances in the chain as some of the substances are mixtures and

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36 A substance can be indicated in more than one use category for notification. Hence, the count of notifications within a use category and the subsequent summation across multiple use categories may artificially escalate the number of substances.

37 See Chapter IV.

the overlapping between the portfolios of individual formulators is not clear. Nevertheless, 20 new substances in 10 years seems to little. These figures, which should be supported in further research and expanded to include notifications relevant to detergents and cleaning agents at the European level, indicate that the development of new substances will have to be stepped up under REACH if it is to make up for some of the raw materials that may be withdrawn.

Table V-14: Estimate of the accumulated notifications of new substances in the supply chain of detergents and cleaning agents by German manufacturers from 1994-2002

	w/o UC	UC 8	UC 9	UC 11	UC 14	UC 36	UC 49	UC 50	UC 98	Total	Corrected total	Share of German new substances
IC 5 ∩ …	1	4	6	2	1	10	4	3	1	32	18	3.8 %
IC 6 ∩ …	1	-	1	-	1	-	-	2	-	5	3	0.6 %

Source: UBA, ECB, internal calculations of Fraunhofer ISI

V.4.5 Time to market and development expenses for formulators of detergents and cleaning agents

Research question: What effect does the flow of product development (time to market, phases in the development process, absolute development expenses) have on the various stages in the supply chain under REACH?

(1) The time to market for preparations ranges from less than one month to 5 years. The shorter periods are customizations; the upper limits, products requiring technical authorization.

(2) At the level of formulators, REACH could lead to delays in product development due to a limited selection of materials and additional searches for substances with suitable identified uses.

Comment: The formulators do not seem to have looked for ways to fulfill REACH requirements during the development process.

(3) The development expenses for the substitution of substances no longer available on the market or no longer desired for environmental or occupational safety reasons depend largely on how many recipes are affected by the substitution.

The typical time to market for formulators ranges from less than a month to 3-5 years depending on the development project. This broad spectrum is due to a number of fac-

tors. Development projects as a reaction to customer wishes are generally quickly completed. With detergents and cleaning agents, the change might concern the color or scent, for example. Even pure application innovations (such as the application of an existing recipe on a new surface) are relatively short projects as certain tests for the formulation are not necessary (such as stability tests). If the scope of the changes (such as exchanging essential components or builders) grows, the changes may affect process engineering, thus increasing the duration of development. Finally, the need for technical authorizations extend the time to market.

One such case is the chemo-thermal disinfection of laundry in commercial laundry technology, such as systems for hospitals. In this application, the chemicals used must pass a test at the Robert Koch Institute (RKI) in Berlin covering several stages and generally lasting 5-6 years. The fee that RKI charges for authorization is around 2,000 euros, and three reports (including a microbiological test and a textile certificate) must be submitted that cost another 5,000-6,000 euros apiece. Several reports and certificates may have to be paid for before a formulation produces the desired result for the microbiological test. The overall authorization costs can thus quickly exceed 50,000 euros.

Two of the formulators surveyed (companies b and e) are not concerned that REACH will cause delays in product development as their recipes are based on mass substances that are sure to be registered soon. But most formulators are worried about delays (companies c, d, f, g, h). The main reasons given were problems that occur when the intended application of a detergent or cleaning agent is not registered as the “identified use” of all of the substances concerned (companies c, d, g, h). In such cases, companies have to spend more time looking for the right registered substance for the desired application or for a manufacturer who has registered the substance for that purpose. This search is even more difficult when multiple safety data sheets have to be checked for the substance’s registered applications. Otherwise, the company has to perform its own risk assessment for the application.

The interviews clearly showed that identified use has caused a lot of concern among formulators, who fear or implicitly assume that these uses will be narrowly defined so that they will not only have to test recipes but also customizations to see whether the use of these products still fits the definition of identified use in all of the cases. On the other hand, the companies said that the raw materials that the manufacturer did not intend for cleaning purposes were only used in a few cases. This shows that the degree of detail that still has to be specified for the delineation between different applications is decisive towards limiting the extra work for formulators who need to fit through the application corridor in REACH.

A second reason for these concerns that was mentioned several times is the limited selection of substances expected from REACH (companies d and f), which would also lengthen the search for suitable components.

In the cases of especially short development times - i. e. projects for the fulfillment of customer wishes - the existing data show the problems from REACH very clearly here: the ability to react to customer wishes is quickly diminished. For longer development projects, formulators still do not seem to be considering whether tests and in-house notification for identified use can take place along with the normal development process. This approach might reduce the overall time to market[38]. However, the extra expenses will not be reduced by this means; indeed, company d believes they will even increase as several options will have to be pursued at an earlier point, and they will all have to fulfill the registration requirements at the same time. Transferring this concept to detergents and cleaning agents under REACH will be a test of the current organization of development processes.

A closer look at the development phase in the interviews revealed that a lot of formulators already take the time-to-market into account for application tests on the customer's / system builder's site. Delays that users fear are thus not to be understood in addition to upstream delays. Furthermore, this type of development process demonstrates the close collaboration between formulators and users for development. The application conditions - and hence a considerable part of the information for the creation of exposure scenarios - are also known among formulators. However, there has not yet been any reason to regularly exchange this information with the substance manufacturers who need it for registration.

Another indicator of the development expenses of formulators is the past substitution costs. The formulators surveyed named the following cases and figures. Here, the financial expenses including staff capacity needed is reported (in euros) as well as the time needed for replacement (in months / years).

- Environmentally dangerous surfactants: 30,000 € (6 months) / 150,000 €
- EDTA (2 mentions): ca. 100,000 euros (2.5 years)
- APEO: 150,000 euros (5 years) / several million euros (100-150 recipes affected)
- 10 raw materials per year that go out of production: 1.5 million euros/y

38 Such options are used systematically in "simultaneous engineering" (s. z. B. Bullinger, Warschat 1997; Eversheim et al. 1995).

The differences in expenses are partly due to the number of recipes affected. In some cases, dangerous substances like environmentally dangerous surfactants are only used in recipes whose buyers place great store on them. For the transferability of these indicators to the costs of replacement substances for those that are withdrawn under REACH, it was pointed out that past substitutions usually concerned the use of individual components in a preparation. If REACH meant that multiple components of a preparation would no longer be available, development would focus on a complete reformulation generally beyond the replacement of an individual component (see Section V.5.2).

Up to now, formulators have been able to recover some of the costs for the substance substitutions mentioned above by means of price hikes, if not through lower margins (companies b, d, and g), volume growth (company h), or the rationalization of production sequences (companies c and h).[39].

V.4.6 Product lifecycles at the various stages of the supply chain

Research question: How long is the economic product lifecycle of raw materials for detergents and cleaning agents and the detergents and cleaning agents themselves? Which factors determine the end of the product lifecycle, and how will REACH affect that? How do the different product lifecycles interact at the meeting points of the stages in the supply chain?

(1) The lifecycles of applications largely determine the length of the lifecycles of substances and preparations.

(2) New insights on the (environmentally) dangerous properties of substances can end these lifecycles.

Comment: REACH is intended to step up research to provide new insights.

(3) The lifecycles of the recipes of formulators are generally between 3 and 10 years and foreshortening.

Comment: This indicates that users of short-lived recipes already know how to deal with a relative fast switch in a formulation and may even have called for it themselves.

39 The companies concerned did not state that jobs were lost here.

(4) The previous reasons why recipes were given up are the availability of better raw materials or better in-house products, lower demand / profit contribution, and the withdrawal of a substance.

Comment: To the extent that REACH affects the last two factors, the product's lifecycle may end prematurely. The effects of REACH can thus not be assessed on a purely additive basis.

(5) The product lifecycles of the users studied are rather long (5-20 years).

Comment: This reduces the effect of REACH on the actors in this supply chain.

The concept of economic product lifecycles[40] which deal with the length of time during which a product is marketed, among other things - has to be interpreted specifically for each stage of the supply chain. Chemical substances are hard to grasp as products; their product lifecycle is closely related to the development of applications. The predominant number of surfactants has thus been on the market for several decades. If there is demand, a substance can be "reactivated" at any time if it and its synthesis method are still known. If an application is discontinued or its production moved abroad, the production of the substance (at the previous location) is called into question.

Another important factor that can end a substance's product lifecycle is the determination of certain (especially environmentally) dangerous properties such as toxicological decomposition products in the case of APEO. Here, the systematic testing of existing substances under REACH could produce new insights, leading to a premature end to the lifecycles of many substances. This would be in line with the intent of REACH.

For formulators, it makes sense to interpret the "product" lifecycle as a "recipe" lifecycle and to separate it from the lifecycle of a brand name (such as ARIEL). Brand names are often kept even when the recipe completely changes. Their lifecycle thus tells us little about changes in the demand for the raw materials in the detergents or in the chemical properties of the products sold. The recipe lifecycle ranges from 3-10 years for most of the companies surveyed, while IKW says that 5 years is the average (cf. Table V-15). Two formulators of industrial detergents and cleaning agents said that their recipe lifecycles were 15-30 years, while household detergents and cleaning agents sometimes have shorter lifecycles of 1-5 years. This suggests that industrial

40 The concept of an economic product lifecycle assumes that a product will not exist forever and divides its marketing phases into, typically: development, growth, maturity, saturation, and degeneration.

recipes have more continuity, though this study was not able to support that hypothesis further. If we take a look at the lower end of the common recipe lifecycles, we see that buyers in this market segment are already faced with reformulations relatively often and that these changes are sometimes demand-driven.

The factors that terminate a lifecycle include economic reasons (such as lower demand and lower profit contributions), the availability of better raw materials or better in-house products, and the withdrawal of raw materials. These factors are related to some of the modes of action of REACH (such as the shift in price relations for the raw materials for preparations and the changing availability of raw materials). The effects of REACH can thus also be interpreted as a premature termination of a recipe's lifecycle in these cases. In other words, no completely new developments that the market does not know were set off, but rather existing tendencies and mechanisms were sped up (see Chapter V.5.2). The effects of REACH thus do not cumulate, but overlap with changes in product portfolios that are already happening.

The shorter lifecycle of user products was often held to be due to special exposure under REACH (such as the electronics industry). The assumption is that the change in a product generation also entails a change in the preparations demanded. The probability of being affected by rationalization or basic reformulations of preparations would then increase, and users would have to adapt. The definition of product lifecycles for users is subject to certain uncertainties as the change of a product generation generally does not involve hard breaks, but rather fluid boundaries. Despite the resulting lack of clarity, it can be stated that the product lifecycles in the applications studies were rather long: 5 to 20 years. This reduces the effect of REACH on the actors in this supply chain.

Table V-15: Empirical data on the innovation effects of REACH

	Im-porter	**Sub-stan-ce manu factu-rer**	**Formulator**							**Users**			
Company	**0**	**a**	**b**	**c**	**d**	**e**	**f**	**g**	**h**	**i**	**k**	**l**	**p**
Employees	780	2000	25	48	170	98	132	150	250	23500	31800	2200	3500
Revenue	1000	1500	5	9	26	31	45	60[5)]	65	328	14000	520	1200
Share of R&D in revenue	n.a.	1.2	0.7	2.6	2.9	1.2	2.0	0.3	2.7	-	-	-	-
Raw materials	-	-	180	187	270	90	207	90	300	-	-	-	-
Products (substances, recipes)	-	-	135	141	180	40	100	1200 [4)]	400	-	-	-	-
Recipes / million EUR of revenue	-	-	28	16	7	1	2	17	6	-	-	-	-
Tome to market (a) min (months)	-	6-12	4	6-12	0.3	1-6	3-6	0.25-0.5	12-18	12	6-12	n.a.	n.a.
max (years)	-	3-5	0.5-1	5	1.5	2	1-3	0.5	n.a.	n.a.	5-6	n.a.	2-3
Product lifecycle (a) [0)]	3-10	n.a.[1)]	10-30	3-10	n.a.[2)]	3-5	1-2	10-15	5	n.a. [1)]	5-7 [3)]	n.a.	10-20

0) For formulators, the recipe lifecycle; 1) the concept does not seem to suit the line of business; 2) the commercial cleaning industry does not have typical product lifecycles; 3) model change; 4) only products formulated in-house, without chemicals trade; 5) 83 % chemicals trade.

V.4.7 Knowledge management and expertise flows

Research question: Which transparency requirements in the REACH system can lead to relevant expertise losses? To what extent does the risk of expertise losses restrict the possible efficiency gains from cooperation in the REACH system?

(1) As in current chemicals law, expertise protection for the composition of preparations is not absolute.

Comment: This shows that market actors are able to deal with a certain amount of expertise spill-over.

(2) Formulators are concerned that REACH will favor the flow of application knowledge to substance manufacturers. Their marketing strategies can make them into multipliers of this knowledge at the level of formulators.

Comment: In order to realize positive spill-over effects overall, the resulting additional incentives for application innovations for substance manufacturers have to outweigh the prohibitive effects for formulators.

(3) The cooperation with competing substance manufacturers that will be necessary to create consortia is viewed skeptically in terms of possible expertise loss. Some of those affected (3 mentions) see one possible solution in the support of associations, which could, for instance, act as intermediaries to maintain the secrecy of knowledge that is sensitive for competition.

All of the formulators and substance manufacturers interviewed fear that REACH will lead to an outflow of competition-sensitive information about expertise in the formulation of preparations and about technical applications of substances. Downstream users of preparations in the processing industry feel that they will be less affected by this risk.

The possibility of getting information about the preparations of competitors via safety data sheets is not something that started with REACH. The German TRGS 220, which is based on the EU Directive for Safety Data Sheets (91/155/EEC, 93/112/EC and 2001/58/EC) and the EU Directive on Preparations (88/379/EEC and 1999/45/EC), stipulates that the following information has to be disclosed:

- The intended or recommended use of a dangerous substance or of a preparation containing dangerous substances and the general technical function of a substance or preparation, such as fireproofing agents (point 6.1.2).

- The identity and concentration (EINECS or ELINCS, possibly also CAS and IUPAC) of the dangerous substances in the preparation that make it classified as dangerous according to the rules in Article 3 (3) of the EU Preparation Directive (point 6.2.3).
- The identity of substances that are dangerous to human health and the environment in preparations not classified as dangerous, provided they do not exceed 1 % (point 6.2.4). For substances exclusively classified as irritants or environmentally damaging, a more general designation (such as those in annex 6 of the preparation directive) can be used in lieu of the chemical identity if the marketer can demonstrate confidentiality problems. This also applies if an irritant or substance that is acutely dangerous to people's health is also highly inflammable, easily inflammable, inflammable, explosive, and environmentally dangerous (point 6.2.4)
- The identity of substances in a preparation for which there are EU exposure limits at the workplace if the concentration in the preparation exceeds 1 % (point 6.2.3).

Authorities in the various EU states interpret the requirements of the safety data sheets somewhat differently (see ECLIPS 2004). The examples given in Chapter V.3 indicate that the safety data sheets thus sometimes contain information that goes much further. One company (c) thus claims that it is possible to reconstruct 95 % of the recipe of a preparation by analyzing such sources of information.

The EU's new detergent regulation 648/2004 stipulates that manufacturers of preparations are obligated to provide experts from the health sector with a data sheet on request listing all of the ingredients by concentration thresholds of > 10 % to < 0.1 %. Company f feels that there is no guarantee that such information will only be used in clinical medicine.

V.4.7.1 Transparency and expertise loss under REACH

The concern that the desired transparency of substance flows under REACH will lead to an outflow of formulation expertise must be taken seriously. One potential way of getting information about the recipes of preparations is from the exposure assessments of dangerous substances required by Article 13. The determination of the "predicted environmental concentration" (PEC) for a certain dangerous substance for a specific application requires its concentration in the mixture of chemicals use, even if the mixture is not classified as dangerous. This represents sensitive information that the manufacturer of the preparation does not want to pass on. If this information has to be taken up in the safety data sheet, it becomes generally accessible. However, the contracted researchers feel it is possible to use the concentration ranges that have to be disclosed in safety data sheets according to current legislation to assess exposures.

The companies stated that Article 30 was a potential source of expertise outflow for substances not classified as dangerous. This provision sets forth the manufacturer's disclosure duties towards downstream users (customers) for substances and preparations that are not dangerous. While this disclosure duty only concerns the identity of the substance and not its concentration, this information is nonetheless felt to be sensitive for competition, and it cannot be ruled out that this information will be passed on to competitors via business relations with customers. One example given was enzymes in detergents. Here, the expertise needed to reconstruct the recipe is the way the enzyme is used, not its concentration. Here, the contracting researchers point out that Article 30 in its current version in the draft regulation is inconsistent (or at least imprecise). According to Article 116.2 (e) and the intention of the draft (as the other Articles make clear), details on the complete composition of a preparation are considered confidential. In addition, substances that are not dangerous in preparations are not the subject of exposure evaluations in the REACH system. It would help to have a clarification of what Article 30 of the draft regulation means.

Another way of losing expertise is the definition of a substance's generic use and the description of safe application conditions in the exposure scenario. Here, the companies repeatedly referred to the concept of exposure categories as an instrument for communication about exposure issues in the supply chain that simultaneously upholds expertise protection to an appropriate extent. The contracted researchers also point out that TRGS 220 already requires information on the intended use of dangerous substances and preparations (including technical functions) but that no standard practices about how to deal with this requirement have crystallized on the market.

Formulators are concerned that they will lose the expertise they have worked so hard to get to competitors. This attitude is counterproductive for the innovation that formulators perform as the innovating company is worried about how it can refinance its R&D expenses when the competition improves its product to make it equal to one's own. At the same time, formulators have an incentive to limit their R&D expenses to have more funding for product imitation. However, it must be kept in mind that the successful diffusion of an innovative preparation on the market is based on the gradual propagation of the underlying knowledge, as is the case in general with innovations. In terms of politics, a general framework has to be created to allow innovative formulators to have a sufficient advantage from their innovations with an appropriate return on their innovation, on the one hand, while the knowledge is gradually disseminated and the returns on the investment gradually drop, on the other.

V.4.7.2 Cooperation and expertise loss

Cooperation among substance manufacturers / importers for substance registration was already discussed in Chapter V.2.2 in the analysis of registration costs. Both companies (0 and a) are principally willing to enter into consortia. However, company a does not see a solution for certain substances whose registration is doubtful as they fear, among other things, that they will have to disclose their confidential application expertise. This is especially true for specialists (see Ch. V.5.2). The contracted researchers believe that these fears are not completely founded: after all, cooperation in consortia requires communication about substance properties and test results. At the same time, confidential application knowledge does not have to be communicated if each consortium partner performs its own exposure assessment.

Most of the formulators interviewed see cooperation with competitors for registration as crucial due to the potential outflow of expertise. Certain rules are needed to prevent or at least limit risk in order to help make this approach an effective instrument towards lowering registration costs. For instance, in cooperative registration associations could act as trustees for information crucial to competitiveness (companies a, g, and h).

But companies even see the indispensable cooperation between substance manufacturers, formulators, and downstream users for registration under REACH as a potential source of expertise loss. The information that substance manufacturers receive about any functions and uses of their substances previously unknown to them could make them competitors. It was not clear how often such problems actually occur in practice.

V.4.8 Entering new application fields and service models under REACH

Research question: To what extent does REACH favor the opening of new application fields for the raw materials in detergents and cleaning agents and in the detergents and cleaning agents themselves? To what extent does REACH promote the development of substance and preparation suppliers into chemicals service providers (from information management to knowledge management)?

(1) For substance manufacturers, opening up new application fields is important for their substances.

Comment: REACH can provide additional incentives here as more knowledge about applications will be circulated or have to be created.

(2) Formulators work very closely with their customers and tailor their detergents and cleaning agents to the cleaning purpose (such as the kind of material to be cleaned) and the cleaning method (system engineering).

Comment: Thus, application-driven innovations already play a large role. It is not clear whether REACH will create additional application knowledge and related innovation incentives at this stage of the supply chain.

(3) In contrast, formulators opening up truly new application fields by using a raw material generally not found as a cleaning agent is not so important.

Comment: Formulators thus rarely get into a situation where they are outside the application corridor defined by the raw material manufacturer and thus have to perform risk assessments themselves.

(4) Service models as operator models between formulators and users have not been crucial in the selected section of detergents and cleaning agents. There are no explicit strategies to expand this under REACH.

Comment: If no other trends amplify REACH's influence, its effect on the development of service models will be limited.

The R&D of substance manufacturers is roughly spread across three fields. One substance manufacturer in the present study devotes very little attention to the development of new substances. Process development is second, with the largest chunk of R&D going to application technology. Here, the question is to what extent and how substance manufacturers get application knowledge. According to the TEGEWA association, collaboration between substance manufacturers and formulators who make detergents and cleaning agents is rather loose. Cooperation with manufacturers of industrial and commercial cleaning agents is said to be closer. As shown below, application knowledge among formulators is very high. If contact between substance manufacturers and formulators is close, it is possible to pass on this knowledge to substance manufacturers. The registration duty under REACH and the required disclosure of exposure and applications mean that substance manufacturers have to get more application knowledge. Current cooperation with formulators could be a starting point here. The additional application knowledge represents an additional incentive for innovation among substance manufacturers.

Today, formulators already have great application knowledge. They often visit customers and tailor their formulations to the object to be cleaned, the type of soiling, and the cleaning techniques. According to IHO, special cleaning agents are often developed jointly with manufacturers of the product to be cleaned. One formulator also says that

collaboration with manufacturers of cleaning systems plays a role. These manufacturers see themselves as system suppliers who offer machines complete with chemical systems. If collaboration does not work from the outset, products are developed in competition specially tailored to certain cleaning systems (such as car washes). Close coordination between cleaning methods and cleaning agents is all the more necessary for water-based detergents and cleaning agents - compared to organic solvents - as they can be used less universally (Umweltbundesamt 1998). If a cleaning agent recipe is changed, the machine generally also has to be adjusted. Here, close collaboration between the machine manufacturer and the manufacturer of the cleaning agent is required and common. The chemicals have to be tailored very carefully to the kind of oils and greases to be removed, especially for fast automatons that use water-based cleaning agents. This requires close collaboration between the manufacturer of the machine and the manufacturer of the cleaning agent. Often, the chemicals supplier makes the settings on the machine.

These examples show that application knowledge for formulators already represents an essential competitive strategy. They have set up several channels by which this knowledge can be generated via customers and system engineers. In light of the high level of application knowledge among formulators, it is questionable that the additional effects of REACH at this stage of the supply chain will produce more innovations based on application knowledge.

As application knowledge represents an essential competitive strategy for formulators, it is also sensitive information that cannot be passed on without further ado. In particular, there are fears that REACH will allow substance manufacturers to gain detailed information about the applications they serve and that they will then act as multipliers towards other formulators and hence towards the competition (see Chapter V.4.7). The innovation returns of formulators from new applications - and hence their incentive to innovate - would thus be reduced. To prevent this, a balance has to be found between the information needs of substance manufacturers and the secrecy needs of formulators. This greatly affects the information required under REACH on exposure scenarios and the possibilities of categorizing this information.

While formulators say that entering new application fields is an important R&D activity, applications that use raw materials not generally used in detergents and cleaning agents are an exception. Only one company stated both that it systematically looked for raw materials outside the common ones for detergents and cleaning agents and that this search was especially important for true innovations. Under REACH, such a strategy would mean that the application would generally be outside the corridor intended by the manufacturer. If the application is to be kept secret for reasons of competition,

petition, the formulator loses the option of demanding that the manufacturer expand its registration to include this application. The formulator would then have to conduct a risk assessment on its own and report the application to the Agency. Under REACH, "exotic" application purposes would be subject to a risk assessment. Therefore, one cannot speak of a general disadvantage for the innovation strategy named. However, the strategy leads to a systematic shift in the assessment task for formulators.

The application knowledge propagated across supply chains under REACH also raises the question of whether the result will be a broader basis for the development of service models between substance manufacturers / formulators, on the one hand, and users, on the other. For instance, formulators might not be paid by the liter for their product any longer, but rather by the number of workpieces cleaned. The interviewees did not agree on whether such operator models were very relevant. One company did not see very many possibilities for such models in detergents and cleaning agents. Another company practiced such a model in which the amount of laundry cleaned (and not the amount of chemicals supplied) was paid for. In such cases, the formulators handles the machine settings as well as the production data acquisition. None of those surveyed will be pursuing an explicit strategy to expand their offer of services under REACH. However, some pointed out current trends to expand general services in the field of chemicals (companies h and k).

A second aspect is the services that could be established on the market to support companies in the fulfillment of REACH requirements. They include IT, consulting, and laboratory services as well as management services for the creation of consortia. The present study only dealt with this aspect marginally. Substance manufacturers and formulators were asked whether and which work they might outsource in connection with REACH. They listed laboratory tests for substances and development work for exposure scenarios and risk assessment. Support in creating a consortium was seen as a task for trade associations. Some of the services previously outsourced - administration of safety data sheets was explicitly mentioned - could increase within companies under REACH to an extent that new staff would have to be hired.

V.5 Other effects of the REACH system

In the following section, the adaptation reactions of companies on various stages of the supply chain to REACH were analyzed to determine whether costs can be passed on and whether there would be any changes in the availability of substances and in international competitiveness. Table V-16 provides an overview of the most important quantitative parameters for formulators based on the interview data. Other raw data are documented in the respective sections.

Table V-16: Indicators of adaptation mechanisms for REACH among formulators

Company	b	c	d	e	f	g	h
Employees	25	48	170	98	132	150	250
Revenue in million euros	5	9	26	31	45	60	65
Share of chemical costs in production costs	n.a.	70 %	60 %	10-70 %	n.a.[1)]	80-90 %	50-70 %
Raw materials	180	187	270	90	207	90	300
Voluntary withdrawal (% of the raw materials portfolio p.a.)	2.8 %	2.7 %	3.7 %	n.a.	n.a.	35,6 %	n.a.
Mandatory exchange (% of the raw materials portfolio p.a.)	1.7 %	1.1 %	0.4 %	1.1 %	1.0 %	5.6 %	3.3 %
Exports outside of Europe (% of revenue)	5 %[2)]	25 %	0	0	6 %	5 %	10 %[3)]

1) This information is confidential; 2) exports into EU and non-EU countries as no separate data are available; 3) important markets outside Europe are also served by local production plants.

V.5.1 Passing on costs

Research question: How can REACH-induced costs be passed on to downstream stages in the supply chain?

(1) The prices of surfactants have been dropping, while the revenue and prices of detergents and cleaning agents have stagnated or dropped.

Comment: This is a poor starting point for price increases to cover cost increases.

(2) Some companies expect price increases from REACH due to the greater market concentration and lower imports of chemicals.

(3) Against the statistical trend, some formulators have managed to raise prices to compensate for some of their additional expenses.

(4) The relation between specific registration costs and the market price for a substance varies greatly according to tonnage range.

Comment: Thus, the pressure on substance manufacturers to pass on registration costs to formulators varies.

(5) Due to the great spread of the share of the cost of chemicals in production costs in a preparation, cost increases for raw materials affect the cost structure of formulators for household products somewhat less than for industrial products.

Comment: In other words, the pressure to pass costs on is lower for household goods.

(6) It is easier to raise prices when all competitors are equally affected and buyers do not abandon ship because they benefit from special terms for established customers.

Comment: If REACH makes raw materials more expensive for formulators, it is possible that some of these additional expenses can be passed on to customers.

(7) Formulators do not see any willingness among customers to pay for preparations based on raw materials registered under REACH.

Comment: Here, it is possible that the advantages of such preparations - namely, the reliability of their quality and availability - were overlooked for the phase-in process.

(8) For the surveyed users of chemicals from outside the chemicals industry, the cost of detergents and cleaning agents generally makes up far less than one percent of the overall production costs. The share of the overall cost of chemicals in production costs is also slight.

Comment: In other words, the margins of users would only be slightly affected if the costs from REACH at downstream stages of the supply chain are passed on even in a pessimistic assessment of the chances of raising prices.

(9) On markets outside Europe, none of the actors in the supply chain expect any advantages from REACH.

Comment: The possibility that these markets might produce their own registration systems, giving REACH a first-mover advantage, was not taken into consideration.

The figures on specific registration costs and a comparison of them with the price range of the substances studied provide an initial indication of how great the pressure on registrant substance manufacturers is to pass on registration costs (see Chapter 2.3). It is important to remember that surfactants are generally inexpensive substances so that the specific registration costs for tonnages below 1,000 t/y will be relatively great (cf. Ch. V.2.2).

To keep the payback times in line with the periods that companies are used to and to a extent macroeconomically useful, prices would have to be raised considerably in the

worst cases, and the contracted researchers do not feel that this is realistic[41]. In the best cases, the pressure to pass on costs is less drastic. In other words, there are great differences even within one substance group such as surfactants.

Both the general statistics on the detergent and cleaning agent industry and our company interviews show that prices and revenue have stagnated in the past few years, if not dropped in absolute terms (see Ch. V). The price competition is thus great. Overall, additional expenses cannot generally be passed on easily in such situations. 5 of the 7 formulators surveyed (companies d, e, f, g, and h) did manage to raise their prices in spite of this stagnation. Under REACH, two of those surveyed expect greater market concentration among substance manufacturers (companies a and f), but they disagree about what the price effects will be. Company f expects the possible REACH-based reduction of the variety of substances on the market to allow substance manufacturers to use production capacity more efficiently so that the production costs - and possibly the prices - of chemical substances might drop. In contrast, the substance manufacturer (company a) expects the remaining (large) companies to have greater leeway to raise prices. Company g points out that the expected reduction in imports of chemicals under REACH and the concentration of domestic demand for domestic chemicals would make price hikes more probable.

Formulators will be affected by any price hikes for raw materials differently depending on the share of the cost of chemicals in production costs. The share of the cost of chemicals among the industrial formulators surveyed ranges from 50 % to 90 % and ainly depends on the water content and the value of the raw materials used (cf. Table V-16). Formulators of household products (companies e and f) also commonly have low shares of chemical costs around 10 - 30 %, which is partly due to the great packaging expenses and very cheap raw materials. These figures make it clear that the cost structures of formulators of household products tend to be less affected by price hikes due to REACH than the cost structures of industrial formulators. The pressure to pass on such costs is thus accordingly lower.

Three of the formulators (b, d, and g) have experienced that additional expenses were at least partially financed with price increases despite the unfavorable conditions. However, this did not always occur immediately and in the full amount of the costs so that slighter margins had to be accepted in the end. The possibility of raising prices for pri-

41 However, it should be kept in mind that substances only made in small volumes that thus have great specific registration costs are often only used in small concentrations in preparations. In other words, the great specific registration costs for small-volume substances would mean that passing on costs would not affect the cost raw materials for preparations greatly.

vate label products is seen as especially unlikely. These products are sold by chains under their own brand name. Formulators feel they are exchangeable at any time under such conditions, even if customer relations are relatively close. The factors mentioned that favor price increases included the fact that all competitors are affected equally (companies g and e) and that buyers are enticed to stay on board thanks to special terms for established clientele. These factors will continue to apply under REACH and thus indicate that it will be easier to pass on price increases due to REACH. However, formulators do not see any willingness among their customers to pay more for preparations exclusively based on components registered under REACH. In principle, no further REACH-induced reformulations would affect such preparations during the phase-in period. In this period, buyers would thus be sure that the preparation would remain constant and available and that the quality would not change; they could thus calculate for any cost increases for this period. The contracted researchers feel that the follow-up costs for the reformulation of a preparation when a raw material is no longer used (see Ch. V.5.2) suggest that there is a certain willingness to pay for substances to be kept on the market.

For the surveyed users of chemicals from outside the chemicals industry, the cost of detergents and cleaning agents generally makes up far less than one percent of the overall production costs.[42] (cf. Table V-17). This astonishingly low importance is reflected in the relative low share of the costs of detergents and cleaning agents in the process step of "cleaning" studied. Here, the cost structure of staff and equipment costs dominates. To the extent that information from the companies was available from interviews, the share of the cost of chemicals in overall production costs is very small. In other words, the margins of users would only be slightly affected if the costs from REACH at downstream stages of the supply chain are passed on even in a pessimistic assessment of the chances of raising prices.

On markets outside Europe, none of the actors in the supply chain expect any advantages from REACH. As all European manufacturers are subject to the REACH system, there are not enough opportunities to set oneself apart from competitors on this basis. In addition, fulfillment of the law is not a good marketing argument. The possibility that markets outside Europe might produce their own registration systems, giving the European economy a first-mover advantage, was not taken into consideration.

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42 At a recent conference on chemicals regulation, figures of the share of the cost of chemicals in *material costs* were presented for various industries (Armstrong 2004). They made up 16 % of the total in the automotive industry but cannot be compared to the figures presented here due to the different basis (material costs instead of production costs).

Table V-17: The importance of the cost of detergents, cleaning agents and chemicals for users

Company	i	k	l	p
Employees	23500	31800	2200	3500
Revenue in million euros	328	14000	520	1200
The share of the cost of detergents and cleaning agents in overall production costs	0.7-2.8 %	0.02-0.03 %[1)]	slight	0,05-02 %
The share of the cost of detergents and cleaning agents in the process stage "cleaning"	10 – 40 %	n.a.	slight[2)]	5 – 10 %
The share of the process stage "cleaning" in overall production costs	7 %	n.a.	n.a.	1 – 2 %
The share of the cost of chemicals in overall production costs	3 %	n.a.	< 1 %[3)]	0.5 %

1) According to information provided by a major industry supplier of detergents and cleaning agents on the cost of detergents and cleaning agents per vehicle and the information provided by company k on production costs per vehicle; 2) dominated by the cost of wages, buildings, and machines; 3) in-house calculation based on detailed information from the companies on the volumes and prices of chemicals purchased and their revenue.

V.5.2 REACH effects on the portfolio of substance manufacturers for detergents and cleaning agents

Research question: To what extent can REACH affect the product portfolio of substance manufacturers and the product and raw material portfolio of manufacturers of detergents and cleaning agents? What does the reformulation of products mean for downstream users when certain raw materials are no longer available?

(1) On the basis of its portfolio analysis, substance manufacturer a does not register 40 % of its substances for economic and strategic reasons. The strategic considerations are based partly on market studies showing how the applications of a substance will developed and on considerations of portfolio design. This company thinks that 5 – 10 % of the substances affected by their withdrawal from the market will disappear completely. It estimates the resulting drop in sales at 5 – 10 %.

(2) Small-volume substances can be those at the beginning of the development process without actually being new substances. REACH will affect them especially, and to top it off: at a sensitive phase of the product lifecycle.

(3) The palette of raw materials among manufacturers of detergents and cleaning agents is less comprehensive than that of paint manufacturers.

Comment: This indicates that the withdrawal of a raw material and cost increases passed on will not affect them as much.

(4) No one voiced fears that the availability of (raw) materials from non-EU countries could suffer under REACH.

(5) For reasons of efficiency (storage, logistics, etc.), companies already attempt to limit the number of chemicals used to the extent possible. The development of the size of a formulator's portfolio of raw materials is, however, growing due to the increasing complexity and multitude of recipes so that overall raw materials portfolios are slightly growing.

Comment: As a result, exposure to REACH effects will increase slightly (withdrawal of raw materials, passing on costs).

(6) The share of raw materials withdrawn from portfolios voluntarily (such as when a recipe is abandoned, demand is low, or to prevent the use of dangerous substances) is generally between 20 % and 40 % of the portfolio over 10 years. The "basic quota of forced substitutions" (such as for legal reasons or because the supplier stops production) is generally between 10 % and 20 % in 10 years.

Comment: In sum, the capacity to exchange of raw materials provides a solid basis on which to meet the challenges of REACH.

(7) At present, there are generally sufficient warning periods (3-12 months) and offers of substitute substances from suppliers to facilitate adaptations of formulators to the withdrawal of raw materials.

Comment: Formulators have been able to deal with the concomitant challenges (price hikes, limited equivalence of the substitute, etc.) in the past.

(8) Users will have to spend more time and money on results and application tests (technical release process) and create new operating instructions when a raw material is withdrawn and detergents and cleaning agents have to be changed. The application tests are generally much shorter than in the paint chain (less than one year).

(9) The product development of users usually does not affect the need for the detergents and cleaning agents used.

Comment: This is why delays in the product development of formulators does not automatically lead to longer product development times for users.

In preparation for REACH, the surfactant manufacturer surveyed (company a) has already produced a quite detailed portfolio analysis. The implications for investment decisions for registration were discussed in Chapter V.2.2. This suggests that the cost/price ratios are not good in the whole range up to 1,000 t/y based on the cost estimates of the companies. For surfactants, this situation is the result of their relative low market prices and the rather small margins in the industry.

For the substance manufacturer surveyed (company a), some 40 % of the surfactants relevant for detergents and cleaning agents are in the sensitive tonnage ranges below 1,000 t/y; in the overall substance portfolio, the figure is closer to 75 %. The company's statement that it will not register some 40 % of its substances thus seems plausible. The expected resulting drop in sales is around 5 – 10 %[43], while the drop in results will be around 10 – 25 %. Here, the substance manufacturer surveyed assesses the registration decision based on the same criteria as other investment projects, i. e. the internal return on capital invested must be 25 %. The option of entering into consortia was taken into account in the estimation of the withdrawal quota. In general, the company sees consortia as a way of lowering costs, which it estimates would cut costs on the average by a third (cf. Chapter V.2.2). For the substances not intended for registration, consortia are either not possible because company a is the only manufacturer, because the company finds the secrecy of internal expertise to be more important[44], or because the costs are felt to be too high even after the creation of a consortium.

In addition to the pure investment assessment criteria for the registration decision, company a also took into account strategic considerations about how the applications of a substance will develop[45]. Furthermore, strategic considerations about portfolio design also play a role, such as the goal of covering a certain application portfolio completely. The company sees a general problem in the additional financial burden of small-volume substances whose low production volume is a result of their early stage in their product lifecycle. This problem is not specific to new substances but can also occur in the "development" of existing substances taken up anew in a company's portfolio. Another example of when existing substances have to undergo a development process is the switch to short-chain surfactants used at low washing temperatures. This

43 80 % of sales in generated with only 20 % of the substances.

44 As mentioned in V.4.7.2, the contracted researchers do not find these fears to be well founded.

45 The contracted researchers point out that low-tonnage ranges only have to be registered 11 years after the regulation takes effect. Hence, studies that cover periods relevant for REACH have to include very distant horizons.

initially caused outgoing air problems in spray drying[46]. In an early development stage, the company found it to be generally difficult to justify development expenses in light of the marketing risk, and REACH will only make things worse in this phase.

The interview went into greater detail about whether the providers surveyed are the sole manufacturers of the registered substances, what the considerations are for registration, and whether / how these considerations were taken into account. The interdependence of an internal registration decision on those of competitors makes reaching a decision more difficult according to company a. The estimate of how many substances not registered will disappear from the market completely when company a pulls out is unclear, though the company estimates some 5 – 10 %.

The palette of raw materials among formulators of detergents and cleaning agents is generally less comprehensive than with paint manufacturers. If one assumes that this ratio also applies to the substances actually used (CAS or EINECS substances, etc.), the formulators of detergents and cleaning agents are less likely to be affected by the withdrawal of raw materials and any costs passed on. This tendency is, however, slightly increasing for the portfolio of raw materials, thus increasing exposure to REACH. This trend seems to be the result of two contrary movements. On the one hand, the growing number of recipes and their increasing complexity has led to an increase in the number of raw materials in portfolios. On the other hand, formulators are trying to keep their portfolios of raw materials as sleek as possible to be efficient (storage, logistics, management of product safety, etc.). Streamlining the palette of raw materials on the market would serve this end to some extent.

Raw materials from outside the EU play a major role in the palette of raw materials of substance manufacturers and formulators of detergents and cleaning agents. For instance, citric acid mainly comes from India. Fatty acids - one of the basic raw materials for surfactants, are often from Malaysia and Indonesia. The formulators often do not know the exact origin of the basic raw materials supplied. No one feared that the availability of such raw materials from outside the EU could suffer under REACH. Rather, the economic importance of the EU market for the countries that export raw materials is found to be so important that these exporters are expected to register their substances.

The selection of raw materials for detergents and cleaning agents by formulators is already subject to constant change. Every year, raw materials are voluntarily taken out

46 Another example is the adaptation of alcohol ethoxylates to the application profile of nonylphenol ethoxylates (NPEOs) by selecting a suitable hydrophobe and degree of ethoxylation.

of portfolios, for instance when a recipe can be switched to less expensive or better raw materials or to prevent the use of certain dangerous substances proactively. For most of the formulators surveyed, this rate is between 2 % and 4 % per annum, with company g being an outlier at 35.6 % (cf. Table V-16). The quotas for voluntary withdrawal are thus around 20 - 40 % when extrapolated for the implementation period of around 10 years that is relevant for REACH. In addition, some raw materials have to be withdrawn by law. The quota indicated by most of the formulators surveyed (companies b to f) was between 1 % and per annum, while one company indicated 3.3 % and another 5.6 %. If the figures from the majority of formulators are used, the “base quota for mandatory substitutions” is around 10 - 20 % for REACH’s approximate implementation period. One reason for the withdrawal of raw materials is new laws; all of the reasons are the result of untested existing substances being on the market. Their problematic properties are only recognized too late - when they have already been included in formulations, etc. In other words, a considerable part of the previous mandatory reformulations is driven by “historic burdens”. According to company b, one difficulty is that suppliers often take full advantage of legal deadlines for the termination of the use of a substance so that the adaptation periods for formulators are quite foreshortened, if not completely eliminated. The withdrawal of raw materials can also have economic reasons on the part of suppliers.

If the quotas for the voluntary and mandatory withdrawal of raw materials are combined, formulators have the capacity to substitute some 30 - 50 % of the raw materials in their portfolios over 10 years. If part of the adaptation capacity currently used for voluntary raw material substitutes is used to compensate for the probable withdrawal of raw materials under REACH, any abrupt, unexpected REACH effects on raw materials will be kept within limits as this capacity provides a sound basis to tackle the challenges of REACH. The formulators surveyed expect a withdrawal of substances under REACH for “small-volume” substances, for instance, though some substances up to 1,000 t/y are included in that group (such as companies a and g). Of the substances groups, special surfactants, anti-corrosion additives, hydrotropes, enzymes, and pigments are considered especially dangerous, as are imported products that usually compete with domestic products produced in far larger volumes.

(Raw) materials used to be taken off the market according to a certain procedure between the substance supplier and formulator. Part of that was “warning periods” of 3 - 12 months and an offer of substitute substances, which, however, do not always match exactly. For instance, EDTA had to be replaced by various substances in differ-

ent applications[47]. In addition, the substitute substances are often expensive. Dealing with these conditions for the withdrawal of a raw material is part of the daily agenda for formulators. Adaptation is made easier because most of the formulators surveyed try, if possible, to have substitutes on hand that are not yet used - partly because of the price, the regionally varying availability, or poor performance - but would allow a recipe to be continued in principle. Under REACH, it also helps that the formulators surveyed say that substances abandoned long ago for detergents and cleaning agents rarely become relevant again. Thus, the question of the availability of substances from "hidden reserves" does not affect the industry much under REACH[48].

If a raw material is withdrawn at the level of formulators, the component in the recipe has to be substituted. Examples of such expenses for reformulation were given in Section V.4.5. Reformulation expenses may even be incurred when the manufacturer of the raw material - as opposed to the raw material itself - is changed. Reformulation is more complicated when several components have to be substituted simultaneously, for instance because several raw materials are withdrawn or the components depend on each other and the replacement of a raw materials would require an adaptation of the recipe. Some formulators expect that the change in the use of raw materials under REACH will exceed the degree to which the raw materials used to have to be substituted and formulations completely revamped. Hence, experience with reformulation expenses does not tell us much about the cost burdens under REACH as these expenses result from the substitution of one or a few components. The contracted researchers believe that this restriction only applies if REACH leads to the withdrawal of a raw material that exceeds the *entire* adaptation capacity, i. e. the quota of the voluntary and mandatory substitution of raw materials, of formulators for this purpose.

In terms of the quality of their preparations, formulators expect the withdrawal of special components to worsen functioning. Their products would no longer be able to be adapted so specifically to the cleaning purpose (type of soiling, material to be cleaned, etc.). They feel that there will be some shift from special cleaning agents to more generic ones. To have the same cleaning effect, several cleaning agents may have to be used, and the ecological effects may be negative. The comment of one user (company i) should be kept in mind for this estimation: one essential innovation direction at the level of users consists in fine tuning the dosage technology and working with closed

47 The problem that subsequent adaptations to the other components have to be made when a raw materials is substituted was not as great in the detergent and cleaner chain as for paints.

48 Here, these are "non-phase-in" substances produced in the 15 years before REACH takes effect in production volumes below one ton per year.

fleets (see Chapter V.4). The statistically monitored drop in sales of detergents and cleaning agents fits this picture. This reduces demand for detergents and cleaning agents so that the overall effect is hard to assess in advance.

If the recipe of a preparation changes or a preparation has to be replaced by another one, the user of the preparation has to adapt in various ways. At the technical level, current production is affected first. In general, the sensitivity of users to changes in recipes increases along with the depth of integration and the interdependence of chemicals and production processes. In the detergent and cleaning agent applications studied, this was only the case in one company. This company has had great interdependence with paint/cleaning agent systems. Changes in the formulation of a detergent / cleaning agent must undergo tests in this case to ensure the compatibility of the equipment, the paints, and the cleaning agents. In the company surveyed, this technical release process takes some 3 - 4 months for detergents and cleaning agents, thus much less than for the technical release of paints. In this company, procurement has an overview of the follow-up costs for a recipe change and can take them into account for price negotiations.

In the three other cases at the level of users, cleaning processes are mostly checked for results, partly because formulators have already tested the cleaning agents in the machine application. The results of the cleaning processes are very sensitive in some cases as poor cleaning results may cause problems in downstream process stages, such as for adhesion and hardening. The test results are, however, less complicated and do not last as long as the application tests.

As far as technical production adaptations to changed detergents and cleaning agents are concerned, some of the application tests are being done away with in general as less complicated test results are seen as sufficient. If application tests are conducted, the interview data indicate that they are shorter than in the paint industry.

Organizationally, a change in the recipe for a preparation necessitates, among other things, a revision of operating instructions; in addition, preparations have to undergo an internal procedure to qualify anew in terms of toxicology, occupational safety, etc. If a preparation used in current production changes, there are fears that REACH will cause delays as the same staff capacity will have to handle a larger number of new qualifications. Marketing needs can also require adaptation. If the reformulation leads to a change in the labeling of the detergent / cleaning agent, the user surveyed in the cleaning service sector felt that this change might lead it to take the detergent or cleaning agent out of their portfolio as its customers sometimes have specifications about acceptable labels.

In addition to the effects on current production among users, the way changes in (the availability of) detergents and cleaning agents affect the time to market also has to be taken into consideration here. In one case, product development was often linked to the use of new materials (such as recycled ones) that require the use of other chemicals, and especially other paint / cleaning systems. Under REACH, the company surveyed expects delays if manufacturers of detergents and cleaning agents need longer to meet these new material requirements. The other three providers surveyed did not see any direct influence from REACH on product development time. This assessment is partly based on the expectation that suppliers of detergents and cleaning agents will announce changes in their preparations ahead of time, allowing any required adaptations to be organized during the product development process. On the other hand, there seems to be little connection between in-house product development and the kind of detergent / cleaning agent used. In conclusion, delays in the product development of formulators do not automatically lead to longer product development times for users.

V.5.3 Selecting a production site and sources for procurement

Research question: To what extent do the requirements for REACH registration directly or indirectly lead manufacturers of substances, detergents, cleaning agents, or products manufactured using detergents or cleaning agents to move their production plants outside the EU or procure from outside the EU?

(1) The major substance manufacturers and formulators generally already supply to markets outside Europe from production lines outside Europe. If REACH leads to a shift on the downstream level of the supply chain for production for export outside the EU, the companies claim that these markets could be served from foreign locations that already exist.

(2) Exports of preparations to countries outside the EU are generally low.

Comment: That means that the markets in which manufacturers of detergents and cleaning agents would have to compete with formulators not subject to the REACH system have generally only played a minor role up to now.

(3) For medium-sized formulators of detergents and cleaning agents, markets outside Europe only play a very minor role. Most of them would not consider moving production outside Europe under REACH even if these markets became more important.

(4) For users, the cost of chemicals in production costs and product development is not very important.

Comment: The influence of (the cost of) chemicals on location decisions is the negligible for the users surveyed. However, if some production sites are already outside Europe, a very cost-oriented location strategy is pursued, and quality problems can be ruled out, any cost increases due to REACH could lead companies to move abroad.

(5) For users, quality is often decisive in preferring European component manufacturers. The effects of REACH are generally viewed to be “subcritical”. However, in some areas purchases of articles from outside Europe already play a great role for cost reasons and supply security.

Comment: Here, the insecurity about how great the (cost) burdens from REACH will actually be on users is palpable. Depending on the volume, suppliers from outside the EU could become more important here.

(6) One user surveyed stated that quality and “supplier purity” were the reasons why it has specifications usually prescribed for European suppliers about the preparations to be used - including detergents and cleaning agents - for manufacturers of components from outside Europe.

Comment: In other words, in this case component manufacturers from outside Europe cannot turn their “exemption” from REACH completely into a competitive advantage over component manufacturers within the EU.

Depending on the stage of the supply chain, the importance of moving production into countries outside the EU offers various means getting around the requirements of EU. Substance manufacturers and formulators of detergents and cleaning agents could supply to markets outside the EU without having to fulfill REACH. Whether this is attractive under REACH will depend, among other things, on the current and expected importance of these markets outside Europe. Here, it is worth noting that the two large substance manufacturers / formulators surveyed already serve markets outside Europe from their production sites outside Europe. If REACH makes these markets grow because downstream stages of the supply chain move abroad, expansion of production there will be seen as an easy way of adjusting.

Among the medium-sized formulators surveyed, exports outside the EU currently only make up 5 % of production, which is relatively negligible (cf. Table V-16). One company states that its export quota to non-EU states was 10 %; a small company put the figure at 25 %. One example mentioned was the markets for automotive chemicals and

surface treatment in Russia and the NIS[49]. That means that the markets in which these manufacturers would have to compete with formulators not subject to the REACH system have generally only played a minor role up to now. In contrast, most of the formulators surveyed emphasized how important goods traffic within the EU is becoming. Export quotas for preparations within EU-25, excluding Switzerland and Norway, ranged from 5 to 45 %.

These medium-sized formulators surveyed have been serving markets outside Europe from Germany. One of the formulators surveyed is considering having its products made in the US in contract production and sold by its own sales department there. All of the others refuse to move production abroad under REACH. The reasons not to move abroad include a lack of financial resources, quality problems in foreign countries, and the mid-term erosion of production cost advantages at these locations.

Moving production outside the EU allows users to produce using detergents and cleaning agents not subject to the REACH system. As these kind of chemicals are not part of the end product, the articles made can be imported to the EU without the substances in them having to be registered (Article 6 of the draft regulation). Nevertheless, two of the users surveyed (manufacturers of utility vehicles) state that REACH would not affect their decisions about locations as the need for chemicals does not play a decisive role (see Sections V.1 and V.2 on the negligible effect of the cost of chemicals in production and of chemicals in product development). Experience moving production abroad - either one's own or that of competitors # is said to be rather disappointing: sales goals were not reached, and sites were moved back home. In addition, the move abroad entailed quality risks. In both cases, REACH will thus not provide any additional incentive to move abroad. In contrast, another user is already operating production sites outside Europe and pursuing a very cost-oriented strategy for siting. This user has managed to overcome quality problems up to now. If REACH leads to increases in production costs, the user would be more likely to move production abroad in this special context.

Users can theoretically also get around the REACH system by purchasing article components from outside the EU. Manufacturers of components could then use detergents and cleaning agents that are not subject to the REACH system. One of the users surveyed (company l) stated, however, that REACH was not a reason to look for suppliers outside the EU. A second company (p) prefers European suppliers for reasons of quality. It doubts that the goods will be high-quality if chemicals from outside the EU are used. For instance, it fears that parts will not be properly hardened if the previous

49 NIW = Newly Independent States (former members of the USSR).

cleaning process does not fulfill its requirements. For this reason, the detergents and cleaning agents that component manufacturers both inside and outside the EU use are prescribed (principle of supplier purity). This may not mean that the detergent or cleaning agent is produced in Europe, but in this case component manufacturers outside Europe cannot take full advantage of their exemption from REACH towards EU component manufacturers. Only in the case of company k did purchases of articles from outside Europe already play a great role for cost reasons and supply security. Here, the insecurity about how great the (cost) burdens from REACH will actually be on users is palpable. Depending on the volume, suppliers from outside the EU could become more important.

V.6 Proposals by companies on how to improve REACH

Companies usually were glad to make proposals on how to improve the current draft regulation of October 2003 in the interviews. Their concerns, which were not always based on profound knowledge of the provisions in the draft, mostly stem from concerns that too much paperwork will be required, thus hampering corporate action.

Here, the proposed improvements aim to simplify flows and reduce requirements. The proposals are summarized below without any prioritization.

- Safety data sheets and product labels should be harmonized in EU member states under REACH. If this can happen, costs would be considerably lowered, for the current incongruent requirements in the member states waste a lot of time and money.
- The competence and rights of the European Agency for chemical substances should be increased to the detriment of national authorities. This is seen as an instrument for the harmonization of enforcement.
- In particular, the results of standards similar to GLP should be recognized for small-volume substances. The costs in the amount of 20,000-30,000 € for repeated CP tests in the strict GLP standard would threaten the production of numerous small-volume substances.
- The work required for the tests should be based on the exposure risk and not on rigid volume thresholds; after all, it makes a difference whether a substance is used in dishwashing liquids or as an additive in concrete.
- All of the interviewees support the concept of exposure categories, in which exposure patterns are grouped together. At the same time, the problem of the outflow of expertise is lessened.
- Downstream users should be included in preregistration, for they often have an essential interest in defending substances that are important for the products they make.

- The transition periods were felt to be too short, especially for large-volume substances.
- Trade associations should support the creation of consortia for the registration of substances, which is felt to be *the* instrument to lower costs. Trade associations could serve as trustees for data crucial for competition in the consortia and should draw up basic contracts specifying the rights and duties of the underwriters.
- A one-substance/one-registration concept is supported in principle, though the details remain to be worked out.

V.7 Specific conclusions for the supply chain of detergents and cleaning agents

The gist of the previous analysis is summed up in the following under the basic question of what pressure there is in the supply chain of detergents and cleaning agents to adapt to REACH compared to the capacity to do so. Furthermore, some starting points are provided for how the pressure to adapt can be reduced and the capacity increased. The extent to which the detergent and cleaning agent industry is affected compared to the other supply chains of paint is dealt with in Chapter VII.

Here, it is pointing out what the empirical basis and the resulting restrictions for generalizations are. A total of 13 companies spread across various stages of the supply chain and various market segments were surveyed. This low number does not allow for any statistically representative generalizations. However, a wide range of various contexts were covered. A case study can only be representative if the sum of the contexts dealt with covers a large part of the supply chain in question. In light of the dearth of previous studies on the detergent and cleaning agent chain in the context of REACH and the low coverage of substances relevant to detergents and cleaning agents in the project due to capacity constraints, generalizations have to be limited in the present study. However, the context for which certain statements apply were documented so that readers are able to transfer the statements made to other areas within or without the supply chain based on their own knowledge of similar contexts.

In terms of the pressure to adapt, it must be kept in mind that one major basis for the quantification of the pressure to adapt in the detergent and cleaning agent chain is missing: the allocation of substances to the chain. It is not clear how many substances are relevant, in which tonnage ranges they are made, and whether their registration costs are completely incurred in the detergent and cleaning agent chain or whether they also come from outside this chain. The reasons for lack of information were discussed in Chapter V.1.4. In order to allow everyone involved to plan for the require-

ment for adaptation to REACH, the contracted researchers recommend creating this basis in cooperation with all of the actors in the supply chain.

The following circumstances are the main ones that **increase the pressure to adapt** (the main stage of the supply chain affected is in parentheses: s = substance manufacturer, f = formulator, u = user):

- Direct imports of raw materials from outside Europe have to be registered at the level of manufacturers of surfactants (s);
- The relevance of small-volume substances for surfactants as well (s, f);
- A large share of dangerous substances in the components of the preparations, necessitating exposure scenarios and risk assessments (s, f);
- Low-price raw materials increase the relative importance of specific registration costs (s); no registration (40% of the substance manufacturer's portfolio is not registered in the example studied).
- Falling prices and stagnating sales make it unlikely that costs can be passed on for detergents and cleaning agents (s, f);
- The increasing market concentration among substance manufacturers and the drop in imports of substances under REACH could raise prices for substances. This will reduce the pressure on substance manufacturers but increase it for downstream stages of the supply chain (s, f, a).
- The appreciation and willingness to pay for better safety data sheets among users seems to be low (f, u).
- A limited selection of substances and an additional search for substances with a suitable indicated use could lengthen the time to market for preparations under REACH (f);
- The raw material portfolios of formulators are tending to grow (f);
- Some market segments (such as small formulators, industrial) are more affected by REACH due to their relatively great product differentiation (withdrawal of raw materials and snowball effect for reformulation needs) (f);
- Recipe changes due to REACH lead to follow-up expenses for the fulfillment of laws outside chemicals law for detergent and cleaning agent manufacturers, such as recipe notification in accordance with the Detergent and Cleaning agent Act (f).
- For users, changed preparation recipes entail adaptation costs for their internal technical and organizational release process (u).
- No first-mover advantages in markets outside Europe if regulations similar to REACH are later instituted there are not expected (s, f, u).

On the other hand, the following issues **reduce the pressure to adapt**:

- Principle openness to enter into consortia, even for small tonnages. However, consortia are sometimes seen und unfeasible for reasons of expertise protection or monopolies (s);
- The relative lack of importance of in-house registration duties for formulators and users from the import of raw materials or preparations from outside the EU (f, u);
- The improbability that the applications of formulators will fall outside the substance manufacturer's defined corridor so that the formulators will have to conduct risk assessments on their own. This requires applications and exposure categories to be defined generally (f).
- REACH affects all of the actors in one stage of the supply chain on the European market equally; this makes it easier to pass on price hikes. (s, f, u)
- The share of the cost of chemicals in production costs for manufacturers of household detergents and cleaning agents - and hence the pressure to pass on any price increases for raw materials - is rather small (f);
- The share of the overall cost of chemicals in the production costs of users is very slight. If these costs increase, the effect on margins will be very slight (u);
- Only a small part (5-10%) of the substances the surveyed manufacturer is not planning to register will be withdrawn if it disappears from the market completely.
- Manufacturers outside the EU register for the EU market (f);
- The effects of REACH can be seen as a foreshortening of the product lifecycle of a recipe. The effects are not then added to the previous level of preparations withdrawn (f, u).
- The breadth of the range of raw materials as an innovation base is less crucial for detergents and cleaning agents than for paints.
- The product development of users does not closely depend on the kind of detergent or cleaning agent, and hence on the effects of REACH on them (u);
- The lack of importance of markets outside Europe, and hence the lack of competition from formulators not subject to REACH, and the lack of pressure up to now to move production abroad to be closer to customers (f);
- The small shares of the cost of chemicals in production costs for users reduce the pressure to move production abroad to lower costs. In rare cases, however, even a slight increase in pressure can lead to a move abroad (u);
- In many cases, European component manufacturers are found to have better quality. Changes in sourcing strategies due to costs are then improbable (u);
- Component manufacturers outside Europe sometimes have to fulfill similar quality specifications as for the detergents and cleaning agents of European suppliers (f).

The following factors **increase the effect** on the **capacity** of actors in the detergent and cleaning agent chain to **adapt**:

- The deep application knowledge of formulators can be used to create exposure scenarios (s, f);
- Under current chemicals legislation, expertise protection is also not absolute. The provision of information by formulators above and beyond the extent currently required by law shows that formulators are able to deal with a certain amount of expertise spill-over (f);
- The lifecycles of preparations are sometimes rather short today at any rate, so that the users affected here are used to coping with changes in recipes (u);
- Substance manufacturers will benefit from better prerequisites under REACH to expand their application innovations thanks to broader application knowledge. Sometimes, however, this reduces the innovation incentives for formulators who already have application knowledge that they use for innovations (s, f);
- Formulators exchange some 30 %-50 % of their portfolio of raw materials every 10 years due to both voluntary and mandatory considerations (f). In other words, there is some capacity to cope with changes in raw materials.
- In coping with the current withdrawal of raw materials, formulators demonstrate that they are able to deal with price increases and inexact matches of substitutes when they are forewarned and have replacement offers (f);

The following factors reduce the **capacity to adapt**:

- Even now, the number of safety data sheets that have to be processed per employee is often quite high (f);
- The lower intensity of research (in terms of the share of R&D in sales) among substance manufacturers and formulators of detergents and cleaning agents compared to the chemicals industry indicates their below-average capacity to adapt. (s, f).
- Small-volume existing substances may be especially sensitive to the requirements for REACH registration at the beginning of a development process for new applications, i. e. in a phase of the production cycle that is already sensitive (s).
- Few new substances are being developed for detergents and cleaning agents (s, f);
- Formulators do not currently think operator models are very important and do not feel that REACH will help develop them much (f);

The part of the supply chain that leads into the market for household detergents and cleaning agents is less affected by REACH than the supply chain of industrial detergents and cleaning agents because

- the share of the cost of raw materials for formulators is lower than in terms of their overall production costs (among other things, because of the great expenses for packaging);
- the number of recipes, and hence the possibility of "snowball effects" from the withdrawal of (raw) materials due to REACH, is smaller; and
- raw materials tend to have larger volumes here.

However, the PPORD regulation is hard to use in this market segment. There were not signs of any systematic differences in the size and structure of the palette of raw materials and the intensity of research.

Finally, the pressure and capacity to adapt cannot be quantified and "set off" against each other. In the end, the various modes of action of REACH simply interact with a broad spectrum of different adaptation mechanisms. A better understanding of these mechanisms can help design the draft of REACH and the enforcement instruments to reduce the pressure and increase the capacity to adapt. However, it remains to be seen how the "reallocation" of current capacities for the voluntary substitution of raw materials in favor of adaptation to REACH will affect competition. After all, the REACH-induced price changes and the withdrawal of substances will temporarily reduce the opportunities to react to customer wishes.

In conclusion, three areas can be identified where the design of the REACH system can affect the pressure and capacity to adapt:

- Special attention should be paid to the degree of details in the definition of uses and exposure scenarios in the further implementation of REACH. Different ideas about how this should be done are currently the basis of many negative attitudes about REACH. The main goal should be to: 1) use the available application knowledge of formulators; 2) distribute the burden of chemical safety reports for individual applications appropriately between the stages of the supply chain of substance manufacturers and formulators; and 3) ensure that formulators have sufficient protection without blocking the flow of general application knowledge too much. Here, formulators and their associations in particular seem to have the knowledge to develop simple, practicable systems.
- The direct costs of registration cross a critical threshold for surfactants with a volume below 1,000 t/y due to the low market prices and margins in this market, encouraging companies to refrain from registration based solely on economic reasons. The gain in product safety may not make up for the costs, if a relatively large share of the costs stems from risk-independent test requirements, in particular for the range below 100 t/y. Chapter VIII thus makes proposals for how to increase the relation between registration costs and product safety in the REACH system.

- The various manufacturers control the competition between already registered substances and substances not registered during the phase-in period of REACH, influencing it by their possibly changed cost ratios and differences in the reliability of their future availability, among other things[50]. As long as a substance has not yet been registered, formulators will not be able to count on it being available in the future and will not know at what price. If formulators replace a substance with one whose fate has not yet been determined, they will face follow-up costs if the raw material is withdrawn or becomes more expensive. The situation of users is similar: they may have tailored their processes to a preparation whose components have not all been registered. In other words, the pressure on formulators to adapt decreases if the REACH system can motivate most manufacturers of a substances to register using a consolidated set of data for the substance.
- No inventory of registrant substances has been taken in either supply chain yet. In addition, formulators and users face a severe uncertainty about the costs to expect and the availability of raw materials. These uncertainties could be overcome if trade associations or other neutral third parties determine an anonymous chain inventory based on CAS numbers (such as the merger of the inventories of two companies) before REACH is implemented. On the one hand, substance manufacturers could cover paint applications from the outset; on the other, the actual cost burden would be estimable at the level of the supply chain.

50 See Chapter III for incentives in the creation of consolidated joint substance data records for similar substances.

VI Impact of REACH on the paint and varnish supply chain

VI.1 Structure of the value creation chain in the German paint and varnish industry

VI.1.1 Structure of the German paint and varnish industry

Following is a list of key facts and figures pertaining to the German paint and varnish industry (source: CHEM Research 2004 and VdL (German Paint and varnish industry Association), unless otherwise indicated).

- Paint and varnish account for 4 % of the chemical industry's gross output
- 2002 industry output amounted to 2 million tons with a market value of €4.5 billion. Sales are stagnating.
- Germany has 250 paint and varnish manufacturers that employ a total of 21,000 (most companies employ 50 - 100; only 10 companies employ more than 500)
- Approximately half of the companies in the industry manufacture industrial paint and varnish, and half of these produce specialized products and are relatively small (20-100 employees)
- Sales are mainly determined by the level of activity in the relevant segments. As a result, the building coatings segment (depending on domestic demand) is currently experiencing excess production. Canned paint is the only product for which sales are lower than in the industry as a whole. The German container deposit law is having a strong negative impact on sales in this segment.
- With the exception of wholly new products, prices are stagnating or in some cases decreasing slightly. The impact of rising production costs has been offset by cost reductions or lower margins.

Table VI-1 shows the structure of the German paint and varnish market (source: Chem Research 2004) and the mean sales price levels for the various segments. Whereas construction industry paints are high-volume, relatively low-cost items, the steep prices commanded by automobile coatings are reflective of (a) the market demand for quality products, (b) the technological sophistication of today's industrial painting processes, and (c) the severe financial consequences of painting flaws.

Table VI-1: Sales and market value in Germany (2002)

Coating type	Percentage of total amount	Percentage of total value	Sale price per kg in euros
Construction industry paint	66	42	1.5
Car finishes Touch-up paint	7.6	18	7.7 10.6
Furniture and wood	4.5	5.7	3.2
Anti-corrosion agents	3	3.6	3
Electrical engineering	2.4	3.5	3.6
Mechanical engineering	3	4.5	3.7
Metal packaging (50 % of which are accounted for by beverage cans)	2.4	2.4	2.5
Metallic finished products	2.1	3.0	3.7
Tape coatings	1.4	1.9	3.5
Other industrial coatings and miscellaneous coatings	8.3	12.8	3.8
Ship paint	1.1	1.6	3.75

VI.1.2 Coating formulations

Paints and coatings are generally composed of numerous substances classified according to function in the table below.

Table VI-2: The substances most commonly found in paints and coatings (RPA 2003d)

Component (5-50)	Content	Examples of substances:
Binders		Polyester resin, acrylic polymer, alkyd resin, cellulose ester, epoxy resin
Solvents		Water, alcohol, aromatic and aliphatic hydrocarbon, carbon acid ester
Fillers, inorganic pigments		Titanium dioxide, barium sulfate, zinc phosphate
Organic pigments		C.I. Pigment Yellow 53 , C.I. Pigment Brown 24, C.I. Pigment Green 7
Additives	0.01 % to 5 %	Anti-corrosion agents, rheological additives, biocides, anti-UV agents, anti-foam agents, drying additives, thickeners, dispersion agents

VI.1.3 Survey design

VI.1.3.1 Companies surveyed

Fifteen companies in the paint and varnish supply chain were surveyed (one importer, two manufacturers of preparation substances, six preparation manufacturers and six downstream users). 13 were surveyed via a standardized oral questionnaire and one (a semiconductor manufacturer that uses photoresists) responded in writing because photoresists are an atypical product in the coatings industry*[1]. Sales volumes are for the most part less than one ton annually, and product prices range from €80 to €1500 per kg. The companies surveyed range greatly in size.

Table VI-3: Size of the companies surveyed

	Role in paint and varnish supply chain	**No. of employees**	**Annual sales (in euros)**
0	Importer	*480*	1 billion
A	Pigment manufacturer	*250*	*90 million*
B	Additive manufacturer	*500*	*308 million*
C	Auto paint manufacturer	*2,400*	*1.75 billion*
D	Wood coatings manufacturer	*65*	*12.5 million*
E	Manufacturer of various topcoats and primers	*630*	*122 million*
F	Manufacturer of anti-corrosion coatings	*80*	*37 million*
G	Manufacturer of various topcoats and primers	*69*	*10 million*
H	Manufacturer of various topcoats and primers	*228*	*55.5 million*
I	Paint user (wood furniture manufacturer)	*1,390*	*240.5 million*
K	Paint user (auto body manufacturer)	*31,800*	*14 billion*
L	Paint user (agricultural machinery)	*2,200*	*520 million*
P	Paint/coatings user (forklifts)	*3,500*	*1.2 billion*
M	Purchasing cooperative (construction industry paints)	*n.a.*	*n.a.*
N	Coatings user (semiconductors)	*5,400*	*n.a.*

VI.1.3.2 Market segments investigated

In view of their relatively small sales volumes (highly specific registration costs) and specialized applications (little leeway for substituting other products), additives, organic pigments and special inorganic pigments are the principal preparation components that

1 One company is unaccounted for in this description.

are subject to REACH registration requirements. In addition, the sheer number of additives and pigments available is one of the keys to successful innovation in paint manufacturing.

However, since binders are polymers, they are currently exempt from registration requirements. As for solvents, they mainly achieve high sales volumes and offer substantial leeway for product substitution. Market volumes are also quite high in the filler and inorganic pigment segment. Hence, it was decided in consultation with the German Paint and varnish industry Association to focus on additives and organic pigments in the present study.

Market segments for this empirical study were selected in consultation with the German Paint and Varnish Industry Association on the basis of jointly elaborated prognoses regarding the extent to which REACH might negatively impact the paint and varnish market. These prognoses were then used to determine how much emphasis the study should place on the industrial paint segment, since it accounts for the lion's share of low-market volume specialty chemical substances.

However, it emerged from the interviews with the six coatings manufacturers that nearly all of the industrial coatings vendors surveyed also sell their products to auto parts manufacturers. In other words, four of the six respondent companies derive a substantial portion of their earnings either directly or indirectly from auto industry customers. Thus, auto industry applications may be somewhat over-represented in the sample of companies surveyed for the present study. However, the principal paint and coating application domains were covered by the interviews, as can be seen in tables VI-4 and VI-5.

Table VI-4: Paint and varnish segments and companies surveyed

Coating type	**Percentage of domestic sales**	**Included in the empirical survey sample**
Construction industry paint	42	1 purchasing cooperative
Auto finishes and touch-up paint	18	4 coating manufacturers, 1 downstream user
Furniture and wood preservation	5.7	2 coating manufacturers, 1 downstream user
Anti-corrosion agents	3.6	2 coating manufacturers
Electrical engineering	3.5	1 downstream user (semiconductor manufacturer)
Mechanical engineering	4.5	4 coating manufacturers, 2 downstream users (auto industry)
Metal packaging	2.4	
Metallic products	3.0	
Tape coatings	1.9	
Other coatings	12.8	
Ship paint	1.6	Not included

Table VI-5: Market segments surveyed

	Market segment and proportion of sales for the company	**Coated finished products**
0	Bulk chemicals 13 % Commodities, washing and cleaning agents 51 % Coating additives and intermediate pharmaceutical products 8 % Plastics 28 %	*No differentiation possible*
A	Coating pigments 37 % Plastics pigments 14 % Printing ink pigments 13 %	
B	Coating additives 80 % Plastics additives 20 %	
C	Auto finishings 32 % Touch-up paint 40 % Powdered or special finishings 14 % Other industrial coatings 14 %	• Auto bodies • Auto parts • Product protection agents • Machines • Pipes • Windmills
D	Furniture and door finishings 75 % Wood floor finishings 25 %	• Furniture • Doors and windows • Floors, panels
E	Auto parts finishings 60 % Furniture finishings 15 % General industrial finishings 25 %	• Auto parts • Furniture • Machines
F	Anti-corrosion agents for finished products 50 % Anti-corrosion primer for pipes 20 % General industrial finishings 30 %	• Product protection agents • Pipes • Industrial installations
G	Auto parts finishings 43 % Mechanical engineering 35 % Miscellaneous industrial finishings 22 %	• Auto parts • Pipes • Pumps for mechanical devices
H	Auto part finishings 25 % Coil coatings 16 % Electropaint 7 % General industrial finishings 5 %	• Auto parts • White goods • Pipes
I		• Furniture
K		• Auto bodies
L		• Agricultural machinery
P		• Forklifts
M		• Building finishings
N		• Semiconductors

It was not possible to reach any empirical conclusions regarding the structure of the paint and varnish industry based on the responses from the six coating manufacturers surveyed and the supported questionnaires administered to selected downstream users. However, the coatings manufacturers surveyed collectively cover a relatively broad range of applications, with the exception of consumer product and special finishings such as semiconductor photoresists.

VI.1.3.3 Inclusion of results from the North Rhine / Westphalia business simulation

The government of North Rhine / Westphalia tested selected elements of the REACH process in business simulations involving, among other elements, a specific paint supply chain (auto touch-up paints). A separate working group also studied the process of registering low-volume substances and in so doing focused primarily on process chemicals for the textile industry, and secondarily on coating additives[2]. For further information regarding the results of the simulation, see http://www.Europa.nrw.de/themen/chemikalienpolitik/index.html. For a summary of the results of and conclusions drawn from the simulation, see Chapter 1 of the present report. In the following, we discuss the simulation results that are of relevance to the paint and varnish supply chain.

Objections to the registration process on the part of respondents in the paint and varnish supply chain

The amount of information required for substances registration is regarded as being excessive. Testing of low-volume substances would result in disproportionately high production cost increases that the respondents regard as an extreme business risk.

The respondents also objected that the amount of data required for a particular substance is determined solely by its production volume to the exclusion of risk factors.

It is also a problem for the respondents that exposure scenarios have to be formulated in such a way as to be intelligible to downstream users. It emerged in this regard that manufacturers do not know enough about downstream users' processes and manufacturing conditions to describe exposure scenarios adequately. Such information gaps can only be bridged through direct communication with downstream users. The significance of these information gaps depends on the amount of detail required for the exposure scenarios.

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2 The results of the NRW business game are documentated in detail on **http://www.Europa.nrw.de/themen/ chemikalienpolitik/index.html**.

Source: ARGE management business game: Erprobung ausgewählter Elemente des REACH-Verfahrens in der Praxis durch Behörden und Firmen im Rahmen eines Planspiels in Nordrhein-Westfalen. Zusammenfassenden Projektbericht – Ergebnisteil (Langfassung 22.12.03); page 18

Data requirements for low-volume substances

Problem 1: The per-ton cost of compiling substance data, estimating exposure levels and administrative work for low-volume substances (100 tons or less per year) is proportionally higher than for large-volume substances. Although the scope of the required REACH tests is smaller for low-volume substances, registering them can generate such high costs for certain companies in certain segments (e. g. (low-volume) textile process chemicals manufacturers) as to constitute a business risk. Respondents in the paint and varnish supply chain feel that an unduly large amount of substance registration information is required under REACH. Testing of low-volume substances would result in disproportionately high production cost increases, which would in turn transform the registration of low-volume substances in the paint and varnish supply chain into an extreme business risk.

Problem 2: The scope of testing called for in Annexes VI through VIII (for volumes of 10 or more tons per annum) enables industry actors to dispense with testing altogether, providing that the exposure scenarios do not lead to impermissibly high human and environmental exposure levels. The respondent companies that are required to gather data on low-volume substances are concerned about the fact that as SMEs they lack the expertise needed to prove to regulatory authorities that the low-volume substances being used are unobjectionable.

Suggested solution to problem 1: The data documentation requirements for the registration process should be determined mainly by potential hazards and anticipated exposure levels and not, as is currently the case, primarily by production or import volumes. This modification in the regulations is necessary, would almost certainly reduce the time, effort and cost involved in preparing registration dossiers, and would also have a highly positive impact on manufacturing processes in the coatings, electronics and allied industries. One way of changing the regulations would be initially to require a modicum of data (e. g. pursuant to the German Chemicals Industry Association's self-monitoring regulations) and then request additional data according to the amount of exposure involved. This process should be elaborated for low-volume substances.

The German Environmental Protection Agency (UBA) takes the view that the environmental requirements contained in Annex V (10 tons or less per year) already lag far behind the German Chemicals Industry Association's self-monitoring requirements.

Thus, as the German Environmental Protection Agency sees it, exposure-related environmental test requirements cannot be slackened any further. Moreover, from Annex VI onward, the statute already provides for exposure-related exceptions. However, the simulation carried out by the state of North Rhine-Westphalia clearly demonstrates that such exceptions can give rise to unforeseen consequences. For example, if manufacturers substantially cut back on Annex VI testing, the likelihood will increase that downstream users will have to conduct such tests themselves, which will again increase costs.

Suggested solution to problem 2: Simple rules and assessment criteria should be jointly elaborated by companies and environmental officials that enable companies to prove that no significant exposure will occur and that therefore no testing is needed.

Source: ARGE management business game: Erprobung ausgewählter Elemente des REACH-Verfahrens in der Praxis durch Behörden und Firmen im Rahmen eines Planspiels in Nordrhein-Westfalen. Zusammenfassenden Projektbericht – Ergebnisteil (Langfassung 22.12.03); page 28

Following is a list of some of the problem areas identified in the North Rhine / Westphalia simulation that were investigated further by the current study:

- The role of non-EU imports of raw materials for paints
- Registration costs incurred by two manufacturers of raw materials for paints, one of which participated in the North Rhine / Westphalia simulation
- A comparison of registration costs with market prices of raw materials for paints
- Scope of the registration dossier for industrial coatings manufacturers; innovative activities, product innovation and raw material substitution procedures; the cost of preparation reformulation and the attendant timelines; the extent to which paint manufacturers have access to information pertaining to use of and exposure to their products.

VI.1.3.4 Perceptions of REACH

The main concern of both substance and preparation manufacturers is that REACH registration requirements will have a negative impact. They are also skeptical about any possible beneficial effects (e. g. optimized information flows, harmonization of legal requirements), all the more so because they feel that current legal regulations and the attendant implementation mechanisms (particularly the facilities available through IMDS (International Materials Data System)) are sufficient. The respondent companies **fear** that REACH will lead to the following (the parenthesized numbers indicate how many times each statement was made):

- Know-how loss (9)
- Withdrawal of raw materials and discontinuation of products (7)
- Unduly high registration costs, as well as increased substance costs that cannot be passed down the supply chain (8)
- EU manufacturers of finished products will be placed at a disadvantage by non-EU imports (7)
- EU manufacturers will be placed at a competitive disadvantage that will force them to relocate their operations abroad (2)
- Delays in receiving information from suppliers (expertise protection), particularly from suppliers located outside the EU (1)
- Impediments to information sharing amongst manufacturers of the same substance, since such sharing would be contrary to the larger companies' competitive interests (1)
- A weakening of EU resolve to institute (a) harmonized conditions and a level playing field in the European market and (b) harmonized and transparent implementation regulations in all Member States (1)
- Substance manufacturers will have difficulty obtaining exposure-related data from preparation manufacturers and downstream users (1)

The respondents made relatively few **positive statements** about REACH:

- Three of the respondents expressed the view that environmental and consumer protection will improve or that there will be a greater choice of applications for the materials they use.
- One respondent said that REACH will improve cooperation between suppliers, manufacturers and downstream users.

All companies surveyed regard the REACH requirements as an added burden whose potential benefits are far from obvious. In our view, this is plainly attributable to the following three factors:

- The companies have thus far been unable to determine which aspects of the law apply to their specific situation from the wording of the law itself and the information about it that has been provided. During the interviews, it was necessary to explain the actual REACH requirements to the respondents repeatedly. The complex nature of the legislation, the fact that it contains some glaring inconsistencies, and the polarized debate about it all provoke unease.
- Most of the paint manufacturers are subject to the pressures of economic globalization and feel caught between the rock of market price "dictates" and the hard place constituted by the major raw material manufacturers and customer segments.

- Inasmuch as the companies surveyed already feel overburdened by current regulatory requirements and the hydra-headed environmental and quality management certification system to which they are subject, they have no reason to believe that REACH will make their lives any easier.

VI.2 Costs arising from substances that are subject to registration requirements

VI.2.1 Scope and nature of materials and product components affected by REACH

Research question: How great is the inventory of substances in the paint chain that REACH affects? To what extent and at what point in time will substance suppliers and preparation manufacturers be required to complete the REACH registration process? For how many products are risk and exposure assessments required?

1. According to the German Paint Industry Association, approximately 500,000 formulations are currently produced in Germany using approximately 7,000 raw materials. Company C's substance portfolio (for example) is made up of approximately 30 % binders and 50 % organic pigments and additives. The binder figure was not calculated for specific raw materials (many of the raw materials can also be used as formulations) and repetitions were not eliminated. One paint manufacturer (company C) with the capacity to generate a computerized breakdown of virtually all their materials (down to 0.01 %) estimates that the number of individual substances they use is approximately twice the number of raw materials they use. Other companies (members of the German Paint Industry Association as well as participants in the workshop held on June 25, 2004) estimate that there are between five and seven substances for each raw material, but these companies have not as yet performed a consolidated breakdown of their raw material portfolios.

   Comment: This data did not enable us to determine which substances, which volume ranges or how many substances used in the German paint and varnish industry will be subject to REACH registration.

2. The formulators surveyed estimate that between 30 and 80 % of all raw materials and 30 and 90 % of all preparations are hazardous. However, it should be borne in mind that to some extent the "hazardous" classification stems from the flammability of the solvent in the preparations.

Comment: Exposure scenarios will have to be elaborated and risk assessments performed (pursuant to Annex 1 of the draft REACH legislation) for a considerable proportion of current raw material portfolios. In meeting these requirements, the REACH law allows companies to use previously gathered information pertaining to employee safety, pursuant to the German TRGS 220 (Technical directives pertaining to hazardous substances).

3. Only in rare cases do coating manufacturers produce their own raw materials or import them directly from non-EU countries. All of the respondent preparation manufacturers except for one (including manufacturers of pigments and additives) import less than 5 % of their raw materials directly from non-EU countries. The importer interviewed purchases his coating additives from EU-registered representatives of non-EU vendors. Only the pigment manufacturers import a substantial amount of material from non-EU countries, but they then process these materials themselves.

   Comment: The cost of self-financed REACH registration and the related problem of expertise protection will probably affect only those paint and varnish supply chain actors that are considered in the present report. However, it should be borne in mind that upstream raw materials that are subject to REACH registration will also probably be imported. For further information regarding the impact of REACH on imports and other importers, see section II.3.2.

4. According to the German Paint Industry Association, non-EU imports account for approximately 11 % of the market value of preparations used in Germany. Apart from photoresists, this level of imported products is not employed by downstream users (i. e. in the auto, commercial vehicle and furniture industries). In contrast, 95 % of photoresists used by the semiconductor industry are imported from non-EU countries. However, the manufacturer's representative for this product is also the importer, which means that registration requirements are waived for the user.

   Comment: Downstream users in the market segments described in the present report will not be required to finance their own REACH registration costs. (For further information regarding the indirect effects of imports on upstream companies, see section II.3.2.)

5. The overwhelming majority of the REACH additives and organic pigments used by the respondent formulators for coatings and plastics applications falls within the 1 - 100 t/y use range. One manufacturer estimated that it would have to register 44 substances, and another put the number at approximately 100.

Table VI-6 shows the proportion of substances classified as hazardous by the substance and preparation manufacturers surveyed. The present draft of the REACH legislation stipulates that manufacturers would be required to perform an exposure and risk assessment for each hazardous substance used. Section 6.8.2 (2) of the German TRGS 220 already contains a similar provision in regard to worker safety (see Chapter IV). However, none of the companies surveyed have complied with this requirement as yet.

Table VI-6: Proportions of preparations and substances deemed hazardous by the respondents

	A	**B**	**C**	**D**	**E**	**F**	**G**	**H**
Percentage of hazardous raw materials	> 7 %	40 %	n/a	10 - 60 %	30 %	30 - 75 %	34 %	80 %
Percentage of hazardous products	n.a.		30 %	5 - 70 %.	60 %	90 %	35 - 40 %	> 30 %

Table VI-7: Proportion of substances imported by the respondent companies (numbers of substances)

Company	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**
Imports from non-EU countries	14 %	2 %	1.6 %	none	2.3 %	< 1 %	virtually none	n.a.x

Table VI-8 shows the number of substances, according to tonnage ranges (where known), that three of the respondents (an importer, a pigment manufacturer and an additive manufacturer) will be required to register under REACH.

REACH registration requirements apply solely to substances that a company imports directly or processes in its own manufacturing facility. Polymers are excluded from this category because the current draft of the REACH statute exempts them from registration. However, to qualify for this exemption, manufacturers must fulfill the relevant criteria. Most substances that the two substance manufacturers surveyed are required to register lie in the 1 - 100 t/y range. The importer surveyed is thus far operating on the assumption that he will have to bear some REACH registration cost but that for the most part this process will be carried out by other actors.

The following section estimates the costs for both of the substance manufacturers surveyed that are subject to REACH registration requirements, based on the volume ranges and the number of substances involved.

Table VI-8: Substance manufacturers' raw materials that are subject to REACH registration

	O	A[3]	B[4]
Number of raw materials for coatings and plastics additives, as well as pigment preparations	250	300	300
Percentage accounted for by imported substances	0 (?)	18	6
Registration of self-synthesized products	0	26	100
Partial assumption by suppliers of the registration costs for special raw materials (B) or for registration carried out by a representative of a non-EU manufacturer (O).	Yes		50
1 - 10 t/y 10 - 100 t/y 100 - 1000 t/y Upwards of 1000 t/y		52 % 24 % 17 % 7 %	17 % 83 %

VI.2.2 Registration costs

Research question: To what extent will REACH registration costs (per kg of material and cumulatively for each company) be impacted by various factors?

1. A medium sized additive manufacturer with a portfolio that will eventually contain 100 REACH substances (excluding polymers, intermediates and EU imports) in the 10 - 100 t/y range would incur (without forming a consortium) registration costs of approximately €8.6 million (European Commission's estimate of basic costs; see Chapter III table 5). In addition, the company would assume the cost of the registration of 50 specialty raw materials by the upstream supplier plus the cost of six registration dossiers for imported substances (divided roughly evenly between 1 - 10 t/y and 10 - 100 t/y substances). If these substances cannot be registered as type 3 intermediates, the company will incur a cost of approximately €2.56 million if no consortium is formed (European Commission's estimate of basic costs). If it is assumed that registering each substance will cost approximately €200,000, the company itself would incur a total cost of approximately €20 - 30 million. According to the REACH timeline, these costs would mainly be payable between 2010 (preliminary registration) and 2017 (definitive completion of regis-

3 Data modified as per annotation in Aug. 14 draft report

4 This estimate was modified on Aug. 4 after speaking with the company concerned

tration for all 1 - 100 t/y substances). The company's annual sales currently total €300 million.

2. A medium sized pigment manufacturer that does not form a consortium and that is required to register 44 substances (of which 52 % are 1 - 10 t/y, 24 % 10 - 100 t/y, 17 % 100 - 1000 t/y, and 7 % > 1000 t/a) would incur a cost of €3.5 million (EU Commission estimate). According to the company's own estimate based on the German Chemicals Industry Association's cost scenario (see section III.1.4; substances exceeding 1000 t/y would incur expenditures of €600,000), the cost would amount to approximately €9 million. These payments of these amounts would mainly fall due between 2007 (preliminary registration of 1000 t/y substances) and 2017 (completion of registration for 1 - 100 t/y substances). According to the company, it is probable that owing to market pressures, most of the costs would be incurred within the initial 3 - 5 years. The company currently earns 4 % net profit on sales of €90 million.

   Comment: The European Commission estimates that additive and pigment manufacturers would incur a cost amounting to approximately 4 % of their sales or 40 % of their annual net profit. With a 5 % margin, the registration costs would account for approximately 80 % of annual net profit, and with a margin of 15 % they would account for approximately 30 % of annual net profit. The lion's share of the registrations would be effected between 2007 and 2017, depending on market conditions.

   Comment: *When the average additive and pigment market prices (€5 - 23 per kg) are compared (as was done in the interviews) with the specific per kg registration costs for one year of production, payback periods (with a 10 % margin) would range from 0.2 to 32 years (see below for calculation). This means that coating additive and pigment scenarios could arise that would prompt substance manufacturers to withdraw substances from their portfolios so as to avoid the attendant registration costs.*

3. Whereas the additive manufacturer feels that forming a consortium will not reduce its costs, the pigment manufacturer has already had considerable experience with consortiums and cost-sharing mechanisms (WGK classifications of inorganic pigments, classifications defined by the EU and OECD old substances program). However, despite this experience, the pigment manufacturer is skeptical about the benefits of forming a REACH consortium in its market segment.

   Comment: Most instances of cooperation between manufacturers for purposes of substance property testing have occurred in connection with high-volume sub-

stances. Hence, the viability of forming cost-saving consortiums of low-volume manufacturers still remains to be tested.

The estimates in chapter III, which are drawn from the European Commission's *Extended Impact Assessment* report, were used as a basis for estimating the registration costs that will be incurred by the two substance manufacturers surveyed. For this calculation, the cost of registering one substance (company liquidity requirements) and the specific costs were spread over one year of production (calculation of payback periods). It was conservatively estimated that the regulations pertaining to intermediates do not apply to any imported substances in the upwards of 10 t/y category.

The following two input parameters from Chapter III were used to estimate payback periods (see below) for specific per-kg registration costs:

- The average scenario from the EU Commission estimate was used to calculate overall registration cost per material. The resulting figure was then compared with the calculations performed by the companies on the basis of the average German Chemicals Industry Association scenario.
- If the average per kg of substance cost for both minimum and maximum production scenarios is spread over a one-year period, the specific registration costs range from €1.20 to €14.10 per kg (1 - 10 t/y) and €0.50 to €16.30 per kg (10 - 100 t/y). «

The specific registration costs were compared with the pigment and additive price range of €5-23 established by the questionnaire. The projected market price range roughly corresponds to the average market price of €18 per kg for the 1 - 100 t/y range in ADL (Arthur D. Little) (2002). Some pigment and additive prices (for companies O, A, B, and C) are considerably higher (€50 - 200 per kg). In addition, it is estimated on the basis of various industry and import case studies[5] that the margin for specialty chemicals will be approximately 10 %.

From the aforementioned data, the following registration cost payback periods can be estimated for the 1 - 100 t/y use range (excluding any costs passed on to formulators):

- 1 - 10 t/y: 0.5 - 28 years
- 10 - 100 t/y: 0.2 - 32 years

This means that paint additive and pigment scenarios could arise that would prompt substance manufacturers to withdraw substances from their portfolios so as to avoid the attendant registration costs.

5 BASF (2004); Goldmann, Bielefeld (2004)

VI.3 Current product safety information accessibility and management capability

Research question: Which human resources, information and mechanisms are required to implement the requirements of the German law on hazardous substances (i. e. the pre-REACH scenario)?

1. Virtually all the respondent companies feel that the safety data sheet and attendant information requirements, combined with the technical advisory sheets, are appropriate information instruments. However, the information pertaining to hazardous components of raw materials was found by 5 of 15 respondents to be somewhat unsatisfactory (incomplete list of hazardous components on the safety data sheet; time consuming querying of the manufacturer).

2. All respondents mainly derive their information from upstream suppliers' safety data sheets. None of the respondents (except one) test the raw materials they use in order to ascertain whether sufficient exposure information regarding each constituent component has been provided.

3. The paint manufacturers in the market segments investigated are for the most part extremely familiar with their customers' application domains and conditions. Only two of the eight respondent companies have a customer service representative for each 100 or more customers. This information has not yet been systematically assessed in accordance with the German TRGS 220 (evaluation of available exposure information and elaboration of concrete risk management procedures).

4. Three of the respondent companies – substance manufacturers A and B, and large downstream user K – find the dearth of substance-related information in safety data sheets highly objectionable. They mentioned the following deficiencies: identity and concentration of hazardous substances; constant delays and omissions in obtaining substance data from upstream suppliers; risk and exposure assessments cannot be undertaken using the safety data sheet alone because the formulations are also needed. The aforementioned companies have the largest human resources capacities for product safety (substance manufacturers) and/or a management system that prompts the preparation manufacturers to ascertain the formulations without the aid of the safety data sheets, thus allowing these companies to carry out their own assessment.

   Comment: The fact that the companies with the largest management capacities drew attention most vocally to the aforementioned information gap suggests that

companies with fewer management resources might well be unaware of the fact that key information is missing. Moreover, it is not a viable solution for user segments with substantial market clout simply to “add” information to their safety data sheets, thereby prompting their upstream suppliers to analyze the formulations, while downstream users with less market clout are forced to make do with the inadequate information placed at their disposal. Although REACH will not fundamentally change the market positions of the companies concerned, an adequate substance safety data sheet that also contains preparation use exposure scenarios will be included in the registration dossier and will thus have a direct impact on both substance marketing rights, as well as the manner in which responsibility for adequate substance safety assessment is assigned. In other words, the underlying factors that motivate the substance manufacturers will remain unchanged.

5. Most SME preparation manufacturers do not have chemical analyses of their raw materials portfolios broken down by substance identity (CAS or EINECS numbers or unique chemical substance designations). This is mainly because some of the raw material components are already formulations whose chemical analyses are unavailable to upstream suppliers.

   Comment: This means (among other things) that the current information gap regarding the environmental and health impact of the substances contained in commercialized preparations has not yet been recognized and is in principle amenable to systematic reduction. Substance manufacturers are not legally required to test old substances when information in regard to these substances is missing andare permitted to sell formulators raw materials for preparations without indicating whether the raw materials concerned are dangerous. The upstream suppliers of preparation manufacturers integrate these substances into formulations and then sell them to the preparation manufacturers without being required to indicate that the products contain components whose environmental and safety risk has not been assessed. The manufacturers then use these allegedly non-hazardous precursor products in their preparations. Thus, under the present system, preparation manufacturers are unable to ascertain exactly where their product safety responsibility lies.

   Under REACH, it will be possible at a minimum to conduct a chemical safety assessment for all substances in preparations whose market volume is 10 t/y or more. This means that right at the beginning of the preparation supply chain, information gaps will be avoided that cannot be remedied further down the chain for reasons of expertise protection.

6. Owing to the high degree of product differentiation in the paint and varnish industry, each company has a relatively large number of safety data sheets. At the same time, only a handful of preparation manufacturer employees are responsible for ensuring that safety data sheets contain accurate information, that the data sheets are kept updated, that any information gaps are detected and eliminated, and that customer queries are answered competently. It can sometimes happen that a single employee is responsible for the technical management of upwards of 1000 safety data sheets.

   Comment: Under REACH, coating manufacturers will be required to cross-validate all exposure scenarios for dangerous raw materials used in preparations, which will necessitate frequent contact between substance and coating manufacturers. In addition, substance manufacturers' exposure scenarios would have to be converted into user scenarios, but there are currently not sufficient human resources available to do this, and hiring any significant number of new personnel is unlikely to be a viable option. Moreover, since the availability of a broad range of raw materials is a spur to innovation, substance portfolios will probably not be reduced in scope. Hence, in order for REACH to be implemented successfully, simpler and more unified mechanisms will have to be developed that allow the know-how and expertise of substance manufacturers, formulators and downstream users to be "translated" into a standardized "language."

The data from the substance and coating manufacturers questionnaire shown in the tables below was used to answer the question that was posed at the beginning of this section. The following background information is key to an understanding of the tables:

- The technical work performed by computer and lab technicians was excluded from the calculation of the number of employees that monitor safety data sheet quality and carry out the attendant management processes. The calculation is based instead on technical responsibility for the actuality, accuracy and appropriateness of product information.
- A consultant is defined as any staff member employed at a manufacturing facility or subsidiary who works closely with customers in elaborating products, or who provides customers with technical assistance regarding applications.
- The number of raw materials was determined in accordance with the categories defined by the various companies' data capture processes, as well as by upstream suppliers' raw material designations. For the most part these are not individual substances with CAS or EINECS designations.
- The number of products is based on the products currently being marketed. The number of formulations is based on criteria such as gloss level, color shade modifications during a product's lifecycle, and solvent type for the same product. The

number of basic formulations is determined by the type of binder system used (basic coating formulation).

- Table VI-10 andVI-11 provide an overview of the respondents' level of satisfaction with the safety data sheet information.

Table VI-9: Management capacity indicators

Company	O*	A	B	C	D	E	F	G	H
No. of employees	480	290	500	2400	65	630	80	69	228
No. of substances		300	300	3,000	1,400	850	400	647	1,350
No. of recipes				20,000	11,000	15,000	3,000	1,000	8,850
No. of products	10,000	930	300	20,000	6,000	5,800	300	1,000	1,650
Basic recipes					800	200			
No. of employees responsible for safety data sheets	3	1,7	2,5	> 20	1	1	0,2	0,1	2
No. of products per safety data sheet employee	3,300	550	120	1,000	6,000	5,800	1,500	10,000	820
No. of customers	25,000	1000	5000	>10,000	850	2300	650	400	450
No. of consultants	60 - 70	70	80	100	7	44	22	7	20
No. of customers per consultant	380	14	63	> 100	121	52	30	57	23

O = Importer; A and B = Substance manufacturer; C-H = Paint manufacturer; J-L = down-stream user

Table VI-10: Level of manufacturer satisfaction with supplier information

	O	A	B	C	D	E	F	G	H
Insufficient		X	X		X				X
Good information									
Response unclear				x		X	X	X	

Table VI-11: Level of downstream user satisfaction with supplier information

	J	K	L	M	N	P
Insufficient		X		x		
Good information	X		X			
Response unclear					X	x

VI.4 REACH's impact on innovation effects

VI.4.1 The significance of innovation for the product supply chain

The preparation manufacturers surveyed have developed the following innovations under the current legal framework:

- Cadmium, lead and chrome VI have been replaced by other substances in color and corrosion protection pigments
- Pigment system light fastness and thermal resistance have been optimized
- Additive systems have been developed for high-solids and water-based preparations
- Water and powder coating systems have replaced solvent based products and have been used as substitutes in spray coating processes
- Ultraviolet curing systems have been developed for rapid bulk coating of metal, wood and plastics
- Dedicated preparations have been developed for plastic surface coating

New processes such as ultraviolet curing come into play here as does the reworking of proven functionalities using innovative approaches. A second key area of innovation in the past as well as today is the environmental optimization of coatings and application processes (substitutions for heavy metals and solvents, reduction of raw material loss during coating processes).

In addition, customer attitudes toward coating products play a central role for all of the companies surveyed. It is often the case that the chemical and technical surface quality and processing characteristics of a preparation are achieved through precise calibration of the binder system and additives.

VI.4.2 Innovation and earning indicators

Research question: How much R&D do companies undertake in order to achieve their long-term sales goals? How important are product differentiation and raw material diversity for the formulators?

1. The respondent substance and preparation manufacturers estimate that their R&D activities represent 3 to 7 % of total turnover and that for individual product segments, the figure may be as high as 13 % or as low as 1 - 2 %.

   Comment: This places the preparation manufacturers among the largest R&D spenders in the German chemicals and specialty chemicals industry (see chapter

1). These substantial R&D expenditures are also indicative of an above average capacity to adapt to REACH, although this should be seen in light of the pressure that is being exerted on these companies to comply.

2. Downstream users employ an extremely broad range of raw materials that form the basis for customized formulations of coating products.

   Comment: It is extremely likely that these actors will be affected by substance withdrawals under REACH.

3a. The preparation manufacturers surveyed make 10 - 100 products per million euros of turnover.

   Comment: Product differentiation is quite extensive compared with that found in the washing and cleaning agents supply chain. Inasmuch as increased product differentiation engenders a high number of formulations, product differentiation also drives up the number of products that are subject to REACH registration.

3b. For the paint manufacturers, new raw materials account for between 1 and 7.5 % of total raw material portfolios per annum (or 10 - 75 % every ten years).

   Comment: This figure clearly shows that for the paint manufacturers, innovation goes hand in hand with the use of an increased number of raw materials.

4. The preparation manufacturers surveyed have between 400 and 3000 substances in their substance portfolios. The ratio of the number of items in raw material portfolios to that in product portfolios ranges from 1:7 up to 1:0.75.

   Comment: These figures reflect the scope of substance diversity that is required (and implemented) for the manufacture of preparations. The raw material portfolio to product ratio is nearly 1:1 for companies that mainly manufacture industrial, customized and specialized preparations or preparations for various niche applications (companies F, G, and H). These raw material portfolios are expanding or remaining at a high level (new and withdrawn substances offset each other) owing to customers' heightened awareness of the problems involved.

5. The preparation manufacturers surveyed make between 17 and 153 new products annually for every €1 million spent on R&D, although the companies all have slightly different definitions of what constitutes a new product or a modified formulation.

   Comment: The statistical indicators we developed (see below) suggest that the companies surveyed use varying product differentiation strategies. The compa-

nies with the highest ratio of products to R&D expenditures will probably be the most affected by any substance withdrawals under REACH.

Innovation indicators for the industrial coatings segment were devised on the basis of the data gathered from the companies surveyed. The following considerations should be borne in mind in connection with these statistics:

- The percentage of new products in the product portfolio is a gross figure, i. e. the companies concurrently withdraw products and formulations from the portfolio. The criteria the companies use to distinguish between active, passive and discontinued products vary according to clientele and company policy. The majority of the companies surveyed indicated that the scope of their preparation portfolios increases continuously.
- This holds true for raw materials as well. Here, too raw materials are concurrently withdrawn from the portfolio and new ones are added, sometimes on a one-to-one basis. For example, companies D and F add three to four new raw materials for every one that is withdrawn, whereas company G's raw material portfolio contains about the same number of substitutions and withdrawals.
- The proportion of substitutions provoked by external factors is an indicator of the extent to which raw materials are substituted owing to products being discontinued, price increases or the introduction of new hazardous substance classifications.

Table VI-12: Data pertaining to the section on innovation

Company	**O**	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**
No. of employees	480	290	500	2400	65	630	80	69	228
Annual turnover (in euros)	1 billion	90 million	308 million	1.75 billion	12.5 million	122 million	37 million	10 million	55.5 million
Percentage of turnover spent on R&D	n.a.	5	6	2 - 5	6.9	6.75	1.1	3	6.4
Time to market for new products (in years) (a)	n.a.	2 - 3	0.5 - 2	6 - 10	1	0.5 - 5	1 - 5	2	2 - 5
Product service life (in years) (a)	3 - 10	> 15	< 15	10 - 15	4	4 - 6	10	5 - 20	0.5 - 20
No. of products	10000	930	300	20000	6000	5800	300	1000	1650
Annual percentage of new products	< 0.1	11	4	n.a.	10	22	1.5 - 3	0.5 - 1	10
No. of raw materials	n.a.	300	300	3000	1400	850	400	647	1350
Annual percentage of new raw materials	n.a.	n.a.	n.a.	5	3.5	2.75	1.9	1.1	7.4
Annual percentage of substitutions necessitated by external factors				Virtually none	0.7	0.6	0.5	0.5	

O = Importer; A and B = Substance manufacturer; C-H = Coating manufacturer

The survey of the substance and preparation manufacturers revealed that in most cases R&D expenditures amount to 3 - 7 % of turnover. In comparison, the German chemicals industry as a whole (excluding the pharmaceutical sector) spent approximately 5 - 6 % of its turnover on R&D last year (Grenzmann et al. 2004; VCI 2003)[6]. This means that R&D expenditures for the substance and paint manufacturers surveyed is about average for the chemicals industry. There is no clear correlation between the scope of the relevant indicator (R&D expenditures) and company size.

On the basis of this indicator, some conclusions can be drawn regarding the extent to which preparation manufacturers and their suppliers will be affected by REACH. The relatively large amount of R&D carried out results in innovation capacity that is characteristic of the sector, as well as a corresponding capacity to adapt to REACH. This aspect relates to the pressure on specific supply chains to adapt discussed below.

Formulators also use the absolute size of their (raw) material portfolio as an indicator of their innovation and marketing strategy. The formulators surveyed have between 400 and 3000 raw materials in their portfolios, which far exceeds the figure for the washing and cleaning agent sector (see chapter V). A comparison of these two supply chains shows that the scope of a company's raw material portfolio plays a crucial role in terms of innovation. Thus, any limitations on raw material use under REACH will have a particularly strong impact on the paint and varnish supply chain. There is no discernible correlation between company size and the scope of its raw material portfolio, as can be seen by the fact that even a relatively small company like company G has nearly 1000 raw materials in its portfolio.

The number of recipes was also used as an indicator of the innovation and marketing strategy of formulators relative to revenue. This indicator makes a distinction between the companies' different market strategies. A high value indicates a great degree of product differentiation, while a low value reflects an attempt to have a streamlined product portfolio and maximum revenue per recipe. The preparation manufacturers surveyed make between 10 and 100 products per €1 million of turnover.

For the assessment of the extent to which REACH will affect a company, it must be kept in mind that product differentiation entails a relatively large number of active recipes, which also indicates a relatively large portfolio of substances used. This in turn drives up the number of substances that formulators will potentially be forced to withdraw under REACH. In addition, the higher the total number of formulations, the more

6 The figure for the German manufacturing sector as a whole was 5 % (Grenzmann et al. 2004).

new formulations will probably be needed when preparation substances are withdrawn (snowball effect; see Danish Paint Makers Association, 2004).

VI.4.3 Drivers of innovation

Research question: Which factors drive innovation? How will REACH impact these innovation drivers?

1. Innovation in the paint and varnish sector is primarily driven by the technical requirements of industrial customers. In other words, innovation is driven either by the need to solve problems or by customers' product and process innovations, which have implications for the preparation qualities required by customers.

   Comment: This means that any positive impact that REACH might have on innovation as a result of increased customer loyalty will be quite limited. In addition, since a relatively large number of formulations is developed for custom orders, there is considerable concern about possible withdrawals of raw materials (see section V.4.2). Thus one short to medium-term effect of REACH will be that for a time R&D resources will have to be channeled into preparation reformulation.

2. Health-related substitutions for solvents, cadmium, lead, and chrome VI have played a major role in the past as well, in the absence of REACH. Industrial customers would like substitutions to be made for well known hazardous substances and would like to modify their product information accordingly. Moreover, a priority concern for the preparation manufacturers is to be exempt from labeling requirements and to have the German "blue angel" environmental icon on their products (and particularly their consumer products) which indicates that the product contains little or no solvent, heavy metals or other hazardous substances. Much of the innovation realized by the additive manufacturers surveyed consists in the development of additives for water-based coating systems.

   Comment: In this regard, REACH is unlikely to be a catalyst for environmental or health-related innovation. However, REACH will increase the quality and quantity of the information provided about raw materials for preparations, and this in turn will promote achievement of the goal of avoiding the use of hazardous substances.

Table VI-13: The relative significance of the various drivers of innovation

	O	A	B	C	D	E	F	G	H
Proprietary R&D		XX			X	X	X	X	
Customers' technical requests			XXX	XXX	XXX	X		X	X
Voluntary substitutions for hazardous substances		X		XX	XX				X
Compliance with legal requirements							X		X
Maintaining a consistent product range	X	X							

VI.4.4 New substances in the paint and varnish sector

Research question: What role do new substances play for substance manufacturers? How can the paint and varnish supply chain benefit from the streamlining of development processes for new substances that is slated for implementation under REACH?

1. For the two substance manufacturers surveyed, the development of new substances plays only a minor role (company B has developed two substances over the past two decades) or no role at all (company A).

2. Pigment-related innovation mainly entails the incorporation of existing chromophors into new product systems. The additive manufacturer surveyed has made extensive use of the existing polymer regulation for the development of new substances that are exempt from registration costs.

3. According to preparation manufacturer C, the positive impact of simplifying the registration process for new substances will be diminished if substance manufacturers are forced to conduct their own tests of underlying toxicological and ecotoxicological properties at an early stage of substance development in order to ensure that the substances are suitable for the market. According to the additive manufacturer surveyed, the putative process simplification benefit for under 10 t/y additives will likewise be undermined by the fact that upon launching a new additive, he would have to register it in the over 10t/y category so as to obtain authorization to supply the product in the event it sells well.

Comment: The present study was unable to confirm empirically that any actual benefit would accrue from the simplification of new substance development processes under REACH.

5.7 % of all new chemical registrations in Europe through 2004 pertained to the manufacture of paint and varnish (ECB 2004), which is approximately the proportion (in terms of production value) of paint and varnish (4 %) produced by the chemicals industry. Approximately 76 % of new registrations[7] in the coatings sector (197 of 259) were realized in Germany, which reflects the position of German raw material and preparation manufacturers in the European market as a whole.

In order to answer the research question posed above, the two manufacturers in the supply chain were interviewed, German government statistics on new substances in the paint and varnish supply chain (IC 14) were analyzed, the distribution of new substance notifications in Germany across the various use categories (UC) was evaluated, and the number of notifications for each notification threshold was ascertained. Table IV-14 provides an overview of all notifications realized in Germany through 2004 for the most prevalent application domains.

Some 33 % of the registrations pertained to pigments (UC 10), 11 % were for process regulators (UC 49 including driers, dispersion agents, and defoaming agents), 9.5 % were for stabilizers (UC 49) and 7 % were for viscosity regulators and anti-skin agents (UC 52) (see table VI-14). Approximately 20 % of the notifications did not specify an application domain.

Only 12 of the notified new substances achieved a market volume of more than 10 t/y, and seven of them achieved a market volume exceeding 100 t/y. Two to seven years elapsed before most of these substances reached the next registration threshold. The chances that any of the new substances notified at the lowest level in this industry sector will achieve a market volume exceeding 10 t/y is just under 8 %. This could be attributable to the following factors:

- The regulatory hurdle for the 10 t/y threshold is so high that many substances “fail”
- Some of the registered substances were developed for a market in which potential sales do not exceed 10 t/y
- Market volumes of 1 - 10 t/y are necessary for new coating and pigment additives in order to conduct technical tests of market feasibility. This means that in this sector, substances “fail” for technical and economic reasons.

7 R&D substances and notified substances > 1 t/a

- New substances have a relatively difficult time competing with existing ones that have comparable functionalities, and as a result market volumes either increase at a snail's pace or stagnate.
- The vast majority of substances developed are polymer binders and additives that are not notified as new substances.

The statistics presented here do not shed any light on which of the aforementioned factors depress market volumes of new substances and the extent to which they might do this.

Table VI-14: New IC 14 substance notifications in Germany through 2004 (German Environmental Protection Agency, 2004b)

	Total	**10 t**	**100 t**	**1,000 t**
Total number of IC 14 notifications (> 1 t) Notified substances (> 1 t) in IC 14 Total number of IC 14 notifications (UCs)	149 138 177	18 18 19	7 7	0
Pigment notifications (UC 10)	58	5	2	
Viscosity regulators (UC 52)	13	3	1	
Process regulators including defoamers, dispersion agents, driers, catalyzers and the like (UC 43)	19	4	1	
Stabilizers (UC 49)	17	3	1	
Biocides (39)	3	2	1	
Solvents (UC 48)	5	1	1	
Redundant registrations	23			

Source: spezific analysis of the statistic for new substances by the federal environmental agency.

The average new substance registration rate for the past 14 years is eight substances per year. When this figure is compared with an existence-substance portfolio devoid of polymers consisting of approximately 5000 substances (see section VI.2.1), the rate of new substance notifications is less than 0.2 % per year. If the relatively low number of over 10 t/y new substances is taken into consideration, it becomes clear that innovation in the paint and varnish sector mainly occurs without the benefit of new substances. This finding was confirmed by the quantitative results of the present study.

Under REACH, the regulation that exempts R&D substances (PPORD), as well as the reduced data requirement for volumes of up to 10 t/y, should theoretically simplify substance development, testing and market launch. This will also reduce the risk entailed by the registration costs for "unsuccessful" substances, i. e. for new substances whose

market volume is well below 10 t/y. REACH will not optimize the process for new substances with market volumes exceeding 10 t/y.

VI.4.5 Time to market and cost for coatings

Research question: What effect does the flow of product development (time to market, phases in the development process, absolute development expenses) have on the various stages in the supply chain under REACH?

VI.4.5.1 Substance manufacturers

1. Additive manufacturers' time to market for a new raw material for paint ranges from 0.5 - 2 years. Development costs (excluding notification) range from €50,000 - 200,000 per product. Approximately 10 new additives are realized (predominantly polymers, exclusive of new-substance notification) annually per €1 million of R&D expenditures. The additive manufacturers do not feel that REACH will cause any delays in effecting deliveries to their customers.

2. Pigment manufacturers' time to market for a new product ranges from 2 - 3 years. These vendors realize approximately 70 products per year for each €1 million spent on R&D. This figure includes various additives for the same chromophors, but excludes new substances developed pursuant to Germany's toxic substances law. The pigment manufacturers likewise feel that REACH will not provoke any delays in effecting deliveries to their customers

VI.4.5.2 Preparation manufacturers

1. Time to market for the paint manufacturers ranges from 0.5 - 10 years, which is reflective of, among other things, the high degree of process integration that comes into play here and the authorization or release periods for certain coating systems.

(2) Up till now, internal costs for the reformulation of products subject to external substitution requirements have ranged from €7,500 - 75,000 per preparation (companies B, D, E, F, and H). Additional costs ranging from €2,500 - 30,000 can also be incurred for external testing in connection with authorizations for drinking water coatings and anti-corrosion agents. These involuntarily implemented substitutions arise approximately 2 - 10 times per annum (companies D, E, F, G). The respondents estimate that the attendant expenditures represent less than 1 % of their annual turnover.

Comment: This means that only a negligible proportion of R&D capacity is currently being used to reformulate preparations after specific raw materials are withdrawn.

VI.4.5.3 Downstream users

1. Time to market for new preparation technologies and systems (e. g. water-based in lieu of solvent-based paint) ranges up to 10 years. This type of development process entails the construction of new facilities, as well as coating development that inevitably gives rise to millions of euros in investment costs. In the auto and furniture coatings sectors, switching over to new products and the attendant change in pigments for the same basic formulation also affect these investments. Time to market ranges from 0.25 - 1 year for furniture coatings and up to five years for automobile coatings.

2. In some cases, it takes years for authorizations to be granted, particularly where stringent product qualifications are involved (e. g. drinking water coatings, the Florida test in the auto industry).

   Comment: Preparation manufacturers' product modification costs are strongly affected by the timing of the (probably necessary) reformulation of a preparation. Preparation manufacturers and downstream users go to great lengths to avoid changing formulations during the lifecycle of a product line owing to the lengthy authorization periods involved and the formulation and process technology modifications they are required to undertake.

VI.4.6 Product lifecycles in the individual phases of the supply chain

Research question: How long are the product lifecycles of raw materials and paints? Which factors bring product lifecycles to an end, and what role does REACH play in this regard? How do the different product lifecycles interact at the meeting points of the stages in the supply chain?

1. The substance manufacturers stated that their product lifecycles are upwards of 15 years.

   Comment: This obviously indicates that the functionalities of the various substances remain in demand for lengthy periods, which in turn means that investments in substance registration ultimately pay off. However, it should be borne in mind that the law requires registration of substances in the less than 100 t/y cate-

gory beginning only in 2017, a point at which some of the current substance portfolios will have reached or will be nearing the end of their product lifecycles.

2. For the preparation manufacturers surveyed, it is a normal phenomenon that product lifecycles vary greatly in length. This holds true, in their view, for one-time special orders (0.5 years), for investment and preparation innovation cycles for industrial customers (4 - 10 years) and for basic products with virtually unlimited lifecycles.

   Comment: This suggests that downstream users of products with short lifecycles either already know how to deal with unexpected formulation changes, or actually request that such changes be made.

3. The product lifecycles of the downstream users surveyed (excluding semiconductor manufacturers) are relatively long, i. e. 5 - 20 years. However, the surface pigmentation of a product sometimes changes during its lifecycle.

   Comment: There is little or no direct correlation between the length of downstream users' product lifecycles and the number of times gloss level or color shades are modified during the product lifecycle. However, basic coating type and application technique are rarely changed during a product lifecycle, which means that REACH will have a varying impact on downstream users' basic formulations and the attendant changes in color and gloss. On the other hand, REACH will have relatively little impact in cases where color and gloss are not major factors.

In this realm as well, the companies have varying criteria for differentiating between basic formulations (platforms), preparations, and changes in preparation pigmentation. The same kind of discrepancies comes into play for the respondents' definitions of product maintenance, product refinement, product redesign, and product application domain.

VI.4.7 Knowledge management and know-how flows

Research question: Are there any disclosure requirements in the REACH model that could lead to significant know-how loss? To what extent does the risk of expertise losses restrict the possible efficiency gains from cooperation in the REACH system?

(1) As in current chemicals law, expertise protection for the composition of preparations is not absolute. The law requires preparation manufacturers to provide in-

formation on any formulation component that is classified as a hazardous substance (see the German TRGS 220).

Comment: The market actors find a modicum of know-how spillover acceptable. However, **additional** know-how loss could be incurred if paint components currently classified as non-hazardous are reclassified as hazardous as a result of information flow optimization under REACH. However, such optimization is also one of REACH's intended goals.

2. In the view of the preparation manufacturers surveyed, the requirement that customers be provided with the registration numbers of all formulation components (see article 30 of REACH) will lead to further know-how loss.

   Comment: It would seem that REACH's stipulations on this point should be made clearer, particularly in regard to the expertise protection guaranteed by article 116 (2).

(3) The preparation manufacturers are greatly concerned about the fact that REACH will promote the flow of application know-how to substance manufacturers. This is because the substance manufacturers could disseminate this know-how to other substance vendors via their marketing strategies or could simply apply the know-how to their own preparations. Moreover, know-how could also be lost through information available over the internet that allows connections to be made between substance identities and specific application data.

   Comment: If REACH is to foster constructive transparency and vertical cooperation, it will be necessary to limit the law's potentially nightmarish effects on manufacturers. Toward this end, a standardized system of application and exposure categories should be instituted that would adequately protect market actors' know-how.

4. The substance manufacturers surveyed each have between five and ten consequential competitors in their respective market segments. The desired substance functions are in some cases provided by the same substances and in other cases by other substances. The respondents hold differing views on the potential benefits of consortiums. The pigment manufacturers have experience with cooperation in connection with the assessment of old substances, while consortiums are out of the question for the additive manufacturers because their substances are developed for one customer only.

   Comment: This means that the willingness to join a consortium also depends on innovation strategies and market position.

Manufacturers and substance manufacturers expressed the greatest concerns about the risk that REACH will enable competitors to obtain formulation know-how and information regarding the technical application domains of substances. Downstream manufacturers of preparations in the processing industry see this as a less significant threat.

Nonetheless, one of the main purposes of REACH is to consolidate information regarding substance properties and exposure scenarios by optimizing knowledge management in the supply chain and thus promote efficient substance safety assessments. Consequently, the potential risk of know-how loss under REACH will now be discussed in greater detail.

VI.4.7.1 Preparation formulations and know-how loss

The risk that competitors might obtain preparation-related information from safety data sheets predates REACH. For example, the German TRGS 220 (which is based on safety data sheet directives 91/155/EU, 93/112/EU and 2001/58/EU, as well as preparation directives 88/379/EU and 1999/45/EU) provides for disclosure of the following types of information:

- Planned or recommended applications of hazardous substances or of a preparation containing such substances, as well as the general technical functions of a substance or preparation such as a flame retardant (item 6.1.2).
- The identity and concentration range (EINECS or ELINCS, and if applicable, CAS and IUPAC) of each hazardous substance in a preparation that would cause the preparation to be classified as hazardous pursuant to the provisions of article 3 (3), item 6.2.3 of the Preparation Directive.
- The identity of substances that pose an environmental or health risk that are components in preparations classified as non-hazardous, insofar as such substances are present in concentrations exceeding 1 % (item 6.2.4). (For substances classified solely as irritating or unhealthy, a generic designation (e. g. pursuant to Annex VI of the Dangerous Preparation Directive) can be substituted for the chemical identity insofar as the vendor can demonstrate that expertise protection problems might arise from disclosing the substance's actual identity. This also applies in cases where an irritating or acutely deleterious substance is also inflammable, explosive or environmentally hazardous (item 6.2.4)).
- The identity of any substance in a preparation whose concentration exceeds 1 % and for which the collective exposure threshold values are exceeded at the workplace (item 6.2.3).

The competent authorities in the various EU Member States do not always agree on how safety data sheet directives should be implemented (see ECLIPS 2004). For example, in Finland the CAS numbers for hazardous substances appear on the safety

data sheet, whereas many other EU countries dispense with substance-group designations.

The concern that the targeted substance flow transparency under REACH will promote know-how leakage is not easily dismissed. For example, the exposure assessments for hazardous substances required by Article 13 could be a potential source of information regarding preparation formulations. In order to ascertain the predicted environmental concentration (PEC) of a hazardous substance for a specific application, the concentration of the substance in the chemical mixture is needed, even if the mixture itself is not classified as hazardous. This is sensitive information that the preparation manufacturers are reluctant to disclose. But if the manufacturers are required to include such information in the safety data sheet, it will become general knowledge. In our view, the concentration ranges that the current legislation requires manufacturers to include in the safety data sheet are sufficient for exposure and risk evaluation purposes.

VI.4.7.2 Disclosure of registration numbers of non-hazardous substances (article 30)

The companies surveyed feel that article 30 of the REACH legislation could lead to know-how leakage. Article 30 defines the information that manufacturers are required to disclose to downstream users regarding hazardous substances and preparations. While this disclosure duty only concerns the identity of the substance and not its concentration, this information is nonetheless felt to be sensitive for competition, and it cannot be ruled out that this information will be passed on to competitors via business relations with customers. The respondents cited specific additives as an example of this, i. e. in such cases, the only information that is needed to reproduce a formulation is the type of substance, not its concentration. Therefore, in its present form the regulations promulgated by article 30 are contradictory or at least unclear. According to Article 116.2 (e) and the intention of the draft as the other Articles make clear, details on the complete composition of a preparation are considered confidential. In addition, substances that are not dangerous in preparations are not the subject of exposure evaluations in the REACH system. It would help to have a clarification of what Article 30 of the draft regulation means.

VI.4.7.3 Definition of generic use and risk/exposure assessments

Another way of lose expertise is the definition of a substance's generic use and the description of safe application conditions in the exposure scenario. Here, the companies repeatedly referred to the concept of *exposure categories* as an instrument for communication about exposure issues in the supply chain that simultaneously upholds

expertise protection to an appropriate extent. It should be noted in this regard that the German TRGS 220 currently requires that information be provided regarding the planned use of hazardous substances and preparations (including their technical functions) but that this has not become standard practice in the industry, as will be the case with the REACH exposure categories.

Application-specific know-how pertaining to industrial coatings and series-production vehicle coatings is a particularly sensitive area for the paint manufacturers. In fact, in any scenario in which the capacity of companies to solve customers' problems becomes a competitive arena, specific substance applications and application conditions take on the status of sensitive information. Thus, the respondents are particularly concerned about the possibility that know-how will be divulged to competitors via information exchange with suppliers and customers, i. e. through the very process that is required by REACH. This means that an inherent conflict potentially exists between the achievement of REACH objectives and the development of innovative products and processes.

VI.4.7.4 Know-how dissemination and innovation

The manufacturers' concerns about know-how leakage to competitors could potentially undermine their willingness to innovate owing to the fear that if they do, they may have to undertake the same R&D expenditures twice in order to keep up with or outdo a competitor that makes changes in his (improved) product and thus comes out with a product of comparable quality. At the same time, formulators have an incentive to limit their R&D expenses to have more funding for product imitation. However, it must be kept in mind that the successful diffusion of an innovative preparation on the market is based on the gradual propagation of the underlying knowledge, as is the case in general with innovations. However, government policy should promote the creation of conditions under which (a) innovative manufacturers feel confident that their innovations will generate revenue and which at the same time allow for (b) the gradual dissemination of the underlying know-how. This means that in order to achieve a proper balance between information disclosure requirements and expertise protection, it will be necessary to devise suitable solutions for the various phases of the supply chain.

VI.4.7.5 Substance identity and consortium formation

The practical benefits of consortiums formed for the purpose of sharing testing costs also depends upon the extent to which the chemical additives or pigments involved are clearly defined and/or whether the exchange of substance identity information alone (including information regarding distribution patterns and impurities) could potentially

provoke know-how leakage in regard to the manufacturing process of the substances in question. The present study did not investigate the significance of this problem for the implementation of REACH registration requirements for raw materials.

VI.4.8 Exploration of new application domains and chemicals services

Research question: To what extent will REACH promote the exploration of new application domains for paints and raw materials? To what extent does REACH promote the development of substance and preparation suppliers into chemicals service providers (from information management to knowledge management)?

1. Providing downstream users with technical support is already a major activity for the respondents (see information regarding numbers of customers per employee in section VI.3). The same holds true for preparation component suppliers providing manufacturers with technical consulting services.

   Comment: It is unlikely that REACH will promote the development of new application domains because potential customers are already quite knowledgeable about the need to solve specific problems.

2. Providing customers with technical consulting services is already a major activity in the industrial coatings industry. As a rule, this support is provided by sales representatives and/or application technicians who generally lack extensive knowledge regarding toxicological, ecotoxicological and exposure assessments for substances. Thus, the product safety departments realize these assessments.

   Comment: The implementation of environmental protection, worker safety and product safety advice in customer consulting processes would enable companies to differentiate themselves from their competitors. The REACH chemical safety assessments (including the definition of safe application conditions) will provide an additional opportunity for companies to offer such services to their customers. Many large industrial customers currently allocate more resources to hazardous substance management than formulators allocate to product safety management.

(3) The example of the Housepainters Purchasing Cooperative in Lubeck clearly shows how distributors can provide technical support in regard to chemical products used by the building trades with a view to implementing current legal requirements.

Comment: The REACH model will promote further development of the aforementioned approaches in that the distribution sector will act as a bridge between preparation manufacturers and trade users in instances where, for example, coating companies do not have their own customer training programs. Customer consultation services should evolve into facilities that provide trade actors with suitable and clearly understandable exposure scenarios and help them carry out risk and safety assessments for all three protection-related domains (instead of for employee safety only).

4. Only large paint manufacturers are in a position to assume the economic risk of providing chemicals services in the coatings sector (e. g. for automobile coating processes). This model is not currently relevant for SMEs, nor is it likely to become relevant to this sector in the foreseeable future.

VI.5 Other effects of the REACH model

VI.5.1 Passing costs downstream

Research question: What opportunities might there be to pass REACH-related costs down the supply chain?

1. Coating prices are stagnating and in some cases have been falling in recent years.

   Comment: Thus the prospects for increasing coating prices in order to pass additional costs downstream appear to be rather dim.

2. The paint manufacturers' experience has shown that optimizing product safety generally does not heighten industrial customers' willingness to pay higher prices, but is instead taken for granted.

3. Tight customer relationships are common in the industrial coatings sector, and process technology rather than coating price tends to be the main coating cost issue in these settings. According to preparation manufacturer C, preparation material cost accounts for only 20 % of total automobile chassis coating expenditures. In addition, highly specific binders and additives are often used in customized industrial coatings, which means that other vendors' products cannot be used as substitutes.

Comment: The practice of shifting REACH costs to downstream users will probably become most prevalent in the aforementioned segments because downstream users and their process technology generally rely on a specific product.

4. The situation is different in the realm of organic pigments. According to companies A and G, in their segment preparations of comparable quality are available from Asian vendors at far lower prices. Thus, paint manufacturers and downstream users in this segment can turn to alternative sources of supply in non-EU markets.

5. Companies J, K, L and P reported that coating materials costs account for 1 % or less of total production costs in the automobile and furniture industries.

   Comment: This means that downstream users' margins would be reduced by only a fraction if REACH costs were passed up the supply chain to them. However, the extent to which such costs can be passed on depends only partially on markup amount. The customer's negotiating position also plays a major role here.

Table VI–15: Proportion of downstream user cost accounted for by coatings or chemicals

	J	K	L	N	P
Chemical costs for manufacturing	< 1 %	n.a.	< 1 %	25 %	0.5 %
Coating costs for production	< 1 %	< 1 %	< 1 %		

Raw materials account for approximately 50 - 70 % of paint production costs (excluding R&D, marketing, profits etc.). This figure is higher (up to 80 %) for raw material manufacturers. According to company C, the aforementioned proportion is as low as 20 % for large companies that mass-produce relatively large numbers of items for the automobile industry.

Table VI–16: Average proportion of production costs accounted for by chemical costs

	A	B	C	D	E	F	G	H
Ratio of chemical costs to production or marketing costs	n.a.	80 %	70 %	64 %	68 %	74 %	47 %	50 %
Ratio of chemical costs to total costs including marketing	n.a.			52 %	66 %	50 %		

In interpreting what has been said here about passing on additional costs, it should be borne in mind that additives and organic pigments generally account for less than 5 % of total preparation components by volume. This means that any substance cost increases will only have a limited impact on overall preparation production costs.

VI.5.2 The impact of REACH on the product portfolios of substance and preparation manufacturers

Research question: What impact will REACH have on the product portfolios of substance manufacturers and the raw material and product portfolios of paint manufacturers? What impact will product reformulation have on downstream users when specific raw materials are withdrawn?

1. The additive manufacturer surveyed (company B) does not plan on reducing the scope of his product portfolio and is reassuring his customers of this as well. The pigment manufacturer (company A) had no opinion on this matter.

2. New raw materials account for an average of 3 % of paint manufacturers' portfolios (range: 1.1 to 7.4 % for the paint manufacturers surveyed). Over the past decade, approximately 30 % of these manufacturers' raw materials have been withdrawn and replaced. The rate of mandatory implemented substitutions is approximately 0.5 - 0.7 % annually (companies D-G, see table VI-12), which works out to 5 - 7 % over a ten year period.

   Comment: This means that under present conditions, the paint manufacturers would be able to deal successfully with a certain amount of raw material substitution.

The secondary costs provoked by substance withdrawal are determined by the number of coating systems the raw material in question is used in and the extent to which its function interacts with that of other preparation components. This means that the modification costs arising from raw material substitution cannot be estimated solely on the basis of the substitution rate. It should also be noted that the high degree of interaction between binder systems and additives could in some cases force a manufacturer to re-engineer a number of preparations.

A DIHT study published in August 2004 shows that raw material substitution is standard operating procedure in the paint and varnish industry. According to the study, approximately 60 % of companies with over 50 employees and 81 % of companies with over 250 employees replace their raw materials either sporadically or regularly.

- A project sponsored by the Danish Paint Makers Association investigated the following question (among others): How many substances will be subject to REACH registration and when would this occur? What will the resulting reformulation costs be for downstream users? In this three year-long project (2001 - 2004), which was financed by the Danish environmental agency, several downstream users prepared for the advent of REACH. A recently concluded study investigated the individual substances in the primary materials used by 12 coating and sealant manufacturers. Some of the results of the study have a bearing upon the present study's findings in regard to the German paint and varnish supply chain. Of the 2660 substances investigated (which came from all 12 companies), a list of 2160 substances with CAS numbers could be compiled. After removing repetitions, 960 of the substances (36 %) remained.
- It was found that half of the substances identified are used by only one company and only two substances are used by all of the companies surveyed.
- For an average of 40 % of the substances, either no CAS number or tonnage range could be found in the IUCLID database. It is likely that the items lacking a CAS number actually contained more than one substance.

The results of the Danish study appear to substantiate the fact that an extremely broad range of raw materials is used in the paint and varnish industry. However, it remains unclear from the results of the study (as well as the present German Environmental Protection Agency study) whether the broad range of substances deployed reflects an equally broad range of functionalities or whether many of the substances are in fact interchangeable.

VI.5.3 Impact of REACH on choice of manufacturing facility location and supplier

Research question: What role will be played under REACH by substances manufactured in non-REACH countries? To what extent will products be exported to non-REACH markets?

Research question: To what extent will REACH registration prompt substance manufacturers, preparation manufacturers and/or downstream users of preparations to move their production facilities to non-EU countries or purchase their raw materials or products from non-EU countries?

1. The companies surveyed export between 3.5 and 63 % of their paints or raw materials.

Comment: This means that paints manufactured in Europe compete on the world market with products containing raw materials not subject to REACH registration costs but which also lack REACH-standard documentation regarding their safety.

2. None of the paint manufacturers surveyed obtain more than 5 % of their raw materials (in absolute figures) from non-EU markets, with the exception of the semiconductor manufacturers, who purchase 95 % of their photoresists from outside the EU. The pigment manufacturers import 14 % of their raw materials.

   Comment: It should be noted that the paint manufacturers do not always know whether or not their raw material suppliers import their products from outside the EU. Thus, the percentage of direct imports given here merely suggests that under REACH the requirement that paint manufacturers register their own products should be the exception rather than the rule. This also precludes any indirect registration requirements for imports from upstream suppliers from the withdrawal of raw materials (see section II.4.2).

3. The situation is quite different in the semiconductor industry, which (according to company N) imports approximately 95 % of its photoresists. Company N is fearful that Japanese photoresist vendors will refuse to sell to him under REACH conditions. Approximately 20 % of the photoresists used fall into the over 1 t/y market volume category. Company N stated that the price of photoresists ranges from €80 - 1300 per kg.

   Comment: A detailed investigation would be needed in order to determine the actual extent of the risk that Japanese photoresist manufacturers and their EU sales representatives would decline to register their products in the over 1 t/y category under REACH and thus risk losing the entire European market. It should be noted, however, that the correlation between m 4. The transport distances are limited for ready-to-use coatings with a high concentration of inexpensive components such as water and solvent and a relatively short shelf life, owing to their susceptibility to heat and cold. Moreover, the tight customer relationships in the industrial coatings industry necessitates a local presence on the part of suppliers. Consequently, it is common for suppliers, including SMEs, to establish production facilities in close proximity to their non-EU customers. Nonetheless, products such as raw materials for quality coatings, specialized coatings produced in small batches and high solids or powdered coatings are also manufactured in Germany and marketed worldwide (cf. export surplus).

5. In view of the fact that numerous production facilities for motor vehicles, pipes and other products are now located outside the EU, many preparation manufacturers fear that their customers will follow suit.

   Comment: It should be noted that the aforementioned information was put forward by a company that has relocated its operations outside the EU for reasons of cost and feels that REACH will greatly increase production costs. However, the company is not concerned about quality assurance problems and feels it is unnecessary to be in close proximity to European customers.

6. Global companies that use industrial and motor vehicle coatings at various production facilities generally approve a **single** formulation for all locations and then use it for a period of years.

   Comment: The following scenario would appear to be plausible in such cases: Downstream users will initially pay part of the substance registration costs because the alternative (switching to a non-EU coating manufacturer and requalifying products while production is ongoing) would be more costly. Inasmuch as this would only involve a calculable one-time price effect, at the conclusion of this phase-in period downstream users would not necessarily begin purchasing their materials from non-EU vendors. It may well be, however, that in the long run REACH will promote the current tendency of product manufacturers to relocate their production facilities outside the EU.

11 % (in value) of paints used in Germany are imports from non-EU countries (VdL (German Paint Industry Association), 2003). German manufacturers' net non-EU export surplus is 30 % (in value) and is rising. Table VI-17 shows the data provided by the substance and preparation manufacturers surveyed regarding direct imports from, and exports to, non-EU markets.

Table VI–17: Export-import data

	A	B	C	D	E	F	G	H
Exports to non-EU countries	20 % of turnover	50 % of products	n.a.	50 % of volume	n.a.	n.a.	n.a.	3.5 % of turnover
Imports from non-EU countries (based on numbers of products)	14 %	2 %	1.6 %	None	2.3	< 1 %	Next to none	n.a.

VI.6 Respondents' suggestions for improving the REACH model

During the survey, the respondents put forward a number of suggestions as to how REACH could be made more practical and efficient. The suggestions are listed below in descending order of frequency and with the number of times the suggestion was made in square brackets. Suggestions that appear in the October draft of the law have been omitted. The suggestions are merely listed here, without any commentary on our part.

- REACH requirements should be based on potential risk rather than on volume thresholds; «testing requirements should be more closely tied to exposure scenarios. Toward this end, a system of exposure categories should be devised [4]
- Expenditures of time and financial resources should be minimized through the development of suitable implementation mechanisms such as rules governing the formation of consortiums and cartel law protection. The watchword should be: one registration procedure for each substance [3].
- The REACH legislation should promulgate comprehensive and effective expertise protection including for customer-supplier relationships and for formulations. The discrepancies and contradictions in the current draft of the law should be eliminated. Trade and EINEC names (CAS numbers) should not be divulged concurrently. [3]
- Substances with a molecular weight exceeding 800 (except for polymers) should not be subject to REACH registration because these substances pose little safety risk. [2]
- REACH should be integrated with other chemical-related regulations pertaining to the environment, hazardous substances and hazardous goods [1]
- Chemical safety reports should not be required for substances that are clearly non-hazardous [1]
- Old substances that have been evaluated previously should be registered automatically [1]
- The classifications and descriptive data from Annex 1 of directive 67/548 should be incorporated into the hazard assessment [1]
- The formulations of imported coatings should be registered with EU authorities, but registration requirements should only apply to components that have not been registered in the EU. [1]
- Downstream users should be exempt from the substance safety assessment requirement [1]
- Only the components of imported preparations that have not been registered in the EU should be subject to REACH registration. [1]

VI.7 Conclusions regarding the paint and varnish supply chain

The key points in the foregoing analysis will now be summarized with a view to answering the following questions: What kinds of pressure to comply will REACH exert on paint and varnish industry actors? Do these actors currently possess the resources to make the required changes? We also make suggestions as to how this pressure to comply with REACH can be mitigated and how the industry's capacity to adapt to REACH can be enhanced. A discussion of the extent to which the paint and varnish supply chain will be affected by REACH compared with REACH'S impact on the other supply chains surveyed (the washing and cleaning agent industry) can be found in chapter VII.

It should once again be emphasized that inasmuch as the present study was carried out on a strictly empirical basis, the findings cannot be generalized. A total of 15 companies from various points in the supply chain and various market segments were surveyed. Such a small sample cannot provide statistically representative findings. In addition, the study covered a very broad range of contexts. A case study can only be representative insofar as the overall context pertains to a substantial portion of the supply chain.

It should also be noted that a key element is lacking that would have allowed for quantification of the aforementioned pressure to comply with REACH: a classification system for the substances in the supply chain. The number of substances that is actually subject to REACH registration remains unclear, as do the tonnage ranges of these substances and whether the attendant registration costs would be borne by paint and varnish industry actors or by actors from other industries.

Below is an overview of the key factors that will tend to **increase the pressure on industry actors to comply with REACH**, including a parenthesized indication of which actors in the supply chain are mainly involved (S: substance manufacturer, F: formulator, U: downstream user).

- Relatively low-volume substances (1-100 t/y) in preparations are of major technical significance for automated coating technologies and specialty applications (S, F). This means that specific registration costs are high vis-à-vis current market prices, particularly in the case of preparation components, for which innovation is a major consideration.
- The proportion of hazardous substances among preparation components is relatively high and thus the obligation to carry out exposure and risk evaluations is of major importance (S, F).

- Certain market segments such as small manufacturers of industrial coatings will feel the effects of REACH more strongly owing to their highly diversified raw material and product portfolios (high probability of the withdrawal of a raw material and formulation modification) (F).
- The availability of fewer substances and the attendant efforts to find substances with suitable “identified” applications and exposure scenarios could prolong time to market for preparations under REACH (F).
- The need to modify formulations will provoke process modification costs as well as costs for technical and organizational changes in approval processes (U).
- To the extent that substance and preparation imports increase in the future owing to globalization (a phenomenon that will occur irrespective of REACH), preparation manufacturers and downstream users will come under increasing pressure to register their products themselves or via importers (F, U).
- During the REACH phase-in period, the medium term availability of certain raw materials will be in doubt. This will in turn put pressure on preparation manufacturers and downstream users to rethink their supply chains and if necessary obtain or manufacture supplies outside the EU (F, U).

The pressure on industry actors to comply with REACH will be mitigated by the following:

- The formation of cost-sharing consortiums can reduce registration costs for manufacturers and importers of high market volume pigments. The potential cost-saving benefit of such consortiums for low-volume additives and specialized pigments is relatively limited, however. Some substances are manufactured by only one company, while in other cases substance identity will have already been disclosed through routine business communication (S).
- There is relatively little risk that formulators’ pigment and additive applications will exceed the scope defined by the substance manufacturers, and thus there is little possibility that formulators will have to carry out their own risk assessments. These substances are often manufactured to order as specialty coating application chemicals. However, in order for this to occur, the attendant registration dossiers will have to cover a broad range of exposure scenarios similar to those that come into play for classic coating applications. Lacking this, communication with suppliers may become more labour intensive, suppliers may incur know-how loss, and preparation manufacturers may have to bear the additional cost of performing risk and exposure scenarios (F, U). Even where widely applicable exposure scenarios are developed, if (as is bound to occur) preparation manufacturers use unusual substances as additives, additional safety evaluations will be needed.
- Scenarios in which additives and pigments represent a relatively minor proportion of preparation manufacturers’ production costs reduce the pressure on these actors to relocate their production facilities abroad in order to keep their prices competitive.

However, in isolated cases, reduced pressure to comply with REACH could strengthen the tendency to relocate manufacturing facilities abroad (U).

- In many instances, European component manufacturers qualify for quality bonuses that greatly reduce the likelihood that they will modify their sourcing strategies for reasons of cost (U).

In some instances, non-EU component manufacturers are subject to guidelines, partially for quality standard reasons, which require that their coatings come from an EU supplier (F).

The following factors will increasingly affect the **adaptability** of actors in the paint and varnish supply chain:

- The characteristically high level of R&D expenditures for specialty products in the industry suggests that the relevant actors are well positioned to effect changes necessitated by REACH.
- Formulators' extensive application expertise will be highly useful for the elaboration of exposure scenarios (S, F).
- Even under the current German hazardous substances law, expertise protection is anything but airtight. Information provided by preparation manufacturers regarding the hazardous components of their formulations clearly indicates that these actors can readily handle a certain amount of know-how spillover (F).
- Preparation lifecycles tend to be relatively short nowadays owing to customers' technical requirements, which means that the downstream users concerned are already accustomed to frequent formulation modifications (U).
- The increased amount of application know-how that will be engendered by REACH will make it easier for substance manufacturers to develop innovative products. However, this same phenomenon could also deter formulators from developing innovative solutions since these actors possess the aforementioned application know-how and already apply it to the development of innovative products (S, F).
- The fact that all actors from the same segment of the European supply chain will be affected by REACH in the same way will ease the task of implementing price increases (S, F, U). However, this will only apply beginning in 2017 to importers and finished product manufacturers whose products contain hazardous substances.
- For downstream users, the ratio of overall chemicals costs to production costs is relatively low in the supply chains investigated (apart from the semiconductor segment). Any increase in this ratio would thus have only a negligible effect on margins (U).
- Preparation manufacturers currently replace approximately 30 % of their raw materials every ten years (this includes both voluntarily and involuntary implemented sub-

substitutions), which means that these actors are well positioned to adapt to REACH (F).

- The fact that preparation manufacturers have handled withdrawals of raw materials successfully in the past clearly indicates that they can deal with price increases and uncertainty regarding the suitability of substitute substances, providing they have advance warning of impending withdrawals and a choice of substitutes for them (F).

The following factors will diminish the **adaptability** of industry actors:

- In some cases, the required number of safety data sheets (and the attendant preparation evaluations) per employee is extremely high (F).
- Downstream users are apparently reluctant to carry out valuations and undertake expenditures for improved safety data sheets and product information (F, U).
- Little in the way of new substance development is currently being undertaken, which means that developing replacements for withdrawn substances will be no easy matter (S, F).
- Declining prices and stagnating sales make it difficult for paint and coating industry actors to pass cost increases downstream (S, F). Application value remains the main determinant of additive prices, which means that at least some REACH-related costs could potentially be passed downstream.
- Inasmuch as the proportion of specific risk-related registration costs per kg of under 100 t/y products is particularly high, downstream users can reduce these costs to only a limited degree through improved product safety and risk management.
- The companies surveyed do not feel that any first-mover advantage would accrue from expanding into non-EU markets that may in any case end up adopting REACH-style regulations in the future (S, F, U).

Finally, the pressure and capacity to adapt cannot be quantified and “set off” against each other. However, it can be stated with certainty that REACH will have a ripple effect on a broad range of adaptation mechanisms. A better understanding of these mechanisms can help design the draft of REACH and the enforcement instruments to reduce the pressure and increase the capacity to adapt. It remains unclear, however, what effect the “rechanneling” of currently available voluntary raw material substitution resources will have on REACH compliance capabilities within the context of market competition. This is a significant factor because the substance withdrawals engendered by REACH will temporarily hinder the efforts of industry actors to meet customer needs. In summary, it can be stated that the following four dimensions of REACH will impinge upon the nature of the pressure placed on industry actors to comply with the law and their capacity to comply with it:

- Owing to the low production volumes involved, direct registration costs for additives and pigments will reach such critical levels that economic concerns alone will

prompt industry actors to avoid registering these substances. A relatively substantial portion of these costs will be unavoidable even if product and application safety are enhanced because these costs are mainly engendered by non-risk related testing requirements. In other words, the current draft of the legislation puts pressure on industry actors to comply with REACH in ways they cannot avoid through the use of non-hazardous substances or by ruling out exposure scenarios for specific applications.

- Paint manufacturers currently have very limited human resources at their disposal for the evaluation of their suppliers' safety data sheets and for the elaboration and updating of their own safety data sheets. Certain provisions of the German TRGS 220 (e. g. pertaining to the evaluation of exposure related information and the definition of significant missing information pertaining to substance properties) have thus far defied implementation in the supply chain. However, under REACH, paint manufacturers will be required to harmonize each and every aspect of their suppliers' exposure scenarios with the intended application conditions. This in turn means that REACH can be successfully implemented only if exposure scenarios and the attendant validation procedure are implemented in a standardized fashion. Special attention should be paid to the degree of details in the definition of uses and exposure scenarios in the further implementation of REACH. Different ideas about how this should be done are currently the basis of many negative attitudes about REACH. The main goal should be to: 1) use the available application knowledge of formulators; 2) distribute the burden of chemical safety reports for individual applications appropriately between the stages of the value chain of substance manufacturers and formulators; and 3) ensure that formulators have sufficient protection without blocking the flow of general application knowledge too much. Here, formulators and their associations in particular seem to have the knowledge to develop simple, practicable systems.
- During the phase-in period of REACH, there will be competition between substances already registered and those not yet registered; this situation will affect prices and future availability, for example. As long as a substance has not yet been registered, formulators will not be able to count on it being available in the future and will not know at what price. If formulators replace a substance with one whose fate has not yet been determined, they will face follow-up costs if the raw material is withdrawn or becomes more expensive. The situation of users is similar: they may have tailored their processes to a preparation whose components have not all been registered. In other words, the pressure on formulators decreases if the REACH system can motivate most manufacturers of a substance to register at the same time using a consolidated set of data for the substance.
- No inventory of registrant substances has been taken in either value chain yet. In addition, formulators and users face a severe uncertainty about the costs to expect and the availability of raw materials. These uncertainties could be overcome if trade associations or other neutral third parties determine an anonymous chain inventory based on CAS numbers (such as the merger of the inventories of two companies)

before REACH is implemented. This would enable substance manufacturers to cover the relevant coating applications from the outset and would make the actual registration costs transparent within the supply chain.

VII Comparison of supply chains and discussion of universalization

VII.1 Estimation of representativity

The investigative results are not representative in a statistical/quantitative sense, even though both supply chains comprise a relevant portion of sales in the chemical industry. The breadth of the investigated contexts decisively affects the representativity and universal applicability of the results from case studies. The contexts that were covered in the chapters on the supply chain analysis in this study are cited below.

Let us first address which contexts are found on the individual levels of the supply chain of the selected **companies**. In both supply chain analyses, formulators are more numerous. This allows a relatively broad representation of different contexts on this level. Both large companies and SMEs are represented, with SMEs predominating. On the substance manufacturer level, only three companies were surveyed, again including large companies (in the cleaning products chain) and SMEs (in the paint chain). On the level of the user, only large companies were included in the cleaning product chain. The same holds true for the paint chain with one exception. Chemical imports were analyzed directly in the survey of an importer; otherwise they were only considered from the perspective of the other surveyed companies. The empirical investigation of the supply chains was only able to offer a very restricted treatment of the relevant contexts for chemical importation. Additional information was therefore obtained through the advisory committee and included in the study (see section II.3.2).

An important context is the selection of the **market segments** investigated in the supply chains. On the substance level, this would be surfactants for cleaning products, and organic pigments and additives for paints. For specialties, the paint chain is more representative than the cleaning product chain due to the considered raw material sector. In regard to REACH, the considered substances are represented in all REACH-relevant tonnage ranges, and different market price levels of chemical (raw) materials are likewise represented. On the formulator level, products for industrial use were considered in both supply chains, and products for use in private households were also considered (cleaning products). Paints and cleaning products differ in how long they remain after application: Whereas paints remain a part of the manufactured article, cleaning products are procedural aids that are disposed after they are used. The REACH mechanisms are hence differently applied, and different adaptation strategies are used. The current foreign trade position of formulators in both chains also differs. More paints are exported to non-EU countries than cleaning products. The size of the portfolios of the formulators in the paint and cleaning products chains vary widely, both

in terms of raw materials and products. Measured in terms of formulator sales, the main industrial segments of users of the formulations are represented.

The investigated users outside of the chemical industry belong to different branches. Each of these branches represents a different context for the use of paints and cleaning products. Measured against the actual breadth of this supply chain step, the investigation only covers a narrow section. This sometimes makes it difficult to establish the relationship between the context and the effects of REACH on users described in the interviews. Given the numerous user branches covered in the project, it was also impossible to paint branch-specific reference scenarios as was done for the chemical industry in section I.7. There is hence no overarching picture of the economic development of the overall respective branch of the relevant users, i. e., in regard to globalization. The conclusions regarding the users of chemicals can therefore only be generalized to a limited extent.

Overall, the results of the supply chain analysis yield a detailed picture of the nature of REACH-induced mechanisms and their interactions. They therefore form an appropriate basis for developing approaches to change management. Generalizable conclusions regarding quantitative cost and benefit are however not possible on this basis and were also not addressed in the project.

VII.2 Comparison of the two supply chains

Water-based products for home and industry were investigated in the cleaning product chain. The survey of the paint chain concentrated on industrial paints. In the cleaning product chain, the focus lay on high-volume raw materials (surfactants); for paints, the emphasis was on raw materials that are typically produced in the –100 t/y range and for which SMEs play an important manufacturing role. These differences also yield some of the deviating findings in the respective chain. Table VII-1 offers a synopsis of important findings. The quantitative data are limited to the determined values from the investigated companies.

Table VII-1: Comparison of findings in both supply chains[1]

Subject	Cleaning Product Chain	Paint Chain
Investigated substance segments	Surfactants Percent of substances < 100 t/y is 35 %	Additives, pigments Percent of substances < 100 t/y is 75 - 90 %
Investigated customer segments	Private households and industry	Only the industrial segment
Market price level for substances (S)	0.7 – 3 EUR / kg (1 - 3 EUR/kg for surfactants < 10 t/y)	5 - 23 EUR/kg for organic pigments and additives
Absolute size of the (raw) material portfolio per company (F)	90 – 300 (raw) materials	300 – 3000 (raw) materials
Percent of hazardous raw materials (F)	60 – 100 %	30 – 80 %
Percent of hazardous products (F)	0 – 100 % Freedom from identification perhaps also important in households	30 – 90 % Freedom from identification and avoidance of prominent toxins also important for industrial customers (poss. prominent subjects of heavy metals and VOC)
Product safety (F)	90 - 600 products per MA	820 to 6000 products per MA
new raw materials p.a. (% of raw material portfolio) (F)	1.7 – 5.6 %	1.1 – 7.4 %
%R+D in sales (S, F, U)	<< 1 - 3 %	3 - 7 %
Formulations per mill. EUR sales (F)	1-28 (for formulators with more industrial customers than the household segment)	10 - 100
	=> There is less adaptation pressure from changes in raw materials in the cleaning product chain than in the paint chain	
New substances (S)	Number of new substances in the paint chain is greater than in the cleaning product chain, but there is a higher overall number of substances there as well	
Special regulation for R+D (S, F)	PPORD regulation not applicable for applications in the household sector	PPORD regulation is relevant for industrial products
Development times on the formulator	0.1 – 5 years	0.5 – 5 years

1 Abbreviations indicate the value chain step to which the numbers refer (S = substance manufacturer, F = formulator, U = user)

Subject	Cleaning Product Chain	Paint Chain
level (F)		
	The developmental expense for paints is usually higher than for cleaning products due to the greater process integration and new technological mechanisms of action.	
Subsequent tasks for users when preparations change (U)	Result test, sometimes use test, adaptation of internal chemical safety management; poss. technical authorization	Time-intensive use and result test; adaptation of internal chemical safety management; poss. technical authorization
	Use tests for cleaning products are usually indicated as being shorter than tests for paints	
Product life cycles for users (U)	Rather long, time-to-market effects not anticipated from REACH; exceptions among photosensitive coatings in the paint chain.	
Export of preparations to non EU markets (F)	rather slight	important
Percent of cleaning product and paint costs in production costs (U)	< 1 %	< 1.5 %
Rate of self-initiated discontinuation of raw materials (% of raw material portfolio extrapolated to 10 years (F)	20 – 40 %	7 – 70 %[2]
Basic rate of forced exchange (% of the raw material portfolio extrapolated to 10 years) (F)	10 – 20 %	5 – 7 %

Based on these findings, we can see that the cleaning product chain fairs better under REACH in comparison to the paint chain for the following reasons:

- The product differentiation and the breadth of the substance palette are lower so that innovative resources are less affected by substance discontinuations due to REACH. Measured against the raw material replacement quotas, the capacity to adapt to raw material changes is comparable to that of the paint chain.

2 Percentage of new raw materials overall, adjusted by the basic percentage of forced replacement. This is particularly reflected in the special situation of the paint chain in which raw materials that are not activiely used are not necessarily dropped but are rather kept passively in stock for a while to be available for formulations for a longer time.

- Personnel resources are greater for product safety management. The number of new raw materials and the corresponding time and effort to evaluate them are just as high as in the paint chain.
- The interaction with developments in applications engineering tends to be lower among cleaning product manufacturers. However, there are subareas where for example there is a high degree of integration in automatic manufacturing chains for surface-processing metal parts.
- Exportation to markets outside Europe is less important to European manufacturers of cleaning products than to paint manufacturers. That is, there is less competition with formulators who produce outside of the REACH system.
- In a section of the supply chain that ends in the market for household cleaning products, the following facts make things easier:
  - the share of raw materials costs compared to overall production costs is less for formulators (due among other things to the major expense of packaging);
  - there are fewer formulations and related snow-balling effects from the discontinuation of (raw) materials under REACH; and
  - the raw materials tend to be at a higher volume.

However in many respects, REACH poses greater demands on the cleaning product chain than the paint chain. This is for example the case in regard to low market prices and margins for surfactants that raise the relative significance of registration costs. In addition, the resources for innovation and hence the adaptability of the cleaning product chain is lower than in the paint chain measured by R&D as a percentage of sales.

There are nevertheless many commonalities between the supply chains despite the different underlying conditions. The following serve as examples:

- The percentage of hazardous substances among the formulation components is high, hence exposure scenarios and risk evaluations are frequently required;
- In instances where substance manufacturers decide not to register, economic reasons are largely responsible, and production safety has a lesser influence. The formation of consortia is not a universal solution in every critical area where the relationship of registration costs to potential profit is unfavorable. The ability to pass on registration costs appears limited by insufficient user appreciation and readiness to pay for improved safety datasheets and product information. On the other hand, the costs of paints and cleaning agents only represent a small portion of user production costs.
- A reduced selection of substances and greater search for substances with an appropriate identified use and corresponding exposure scenarios can lengthen the development time of formulations under REACH.

- At present, there is not much development of new substances. That is, existing substances that will be discontinued cannot be easily replaced by new substances.

These facts illustrate the necessity of implementing the minimum scenario of the EU Commission, maximizing the risk of forgoing registration costs, and appropriately expanding the definition of applications and exposure scenarios. In regard to the latter, formulators have a broad knowledge of applications in both supply chains that can be exploited.

It has been shown that no sound quantitative estimations of substance discontinuation can be made for the supply chain as a whole for both paints and cleaning substances given the paucity of data on value-chain-relevant substances, the number of their manufacturers and amounts produced. The recommendation to be drawn from both supply chain analyses is therefore to take a chain-specific inventory of substances requiring registration. This would allow substance manufacturers to identify the use of their paints and cleaning agents from the beginning when registering. In addition, the actual cost burden would be estimable on the level of the supply chain.

Finally, comparing the competitive situation of already-registered substances with unregistered substances during the REACH phase-in period in both supply chains reveals that manufacturers should be further stimulated to jointly register a consolidated substance data set.

These commonalities are also based on the suggestions in Chapter VIII for improving REACH's cost/benefit ratio.

VIII Conclusions

VIII.1 The context of the study

The present study is based on two assumptions: 1. The REACH system will be implemented in the European Union. 2. ***How*** this happens will continue to be a hot topic and the subject of much development. This development work will take place in a number of current European processes which include

- the development of EU guidelines within the REACH Implementation Project (RIP),
- the proposals by the ad-hoc working party on chemicals from the member states for modifications to the draft regulation,
- practical experience with REACH mechanisms in the SPORT initiative[1],
- developing a better understanding of the chain of effects triggered by REACH on the market by the stakeholder workgroup “Further Work on Impact Assessment” under the direction of the DGs Environment and Enterprise.

In the context of these work processes, the results of the present study aim to contribute to a better understanding of the mechanisms affecting the relation between the benefits and costs of the REACH system. The findings and conclusions are summarized by topic as in Chapter II. Then, proposals for the optimization of the REACH system are presented and areas that require further research are discussed.

VIII.2 Results and conclusions

VIII.2.1 The amount of direct registration costs and influences

The **design and concretization of the REACH rules** have only just started especially with regard to the recognition of existing data, waiving tests in the case of no relevant exposure, and defining exposure scenarios. This means that the cost-determining factors are able to be identified, but only roughly quantified. The flexibility demanded in Annexes I, V and IX of the draft regulation means that various scenarios (cf. Chapter III) had to be used for cost estimates. Here, it is clear that the maximum and minimum variants of the cost scenarios vary greatly. In the light of this situation, the conclusions on potential costs are limited to the following:

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1 Strategic Partnership on REACH Testing. A management business game on the registration and evaluation of 9 substances based on a strategic partnership between the EU Commission, various member states and industry:

(1) The essential cost-determining factors can be identified and designed in the ongoing development process: rules for the recognition of existing data, analogous treatment, QSARs, and group assessment; rules for exposure-based exemption from standard test requirements in Annex VI; the design of instruments for assessing exposure.

(2) The registration costs for phase-in substances depend on which information from the substance manufacturer is missing and which kinds of risks the intended application of the substance involves. In its estimates, the JRC has already taken into account the voluntary VCI obligations in place for the provision of a minimum of information for each substance > 1 t/y in Germany (the data should thus be available) and the data that many substance manufacturers already have about the potential subacute or chronic-toxic effects of their substances.

(3) The Commission's cost estimates are based on relatively optimistic assumptions about the long-term applicability of validated, non-test-based methods of substance analysis. This estimation is plausible: until the registration of substances with a market volume < 100 t/y begins (2012 to 2017), the development of inexpensive, valid techniques to predict substance properties (without conducting animal tests) must be stepped up.

(4) Those who are obliged to register are not able to influence a certain share of the registration costs, for instance by designing their products and marketing strategies to minimize risks. This pool of costs may lead to the withdrawal of such substances from the market, especially those < 100 t/a due to costs.

(5) The registrant companies can resort to different strategies to determine which information gaps can be closed at what cost and at what **time** between 2004 and 2017.

(6) The limited data meant that the **registration costs** could only be estimated in a few cases based on scenarios for three companies in the supply chain analyses. The specific registration costs per kg were compared to the current market prices of the substances investigated. Here, the registration costs were interpreted as an "investment" in the right to continue to market the substance. The payback times for the EU Commission's mean cost scenarios will very probably cause companies to remove certain substances from their portfolio.

(7) The theoretical potential of **creating a consortium** depends mainly on how many manufacturers and importers produce identical substances. The situation of the three companies investigated here differed: the surfactant manufacturer could have found a consortium partner for some of its substances, but not for the others. But even if costs were shared, registration would not have paid for itself for a number of substances in its portfolio. The additive manufacturer in the paint chain did not have any strategy to lower costs, partly to protect his expertise and partly due to a lack of consortium candidates. The pigment manufacturer could have entered a consortium, but such cooperation would lead to competitive difficulties.

(8) The **possibility of sharing costs** also depends on the extent to which related substances (or mixtures with certain substance distributions) can be assessed as a group. Here, the modes of action of these substances have to be well understood. To the extent that collaboration in the consortium mainly concerns the chemical-physical and (eco-)toxicological properties of the effects of the substances, antitrust laws and expertise protection do not represent significant obstacles to collaboration.

VIII.2.2 The potential benefits for chemicals safety

Certain potential benefits in the registration system and REACH's information mechanisms for specific chains were derived from the analysis of documents in Chapter IV and partially empirically tested in the supply chains analysis. As a result, the following potential benefits were detected:

(1) The REACH system will significantly improve the information basis for the health and environmental properties of substances not previously judged to be dangerous as a legally binding catalogue of information requirements will be introduced to the market. The formulator and downstream users can thus better assess the properties of the raw materials they use and document the safety of these substances. The companies are thus better protected against risks of reputation losses and liability.

(2) The current competitive advantage for substances whose danger cannot be assessed based on the data available will be eradicated. The risk-relevant properties of raw materials are comparable thanks to the obligatory set of basic data in the REACH system. REACH will mean that companies would no longer be able to enjoy a market advantage from not having to label hazards because the information is not available or was not collected (as is the case under the current system). At the same time, the authorities will have to enforce this system in the traditional manner.

(3) According to the knowledge gained from the analysis of supply chains, companies do not expect any willingness to pay higher prices for "safe products" that have good REACH documentation. In addition, the mandatory documentation will apply equally to everyone on the European market, thus limiting any adverse effects on global competition.

(4) REACH will introduce a common system for the systematic, stepped evaluation of existing data stock and the generation of additional information needed on substance properties and exposure patterns. The multi-stage, iterative evaluation process in Annex I, the standard information requirements in Annexes V to VIII, and the possibility of using other kinds of information instead of new tests (Annex IX) make the system flexible. The current information gaps regarding existing substances can thus be closed in a cost-effective, harmonized manner. However, some of the necessary instruments for the implementation of the concept are still

missing. In addition, working with flexible information requirements in the new relegation of competences between authorities and industry requires a process in which the rules of the new system are jointly concretized and practised (see RIP and SPORT).

(5) The substance manufacturer's estimation of exposures for the application of substances and the description of the practicable, safe application conditions are prerequisites for marketing a substance. The substance manufacturer can thus support formulators and users – especially small and medium-sized enterprises – in assessing potential dangers (risk assessment) and product safety.

(6) In addition, a mechanism is put into place that forces substance users to decide whether they want to agree with the substance manufacturer on the conditions for safe application or whether they want to assume responsibility for the exposure and risk assessment themselves. This mechanism clearly demarcates responsibilities. Hence, the system provides the first European management standard for information about product safety and responsibility across chains; furthermore, the standard provides incentives for the transfer of information from substance users to substance manufacturers. Chapter IV explained why the EU safety data sheets / TRGS 220 were not able to do that.

(7) The interaction of chemical law and substance-based health and environmental protection has already become too complex for small and medium-sized enterprises to manage. If the information and evaluation processes cannot be simplified in the course of implementing REACH, the already existing implementation deficit will only increase. In other words, business practitioners and researchers have to work together to develop the implementation instruments for the specifications of the REACH regulation. This may be possible in the RIP process, for example. The instruments already implemented and those to be implemented will have to be used as much as possible. At the same time, the member states should systematically and incrementally eliminate substance-specific duplicate rules between REACH and current legal requirements for health and environmental protection.

(8) Chapter IV investigated whether and how the REACH system could contribute to preventing costs due to chemical damage based on various historic and current cases. The analysis produced the following insights:

- REACH does not help to detect new impact mechanisms of substances as the information requirements in Annexes V to VIII only contain standard end products. In other words, even after the REACH system has been introduced, there will be "surprises" in terms of the effects of substances. Example: the destruction of the ozone layer by CFCs was first discovered in the early 1970s.
- REACH will not be able to reduce the health and environmental damage caused if the available information is ignored and laws are not enforced any more than current legal requirements can. For example, skin protection is not always used sufficiently when handling chemicals at the workplace.

- REACH can promote the systematic identification of substances that harm the skin and thus help prevent skin damage at the workplace and in private life.
- The greater importance of the assessment of exposures in the REACH system and the definition of safer application fields and conditions improves environmental and health protection with regard to substances whose effects are known to be harmful.
- In the documented cases, the **estimated** amount of the costs of damage per inhabitant is 0.5 to 5 EUR per year. The extent to which REACH could prevent costs in current cases cannot be quantified because REACH can only affect some of the causes of the damage. In the historic cases (CFCs and PCBs), REACH would not affect costs.

VIII.2.3 Innovation incentives and obstacles

In the supply chains investigated, the number of new substance registrations in the past was very low. It will not be possible to compensate for any withdrawn existing substances. While REACH will lower the requirements - and hence the registration costs - for the development and product release of existing substances < 10 t/y, substance manufacturers in both supply chains find these reductions to be ineffective as they do not apply to the range 10 > t/y.

Among other things, REACH aims to provide greater transparency of exposure patterns. Substance manufacturers need information about the specific application for a substance and the amounts used in order to come up with practical measures for risk management. Both kinds of information simultaneously represent market knowledge that generally touches a company's economic or technical expertise for innovations. In both of the supply chains studied, technical, customer-oriented application knowledge has been the basis for innovations of new substances and preparations. Formulators have the most application knowledge. REACH will not significantly improve their knowledge about customers' needs to solve problems (minor effect on innovations). However, substance manufacturers may derive innovation incentives from the in-flow of application knowledge to the extent that protecting the expertise of formulators permits.

In turn, formulators are concerned that REACH will cause a loss of expertise. One solution to the conflict in the goals mentioned above may be the development of categories to describe substance applications and exposure scenarios for specific issues in the paint / detergent chains. This approach could solve the conflict between protecting know-how and sufficient concretization of safe application conditions. REACH already contains such options. They include: 1) the possibility of defining narrow or broad exposure scenarios; 2) the possibility of deciding at the user level whether the supplier is

to be informed of applications or whether assessment will be done in-house; and 3) the general confidentiality of application details, recipe details and customer relations (cf. Article 116).

Wherever dangerous substances are used for certain functionalities, conditions for “safe application” can be integrated in the design of products and processes. Here, the REACH system offers an opportunity to set reasonable limits for the safe application of even hazardous substances and to document and justify these reasons. REACH opens up the potential for the innovation of a more integrated evaluation of chemical products, especially where there are environmental and health reasons (such as resource efficiency or allergy prevention) for using substances with well characterized, dangerous properties.

VIII.2.4 Rationalizing substance portfolios

A substance manufacturer decides to register a substance based on economic considerations and strategic aspects, such as customer retention from a broad product range. The three substance manufacturers surveyed judged the situation differently.

- The surfactant manufacturer has already checked his portfolio and concludes that under REACH he would remove about 40 % of his substances from the market. In 5 % - 10 % of the cases, the substance would be withdrawn; in other cases, production would be concentrated among other manufacturers.
- The pigment manufacturer had not yet conducted an analysis on the continued marketing of his products under REACH conditions.
- The additive manufacturer expects to be able to continue to offer his customers all his current functionalities.

Registration for the REACH process will reduce the number of existing substances and applications per existing substance on the market. At the same time, the diversity of the available functionalities will not decrease to the same extent as the market usually offers several alternatives for the functionality of a substance. In addition, manufacturers try to offer their customers an alternative for each functionality.

The advisory committee pointed out repeatedly that REACH could have effects on industrial chemicals comparable to the effects of the EU biocide directive on the biocide market. A cursory comparison (see Chapter II.3.3) of the two regulation areas, however, revealed differences that make similar market streamlining due to REACH improbable. Above all, this concerns the costs for an average biocide authorization dossier (> 1.4 to 4 million EUR) and the current market price of substances previously categorized as biocide (compared to the market prices of industrial chemicals).

When “rationalization” closely correlates with the various environmental and health risks for the application of the substance, REACH will have attained an essential goal during the registration phase, and companies will simultaneously tighten up their portfolios. If, however, selection is purely cost-driven and due to data requirements, REACH will have missed an essential target, and the innovation basis for formulators will also be weakened (cf. section VIII.1 on costs). The ratio of the risk-driven rationalization of substances to the risk-independent rationalization of substances depends on the basic features of the system (cf. proposals under VIII.3).

VIII.2.5 The consequences of the rationalization of substances for formulators and users

If a substance or functionality is withdrawn, formulators and users of preparations will have to adapt to this change. In the empirical analysis of supply chains, indicators of the current adaptation quota for formulators were determined and extrapolated for the forced withdrawal of substances. If the previous withdrawal rate of raw materials at the level of formulators were to continue, 5 - 7 % of the raw material portfolio for paints and 10 - 20 % of the ingredients in detergents / cleaners would be withdrawn in 10 years. The overall rate of fluctuation for raw materials (including the self-determined exchange of raw materials) is generally much higher.

In addition, the costs and time required by the formulators in the past to redesign products and processes in order to replace substances were quantified. The expenses range widely from 10,000 EUR to 150,000 EUR per case (cf. Sections V.4.5 and VI.4.5). In the light of the large number of raw materials and recipes, especially in the paint chain, a REACH-induced withdrawal of a substance above the current base level would cause the formulators considerable follow-up costs.

Formulators also provided information about the expenses for updating safety data sheets due to the re-categorization of certain ingredients. These costs included cases in which substances (corrosion protection pigments) had to be replaced several times because the substitute was eventually categorized as hazardous. If the REACH system managed to create a more robust information system for the raw materials generally used for paints, detergents and cleaners, the expenses connected with repeated adaptation to new substance information would **then** be lower. The substances with the same functionality could then be assessed comparatively for the environment and health on the basis of standard information specifications. However, this benefit of REACH will only occur after the phase-in of existing substances has been completed and only if various substance manufacturers register the same substance (in comparable purity) only once (cf. the proposal in Section VIII.3.1). The long-term valuation of

substances according to social aspects will, however, continue to take place, requiring adaptation of the companies even if all the substances are registered with a standard set of information.

If the recipe for a preparation changes, users of that preparation will have to make various adaptations starting with their ongoing production. The new preparation will have to undergo process-engineering application tests, and the results of the processes will have to be tested (quality of the paint surface, cleanliness of the object cleaned, etc.). This may lead to production delays. For detergents and cleaners, the technical integration and dependence between the chemicals needed and the production process is low in many applications. Therefore, the companies surveyed sometimes forego process-engineering tests in order to focus on less complicated test results. Where application tests are conducted, they are shorter than the tests of new paint recipes.

VIII.2.6 Passing on costs

If material prices increase, formulators and users of preparations have to adjust to these changes. All of the companies surveyed find it improbable that registration costs could be passed on as higher prices to manufacturers of preparations and from there, to users of the preparations. From the perspective of formulators, the experience gained from price negotiations with major buyers (paint supply chain) and vendors (detergents and cleaners) and the general possibility of moving overseas - such as in the automotive or electronics industry - in the course of globalization both speak against optimistic assumptions about passing on costs. The paint chain also has experience with pricing for environmentally-friendly paints or especially environmentally-friendly raw materials (pharmaceuticals). Higher prices cannot be set for such qualities. At the same time, companies have experienced that certain raw materials for paints, such as organic pigments from Asia, are imported at lower prices and that European users rarely pay attention to the higher pollutant content of such goods. While the import rules in the REACH system may provide a more even playing field in Europe because the importers of substances have to document the degree of impurity for registration on the European market (see Annex IV of the draft resolution), REACH cannot impose such rules on the global market. In other words, market actors feel that they will not be able to pass on their costs to consumers in most cases.

On the other hand, certain paint and additive suppliers also have greater customer retention thanks to customized product differentiation. In addition, the design of paint products closely interacts with the user's process engineering. The contracted research institutions can imagine that the one-off registration costs for technically essential sub-

stances might be strategically shared in such cases. The pessimistic assessment of detergent and cleaner manufacturers is qualified by the fact that many of the companies surveyed were able to pass on additional expenses via price increases in the past, though not always completely or immediately.

In addition, the main components of paints and cleaners are generally substances traded in large volumes or (in the case of paints) polymers, which are exempt from the REACH requirements. Hence, the pressure to pass on costs is low. Preparations often only contain low concentrations of small-volume functional additives (< 5 %) so that the registration of these substances will only make up a small part of the cost of raw materials for the paint or cleaner. As with the share of chemicals in general, the share of the costs for paints or detergents / cleaners in the production costs of users is relatively low in the industries studied (1 % or less, with the exception of the semiconductor industry), which suggests that higher prices for chemicals could be absorbed to some extent.

VIII.2.7 International competitiveness

The production of substances and preparations already generally follows global consumer markets and production sites of industrial customers. Such industrial customers include automobile manufacturers, manufacturers of appliances, and manufacturers of tubes. In turn, these industries follow their markets and/or the global disparity in the cost of labour and/or raw materials and/or the global gap in employee knowledge and qualifications. Given the current globalization trends, it is difficult to empirically determine the additional effects of REACH for the future. This study focuses more on tracing a few principle mechanisms for the stages of the supply chain under investigation. However, the study can only roughly estimate their importance in actual future developments.

To the extent that raw materials are already imported from outside the EU today, REACH will lead to a harmonization of the documentation requirements for pollutants and tests for both EU and non-EU suppliers. Here, it is possible that European substance manufacturers with good safety documentation will improve their competitiveness and/or lose their previous disadvantage to imported goods.

At the same time, the registration mechanisms in the current draft regulation and the amount of the registration costs in the Commission's mean scenario represent a relevant technical and economic obstacle for importers of chemicals. On the one hand, in-house registration of all components in the imported preparations is not completely feasible technically or in terms of recipe expertise. On the other hand, **importers** have to have much shorter payback periods for one-off or irregular imports than **manufac-**

turers of chemical products. In other words, import traders cannot always afford to register on their own. In Section VIII.3.1, possible solutions are discussed.

Manufacturers of industrial paints, including medium-sized companies, are working globally to an increasing extent. In the process, production stages based heavily on research (such as R&D or the production of special paint components like additives) remain in Europe for the time being, while formulators of paint products and customer service may be moved closer to the customer. This trend has nothing to do with REACH.

In the detergent and cleaning products chain, markets outside Europe have played a very minor role for medium-sized formulators. In contrast, the major companies among the substance manufacturers and formulators generally already supply to markets outside Europe from production lines located outside Europe. If REACH results in production shifts to outside the EU on the downstream level of the supply chain, these markets will be able to be served from existing foreign facilities.

Among the customers of the preparation manufacturers surveyed are companies which release certain paint or cleaner products globally for all locations (especially for technically demanding products). In such cases, the quality specifications fulfil the standards for European production plants. In other words, component manufacturers outside Europe that do not have to fulfil REACH may not be able to take (full) advantage of their location. In addition, the share of pure chemicals costs in the cost of one-off production for paint and cleaner systems developed especially for complex industrial applications (such as automated spray coating systems or automated cleaning systems for metal processing) is relatively low (1 % or lower, with the exception of the semiconductor industry). In other words, moving industrial production abroad just to avoid the REACH registration costs will hardly bring any advantages in these innovative areas.

Overall, the contracted research institutions find that all cost increases within the EU, regardless of the reason, have the potential to reinforce the trend to move abroad unless these cost increases directly or indirectly increase innovation, revenue, and/or profits. This empirical study found that some feared that REACH would only strengthen this trend. However, no concrete connection to REACH could be identified as a **decisive** driver for moves abroad. It must be kept in mind here that environmental protection and health standards differ in many respects from the EU standard for non-European producers. REACH did not cause this situation; it is an integral part of European environmental and health policy.

In accordance with the obligations undertaken at the *World Summit on Sustainable Development* in 2002 in Johannesburg, by 2020 chemicals will have to be produced

and used in environmentally-friendly ways that do not pose health risks (United Nations 2003). That means that all leading, global economic spheres will have to develop management systems to ensure product safety for specific substances in a system of globalized supply chains and capital flows. If the basic features of the REACH system can be implemented in Europe, European companies could benefit from being first movers on the world market.

VIII.2.8 Pressure and capacity to adapt

The pressure and capacity to adapt were used as higher evaluation categories for assessing the empirical findings. The costs and other expenses for REACH registration exert adaptation pressure on importers and substance manufacturers. The resulting changes and rationalization of the substance portfolios of manufacturers and importers in turn exert pressure on formulators and users to adapt. They also all have a certain capacity to react. The comparison between the two supply chains based on indicators led to the conclusion that the pressure to adapt to REACH will be greater in the paint industry, which will also have greater capacity to do so (cf. Chapter VII). The pressure and capacity to adapt cannot, however, be quantified and "offset" against each other (no net balance). It remains to be seen how competition will change when the current capacity - such as chosing which raw materials to exchange - is devoted to adapting to REACH requirements. After all, the REACH-induced withdrawal of substances will temporarily reduce the possibilities of reacting to customer wishes.

To summarize, this empirical study identified 5 areas where the basic features of the REACH system could affect the pressure and capacity of companies to adapt (cf. Chapter V.7 and VI.7). The proposals made in Chapter VIII.3 concern the problems described here:

(1) The direct costs of registration for substance manufacturers are critical for additives, pigments, and surfactants; in some cases, registration may become too expensive. Substance manufacturers would not be able to avoid a relatively large share of these costs as they are largely due to test requirements not related to risk. In other words, the current draft regulation puts pressure on substance manufacturers to adapt, and these companies cannot react to this pressure by using less dangerous substances or preventing exposures in applications. Chapter VIII.3.2 thus makes proposals on how to increase the connection between registration costs and product safety in the REACH system.

(2) Actors in both supply chains already deal constantly with the exchange of raw materials, whether by choice or by obligation. Hence, the REACH-induced rationalization effects on substances should be able to be managed on the market up to a certain level. However, where REACH induces the withdrawal of a substance or functionality that exceeds the capacity to adapt, the biggest "losers" will be

companies with a broad range of special products. Therefore, some proposals are made in Chapter VIII.3.2 about which strategy would reduce the withdrawal of substances in the volume range typical for specialized chemicals.

(3) During the phase-in period of REACH, there will be competition between substances already registered and those not yet registered; this situation will affect prices and future availability, for example. As long as a substance has not yet been registered, formulators will not be able to rely on it being available in the future and will not know its price. If formulators replace a substance with one whose fate has not yet been determined, they will face follow-up costs if the raw material is withdrawn or becomes more expensive. The situation of users is similar: they may have tailored their processes to a preparation whose components have not all been registered. In other words, the pressure on formulators decreases if the REACH system can motivate most manufacturers of a substance to register at the same time using a consolidated set of data for the substance. Proposals are thus tested in Chapter VIII.3.1 which aim to motivate the manufacturers of a substance to create a joint data record on the environmental and health properties of the substance.

(4) This empirical study finds that the formulators currently do not have management capacities suitable for translating the future substance information from manufacturers into decisions about the selection of raw materials and information for customers. The same is true for translating the application knowledge of formulators into exposure information for substance manufacturers. The current staff capacity for evaluating safety data sheets from upstream suppliers and the creation and updating of in-house safety data sheets is already very limited.

As most medium-sized formulators cannot simply expand their staff capacity, the organization and use of existing knowledge must be improved for the efficient evaluation of a substance's safety (such as saving test costs by means of precise exposure characterizations). Adaptation capacity will depend on whether substance manufacturers, formulators and users of formulations can find a common "risk language" and whether they are willing and able to share the knowledge they already have. In other words, the introduction of REACH will only work if

- the definition of exposure scenarios and their counter-checks is standardized;
- the quality of information in the substance-based safety data sheets is improved so that they make work easier for the responsible staff at the formulators;
- the communication instruments in the supply chain for all three levels of actors consistently use the "same language".

Special attention should thus be paid to the degree of detail in the definition of uses and exposure scenarios in the further implementation of REACH. Different ideas about how this should be done are currently at the bottom of many negative attitudes concerning REACH. The goal should be to: 1) use the available application knowledge of formulators; 2) distribute the burden of chemical safety reports for individual applications appropriately between substance manufacturers

and formulators; and 3) ensure that formulators have sufficient protection without blocking the flow of general application knowledge too much. Here, formulators and their associations in particular seem to have the knowledge needed to develop simple, practicable systems.

All three key actors in the supply chain are included in REACH for the assessment of application risk and the description of safe application conditions. Better knowledge management may relieve some of the burden on all three actors. The contribution of each individual actor in the joint evaluation has to be clearly assigned in each chain. For instance, a substance manufacturer cannot define every detail of the application conditions, but can do so for certain types of necessary risk management measures or applications to be avoided. Proposals for designing the exposure assessment in the REACH system are made in Chapter VIII.3.3.

(5) No inventory of registrant substances has been made in either supply chain up to now. In addition, formulators and users face severe uncertainty about the costs to expect and the availability of raw materials. These uncertainties could be overcome if trade associations or other neutral third parties determined an anonymous chain inventory based on CAS numbers (such as the merger of the inventories of two companies) before REACH is implemented. On the one hand, substance manufacturers could cover “safe applications“ from the very beginning for registration; on the other, the actual cost burden would be predictable at the level of the supply chain (cf. Section VIII.3.5).

VIII.3 Proposals for the optimization of the REACH system

Insights into the effects of REACH on the realization of potential costs and benefits have been gained from the document analysis, interviews in the supply chains, and discussions in the advisory committee. Some of the following proposals were newly derived from these insights. Other proposals have already been discussed in the EU Council’s REACH workgroup and are followed up here as possible solutions. The proposals are made at different levels: some concern changes in the regulation itself; others, the development of guidelines and similar instruments for the implementation of REACH.

VIII.3.1 One registration per substance

One possible way to reduce specific registration costs is to distribute the costs of characterizing substance properties across all manufacturers / importers of the substance. Provided that manufacturers are able to unambiguously assign the identity of their substances (with consideration of impurities), a distinction can be made between three cases:

- There is no other manufacturer of the substance. Costs cannot even be shared theoretically. This may be the case with paint additives for special applications.
- Two or more manufacturers produce the same volume of the substance; i. e. competitors would then simultaneously be registrants.
- Different competitors make the substance in different volume ranges. Some manufacturers would then have to register 5 or 8 years earlier than others according to the regulation currently proposed.

The regulation currently proposed offers a platform - mandatory pre-registration and the establishment of *Substance Information Exchange Forums* (SIEF) (Articles 26 and 27) - for the common use of existing data from tests on vertebrates and other studies and the exchange of information in preparation for new studies required, for instance when one manufacturer is to undergo the study on behalf of everyone. This cooperation is purely voluntary. The Agency will only make the results available to later registrants if some of the costs are covered in cases where studies on vertebrates were conducted for registration. A refusal to make existing studies on vertebrates available for compensation is subject to sanctions. However, the regulation as currently proposed has the following weaknesses in terms of the problem discussed here:

- Dossiers of various manufacturers may contain different information about the chemical-physical and (eco)-toxicological properties (including classification) of a single substance. The empirical study also discussed the different classification of a single substance by different manufacturers. This problem already exists in the current legislation, although the reduction of harmonized EU classification of CMR cases under REACH might exacerbate the problem.
- Checking the various dossiers for the same substances also adds to the paperwork authorities have to perform.
- Manufacturers and importers of substances with small volumes can only use data from studies not based on vertebrates in the first registration phase if manufacturers of larger volumes give their consent.
- Though manufacturers and importers of small volumes of substances may take part in SIEF in the first registration phase, they do not have the right to take part in cost operations and cost-sharing agreements. Later registration would, however, mean smaller market shares as users will prefer the delivery reliability of a provider already registered.
- Importers of substances react to short-term supply and demand on the market. It does not pay for them to have their own registration dossiers on stock. The regulation currently proposed does not provide any means of “buying into” the data stock already registered.

A joint proposal by Hungary and the United Kingdom in the Council's workgroup aims to modify the proposed regulation so that only one dossier per substance is created (OSOR = *one substance - one registration*). The following changes are planned to this end:

- Pre-registration for the first registration phase (HPVs and CMRs) takes place 6 months after the regulation takes effect. The Agency shall publish a list of the pre-registered substances. Manufacturers of small volumes of the substances listed will then also be able to pre-register and take part in SIEFs. There is only a general duty to make one's own data on substance properties (not just studies of vertebrates) accessible to others who cover a share of the costs.
- One or a few "lead registrants" should hand in information about substance properties and test proposals to the Agency on behalf of other substance manufacturers. Each manufacturer will, however, submit independent information on the identity of substances, their manufacture, and applications. The Agency then compiles a data record using all these information sources.
- In accordance with Annexes V and VI, only one manufacturer in the SIEF shall conduct tests on behalf of all the others. In accordance with Annexes VII and VIII, the proposed tests for exposure shall specify which company conducts the test.
- The allocation of costs shall be regulated among the actors flexibly using a guideline (outside the regulation). An ombudsman shall be available to settle disputes concerning the distribution of costs in SIEF.

The main discussion points between member states regarding this proposal relate to the question of whether an obligation to share data on studies that did not use vertebrates is legally enforceable and whether one pre-registration phase for all substances is better than various stages. In addition, opinions vary as to whether fixed rules on cost sharing should be specified in the regulation or whether this should be done between market players based on an EU guideline.

The OSOR proposal would mean that manufacturers and importers of small volumes would take part in the information exchange in the first round of registration and that the existing data stock would be available to them at a charge. In addition, if necessary, the information requirements in Annexes V and VI would only have to be fulfilled once for all manufacturers. Manufacturers of small market volumes and importers of fluctuating volumes could "buy into" registration (even before they actually have to register).

Information on manufacturing processes and applications is not exchanged in SIEF under the Commission's current proposals or in the OSOR approach. Wherever the identity of a substance (such as the degree of impurity) or a manufacturer's registered applications do not match the common data record for the substance, the Agency or the member states would conduct plausibility tests and make the necessary correc-

tions. The OSOR proposal also provides for different tests on applications or exposures > 100 t/y by manufacturer.

In the supply chains studied, such a regulation can offer advantages when substances widely used by various manufacturers or importers are produced in different volume ranges (such as surfactants). Here, a substance's share of registration costs is proportional to the number of manufacturers, while the exposure share of costs is not affected. It must also be kept in mind that substance manufacturers incur interaction costs in OSOR that will reduce the potential cost savings. Here, rules are needed for negotiations between companies[2]. The RIP process[3] and the SPORT initiative[4] are expected to provide further insights.

VIII.3.2 Knowledge management in REACH based on Annexes I-IX

In the REACH system, test costs are incurred if the standard information required about the properties of a substance is not available or not of sufficient quality. Some of the test costs in the REACH system are incurred when screening tests - whether old or recent - indicate there may be dangers (hazardous properties suspected) and the manufacturer does not want to withdraw the substance. In such cases, the costs in the REACH system depend on the past and future behaviour of the registrant. Chapter III presents some examples of such cases.

Other test costs are related to the requirement to have certain basic information for each substance regardless of the known properties or the expected exposures. The behaviour of registrants cannot really affect the test costs not based on suspicion or risk. The cost-intensive end points of the REACH system in the range of 1-100 t/y include tests for subacute toxicity (Annex VI), the screening test for reproduction toxicity (Annex VI), the cytogenesis study on mammalian cells (Annex VI), the skin sensitization test (Annex V), and the hydrolysis test (Annex V). Two factors make these areas cost-dominant: the expected applicability of QSARs as a secondary method is estimated to be low in JRC (2003) for certain end points (skin sensitization and hydrolysis); and the information requirements not related to risk in Annexes V and VI (even when information not based on tests is used) head the relatively high specific registration costs for small volumes under the EU Commission's current cost assumptions. To pre-

2 However, the previous estimates of the interaction expenses in RPA (2003d) are from the ICCA programme and cannot be transferred completely to REACH (no regulatory framework, no standardized platform for the organization of the joint use of existing data).

3 REACH Implementation Projects

4 SPORT = Strategic Partnership on REACH Testing (cf. Section I.2.2)

vent large numbers of substances from being withdrawn regardless of risks, the information requirements must be related more closely to risk and to lower test costs in general (for example). Such examples include:

- The option of doing without tests for reproduction and development toxicity for substances < 100 t/y if there are exposure assessments available and
- the development and use of techniques not based on tests to forecast the potential to cause skin allergies.

The basic possibility to reduce the test requirements for toxicity if there is no “relevant” exposure (6.6.1 and 6.7.1) in the range 10-100 t/y has already been listed in column 2 of Annex VI. However, there is no standardized way for registered companies to exercise this option. In specifying the concept for the categories of usage and exposures (cf. the comments of the German Assessment Authorities, *Bewertungsbehörden* 2004), the prerequisites should be defined for cases in which the information on reproduction and development toxicity can be dropped.

In contrast, the cost estimates of the Commission are based on the assumption that this information is necessary for 90 % of all substances in this volume range (JRC 2003), while at the same time QSARs and analogous conclusions would make most tests redundant. Thus, the question is which of the two strategies would be more efficient in the long term to avoid tests for substances < 100 t/y:

- More intense research to support QSARs scientifically and to standardize them (and other prediction techniques), or
- more intense research on the further development of standardized exposure models.

Both options could benefit from a temporarily restricted use of QSARs and waiver options for exposures in the first registration phase for high-tonnage substances to quickly improve the data basis for the validation of the respective models.

For substances < 10 t/a, the current draft regulation does not require an exposure assessment or an indication of acute or chronic human toxicity and biodegradability. In other words, the REACH Annexes do not currently constitute a basis for the systematic identification of risks including categorization. The benefits of the REACH system could be increased without an additional significant burden if the following modifications were made:

- the minimum data required (Annex V) should also contain end points on human toxicity (acute toxicity) and biodegradability. Neither end point would entail additional costs for companies that have implemented the VCI’s voluntary agreement of 1997.

- For substances between 1-10 t/y, a simplified exposure estimate also has to be performed as the substance data in the minimum data do not nearly suffice to classify the substances in terms of toxic properties in the event of long-term or repeated exposure. To identify a risk potential and derive the appropriate risk management measures, exposure-relevant substance applications should be identified during registration.

Annexes I to IX in the REACH regulation can be interpreted as a basis for efficient, effective knowledge management so that EU market actors can ensure product safety for specific substances. From this perspective, there is another strategic option to the detailed fine tuning of Annexes I to IX (see above): the reduction of Annexes V to IX to the standard information requirements for each volume range and the listing of all justifications for exemption from certain tests (the use of existing data, QSARs, analogous conclusions, group evaluation, waiving of standard information requirements based on exposure) in a guidance document. The advantage of this is that the means of procuring information and the case-by-case exemption of manufacturers from the duty to provide certain information can be described as “soft” rules that are best developed outside the regulation text. The drawback is that the classical legal instruments for enforcement cannot be used and the system places new demands on the organization, communication, and planning of companies and evaluating authorities.

One final aspect concerns quality assurance. No quality assurance mechanisms have been formulated in the iterative CSA evaluation process. The test of completeness and the dossier evaluation that the authorities conduct do not suffice for the 1-100 t/y range. The test of completeness does not deal with the quality of the information supplied, and the evaluation of some 22,500 dossiers is not feasible - except in the very long term - for the member states. The regulation should thus contain an obligation to use suitable quality assurance systems when creating CSAs and dossiers.

VIII.3.3 Categories of use and exposure

Chemical products such as paints and detergents / cleaners can be used for all kinds of applications, surfaces, and functions. In addition, preparations differ in terms of the application technique used (immersion, rolling, spraying etc.), and paint products also differ in terms of the base used (powder, water, high solid, UV drying etc.). Users of preparations are companies from different industries, skilled trades, service providers, and private consumers. In other words, the application conditions for the various ingredients in the preparation vary greatly. In addition, many ingredients in paints and cleaners are also used in other products under other conditions. For instance, many paint additives and pigments are also used in plastics and printer inks.

Substance manufacturers will not be able to subject all imaginable conditions to detailed, individual assessments. In addition, this would not be desirable for the following reasons: a description of the safe conditions for use that is too detailed would restrict the necessary flexibility in the application of the substance and be dependent on the comprehensive transfer of (possibly sensitive) application expertise to the substance manufacturer. In addition, substance manufacturers might feel forced to define safe substance applications so narrowly that the burden of assessment would be transferred to the user.

Having a simple indicator of the expected exposure pattern for the intended applications for the substance would also be the key towards better risk control in the phase-in stage of REACH. If each substance were labelled with an exposure indicator for pre-registration, a reference to exposure could be added to the volume-based and CMR-based setting of priorities.

These considerations suggest the necessity of collating applications and types of exposures into case groups that

- share exposure patterns and parameters which determine the type of exposure: the means by which the substance enters the environment, is absorbed by people, the location of exposure, the duration and frequency of the exposure; substance properties that determine exposure, the volume of the substance / its emission factor, the type of use, the value of the expected exposure and protective measures (cf. *Bewertungsbehörden* 2004) and
- allow a clear delineation of the contributions to the safety assessment of substances by actors in the supply chains[5].

The current Annex I to the REACH regulation does not rule out such groupings but also does not offer an approach for a standard system to create case groups that reflect common practice. Without standardization and EU-wide acceptance for a grouping system, it will hardly be possible to promote efficient communication between the market actors. At present, various systems are used to classify application patterns and potential exposures, including:

- the system of industrial and application categories for the notification of new substances (cf. the EU Technical Guidance Document on Risk Assessment);

5 The manufacturer of a surfactant for industrial use, for instance, can provide information about the substance's properties and generally suitable application conditions related to the substance's properties and volumes. The manufacturer does not, however, have any information about the volume of the substance actually used or local water conditions.

- industry's, the OECD's and the EU's emissions scenarios for specific products or processes (for the environment);
- exposure scenarios for consumer protection in the EU's EIS-CHEMRISK project;
- safety measures for types of workplaces and activities in accordance with TRGS 430 (exposure scenarios) and the British COSHH Essentials.

It should thus be possible to further develop the existing systems until REACH takes effect so that they can be used within the REACH system. One can imagine having them connected as EU guidelines or as an annex to the regulation itself.

In a joint evaluation by the German government, VCI, and IGBCE on August 21 2003, it was proposed that an exposure assessment be made based on the ***categories of use and exposure*** in a staged approach to simplify the exposure assessment on various levels. Since then, the German government has also made this proposal to the Council's workgroup. The approach has yet to be made concrete and integrated into the present REACH proposal. In May 2004 (VCI 2004), VCI formulated its ideas and comments, as did the German evaluation authorities in September 2004 (Bewertungsbehörden 2004). Most of the actors surveyed in the present study were of the opinion that exposure categories are necessary to make the REACH system manageable.

VIII.3.4 The development of instruments and methods

The companies surveyed did not see the flexibility in the proposed REACH system for the evaluation of safety (the use of existing information; exposure-based test requirements) as an advantage for the practical realization of the system's goals, but rather as the risk of being subject to different interpretations by various authorities (in the evaluation of dossiers) and market players. In addition, authorities are expected to demand complete data and maximum data quality at all times if the law allows. In turn, the authorities often expect companies to use every loophole available to them in order to save costs.

The instruments required for essential tasks to implement REACH are not yet ready to be used (such as exposure assessment; the integration of risk management in the assessment of chemical safety, and the deployment of sufficiently validated QSARs). Only if the authorities and economic actors work together to come up with practicable solutions do both parties believe that REACH will work. The contracted researchers feel it is important that clear rules be drawn up (decision trees) for the interpretation of flexibility (the use of existing data and QSARs, group assessments, waivers) in this process. Here, not every detail need be specified as companies will need some leeway to conduct evaluations on their own that are tailored to their specific conditions.

The RIP processes should thus begin soon in coordination with the market actors (not only representatives of associations and researchers) and the authorities, and the current status of the process should be communicated in the respective networks. The market actors would provide the enterprise perspective, while the authorities would contribute their experience with risk assessments of substances and their knowledge about data stock and assessment methods. The process should be designed to run parallel to the launch of REACH and use the experience of actors and authorities for an incremental optimization of instruments. In particular, the usefulness of QSARs, analogous conclusions, group assessments, and exposure modelling instead of tests should improve considerably due to the experience gained in the first phase of registration and evaluation (some 5 years after the regulation takes effect).

VIII.3.5 Information about REACH for companies and preparation for REACH

In the interviews, the contracted researchers discovered that formulators and users of formulations in particular need more exact information about REACH requirements relevant for them and their role in the overall system. The following misunderstandings about REACH's requirements were widespread and had to be clarified:

- the REACH system does not require formulators and users of preparations to register unless they directly import substances and preparations from outside the EU.
- Recipes, application details, and manufacturer/customer relations are expressly protected as confidential [Art 116 (2)] and the disclosure rules for dangerous recipe ingredients were adopted in REACH almost wholly in accordance with the Directive on Safety Data Sheets. However, the formulation of Article 30 of the draft regulation (passing on the registration numbers of non-hazardous substances to customers) caused some confusion. There is a need to clarify the draft regulation.
- The REACH system does not impose any rigid data requirements but is flexible, for instance in terms of the breadth of exposure scenarios and information about the health and environmental properties of substances.
- If a substance is to be used for a "non-identified" application that the manufacturer has not evaluated, the formulator of the preparation does not have to hand in its own registration dossier but instead merely inform the Agency of this special application and conduct a safety assessment on its own for this special application.

In addition, the companies surveyed were not sure how the further legislation process was going to proceed, how important the RIP process was here, and how they can prepare for changes due to the REACH system.

The insecurity among the formulators in the supply chains surveyed also stems from the uncertainty about how many substances in the supply chain will actually have to be registered. The relatively large number of “raw materials” is the only figure known, but this cannot be a measure for the individual substances with CAS numbers. In the textile industry, for example, some 7,500 different textile auxiliary preparations are sold in Germany according to the textile auxiliary catalogue (TEGEWA 2004), but these only consist of some 400 to 600 different substances.

In the light of this situation, companies need correct information about REACH for specific actors and assistance in preparing for the system. The state and federal authorities should make sure that neutral information is available to inform companies about what REACH actually demands of them, what work processes and forums are currently taking place to define the REACH system, and how companies can prepare despite all the uncertainties about the final basic features of the system. Here, support is needed from trade and economic associations.

In particular, the identification and quantification of possible economic risks in the various supply chains could be improved if substance manufacturers made inventories of their portfolio for various lines of business and estimate where the relevant information gaps are. Guidelines for small and medium-sized companies can support the estimation of the extent to which a company is affected. An overview of the number of substances that actually need to be registered for special applications in paints and detergents / cleaners or other specific supply chains is best done at the level of formulators on their own initiative. However, independent third parties (contracted, for example, by the trade association) will have to become involved for the consolidation of company data in the inventory of the whole supply chain. The advantage of such an inventory over the currently planned pre-registration of individual substances is that substances can be assigned to certain rough applications, such as “paints, varnishes, and other coatings”. Formulators in a certain supply chain will also be able to make the necessary standard exposure scenarios available quickly. Based on an inventory of substances and suitable standard scenarios, substance manufacturers would be able to cover the main applications of formulators from the outset in their chemicals' safety assessment.

VIII.4 Need for further research

The actors surveyed in this study focused on the supply chain stage of formulators. At the level of users outside the chemicals industry, it was only possible to map the relevant contexts roughly in terms of the actual breadth of this stage of the supply chain. This limits the generalizability of statements made about the stages of the supply chains (cf. Ch. VII). At the same time, the advisory committee had a strong interest in

shedding more light on the situation of users and in making aggregated, quantitative conclusions, such as on international competitiveness (the importance of moving abroad, import trends of products from outside the EU, the development of foreign investment etc.). To this end, another research approach would have to be pursued, one with a degree of aggregation on the sector-specific mesoeconomic level. The basic effects of REACH on the international competitiveness of users identified in this study can only be taken as initial input to such aggregate analyses.

For reasons of simplicity, the present study had to be limited in several respects (cf. Ch. I.6). Hence, no facility suppliers were surveyed, which means that aspects of interdependency between REACH and the development of process techniques for the applications of preparations (coating systems, cleaning systems) could only be addressed from the perspective of chemicals users. For areas of the supply chain with a high degree of process integration, it might be interesting to take a closer look at the roles of all those involved in process development.

Finally, the interfaces between REACH and legal areas outside chemicals legislation were the subject of intense discussions in the advisory committee. The companies surveyed also showed a lot of interest in removing redundancies and contradictions between REACH and the current regulations concerning environmental protection, consumer protection, and occupational safety. In the present study, these issues could only be dealt with cursorily (cf. Section IV.1.2). In the process, various interface aspects were revealed and dealt with at different levels. First of all, the business community and, to some extent, the advisory committee, see the need for REACH and related legal areas to be harmonized and, at the same time, for REACH's complexity to be reduced. Second, policy needs to be integrated in terms of the further interaction of existing legal instruments for substance-based risk management (such as environmental protection for systems and products) and REACH's instruments for the assessment of substance safety over the entire product lifecycle of substances. The design of an incremental integration process would be a joint task for politics, public administration, and the business community.

Further research is also needed on the methodological question of how the additional effect of a new regulation (i. e. additional costs and benefits) can be reliably assessed in a *Regulatory Impact Assessment* against the backdrop of the current, complex set of regulations which have developed over time. The goal here would be to develop methodologically and theoretically sound criteria for a limited selection of rules. As is common in Regulatory Impact Assessments, the present study starts mostly from regulations that the new legislation is to replace (here: various regulations on chemicals) and adds a few additional regulations to them. The criteria for selection may seem plausible

(chemicals legislation and references to the supply chain). However, in view of the actual stock of rules with substance-based requirements, it would be desirable to have criteria which are well-founded and generally recognized and applied.

References

ARGE Planspiel (2003): Erprobung ausgewählter Elemente des REACH-Verfahrens in der Praxis durch Behörden und Firmen im Rahmen eines Planspiels in Nordrhein-Westfalen. Zusammenfassender Projektbericht - Ergebnisteil (Langfassung 22.12.03; http://www.Europa.nrw.de/themen/chemikalienpolitik/index.html)

Armstrong, K. E. (2004): APEC as a driving force for trade and harmonization in the chemical sector - Paper presented at the ChemCon Conference 2004 (International Conference on Chemical Control Regulations), Berlin, May 3 - 7, 2004, Berlin.

Arthur D. Little (Ed.) (2002): Wirtschaftliche Auswirkungen der EU-Stoffpolitik - Bericht zum BDI-Forschungsprojekt, 18. Dezember 2002, Wiesbaden: Arthur D. Little GmbH.

Arthur D. Little (Ed.) (2003a): Economic Effects of the EU Substances Policy - Supplement to the Report on the BDI Research Project of 18th December 2002, dated 31st August 2003, Wiesbaden: Arthur D. Little GmbH.

Arthur D. Little (Ed.) (2003b): Economic Effects of the EU Substances Policy - Second Supplement to the Report on the BDI Research Project of 18th December 2002. Analysis of the Effects of the legislation draft September 2003, Wiesbaden: Arthur D. Little GmbH.

Arthur D. Little (Ed.) (2004): Economic Effects of the EU Substances Policy - Supplement to the Report on the BDI Research Project of 18th December 2002. Analysis of the Effects of the legislation proposal October 2003, Wiesbaden: Arthur D. Little GmbH.

Barker, C. A. (2004): Ökonomische Effekte aus einem besseren Informationsfluss entlang der Wertschöpfungskette, Präsentation auf dem Workshop des Umweltbundesamtes „Investieren in REACH – Start in eine chemikaliensichere Zukunft", 1.September 2004.

BASF (2004): Estimating the Costs of Complying with REACH (Folienvortrag 01-2004/se_mm-001). Ludwigshafen: BASF Aktiengesellschaft, Environment, Safety and Energy.

BAuA – Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (Ed.) (2002): Kosten arbeitsbedingter Erkrankungen. Schriftenreihe der Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, Fb 946, Wirtschaftsverlag NW, Dortmund Berlin, 2002

BAuA (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin) (2004a): Kostenabschätzung zu Anhang V der REACH-Verordnung, September 2004

BAuA (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin) (2004b): Stellungnahme zur UBA Studie Kosten und Nutzen von REACH, 23.8.2004 und 13.9.2004

Berkhout, F.; Ilzuka, M.; Nightingale, P.; Voss, G. (2003): Innovation in the chemicals sector and the new European chemicals regulation - A report for WWF-UK, Godalming / UK: WWF-UK.

Bewertungsbehörden (2004): Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, Umweltbundesamt und Bundesinstitut für Risikobewertung: Das Konzept "Verwendungs- und Expositionskategorien" - Standpunkt der deutschen Bewertungsbehörden.

Bonn, Stadtbauamt: Sanierungskonzept Schulen (2003), http://www.bonn.de/umwelt_gesundheit_planen_bauen_wohnen/gesundheitsportal/schadstoffmessungen/00842/index.html?lang=de

Bullinger, H.-J.; Warschat, J. (1997): Forschungs- und Entwicklungsmanagement - Simultaneous Engineering, Projektmanagement, Produktplanung, Rapid Product Development, Stuttgart: Teubner.

Bunke, D., Reuter, W., Kohla, M., Ahrens, A (2004): Die Erprobung ausgewählter Bausteine von REACH in der textilen Kette; UWSF 16 (3) 200-207.

Canton, J.; Allen, Ch. (2003): A microeconomic model to assess the economic impacts of the EU's new chemicals policy, Brussels: EU DG Enterprise.

CEC - Commission of the European Communities (Ed.) (2003a): Proposal for a regulation of the European Parliament and of the Council concerning the registration, evaluation, authorisation and restriction of chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) on Persistent Organic Pollutants - COM (2003) 644 final, Brüssel: CEC - Commission of the European Communities.

CEC - Commission of the European Communities (Ed.) (2003b): Commission Staff Working Paper “Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) on Persistent Organic Pollutants” - Extended Impact Assessment {COM (2003) 644}, Brüssel: CEC - Commission of the European Communities.

CEC - Commission of the European Communities (2001): Weißbuch - Strategie für eine zukünftige Chemikalienpolitik [Com (2001) 88]. Brüssel: CEC - Commission of the European Communities.

CEFIC (Ed.) (2004): Chemical Industry 2015 - Roads to the future. Final Report, Brussels: CEFIC (European Chemical Industry Council).

CESIO (2002): Surfactant Statistics for Western Europe 2002. http://www.cefic.be/files/Publications/cesio02-010903.xls

Chem Research (2004): CHEM Research GmbH: Der deutsche Markt für Farben und Lacke, Zwischenbericht, Frankfurt, Januar 2004

CLEEN – Chemical Legislation European Enforcement Network, EU enforcement project "EuroCad", final report, Ministry of Housing, Spatial Planning and Environment (VROM), The Netherlands, December 2001

Danish Paint Makers Association (2004): Temperature measurement – Part 1 of a project on preparation for REACH; personal communication, 2004

DIHK (2004): Deutscher Industrie- und Handelskammertag: Auswirkungen der EU-Chemikalienpolitik auf deutsche Unternehmen, Brüssel, August 2004

ECB - European Chemicals Bureau (2003): TGD – Technical Guidance Document on Risk Assessment, European Chemicals Bureau, European Communities.

ECLIPS – European Classification and Labelling Inspections of Preparations, including Safety Data Sheets, Final report, June 2004

EEA – European Environment Agency (2001): Late lessons from early warnings: the precautionary principle 1896–200. Environmental issue report No 22, Luxembourg 2001

EUREX (1999): European Inspection project Existing Substance Regulation, final report, Ministry of Housing, Spatial Planning and Environment (VROM), The Netherlands, July 1999

European Chemicals Bureau (Ed.) (1997): Technical Guidance Document on Risk Assessment - Part III - Edition 2, Ispra: European Commission Joint Research Center.

Eversheim, W.; Bochtler, W.; Laufenberg, L. (Ed.) (1995): Simultaneous Engineering - Erfahrungen aus der Industrie für die Industrie, Berlin,Heidelberg,New York: Springer.

Fleischer, M. (2002): Regulation and Innovation - Chemicals Policies in the EU, Japan and the USA. In: IPTS Report, 64 (May 2002), S. 4-17.

Fleischer, M. (2003): Regulation and innovation in the chemical industry - A comparison of the EU, Japan and the USA. In: Surface Coating Interantional Part B: Coatings Transactions, 86, B1, 1-90 (March), S. 21-29.

Fleischer, M.; Kelm, S.; Palm, D. (Ed.) (2000): Regulation and innovation in the chemical industry, Sevilla: DG JRC-IPTS.

Goldmann GmbH & Co (2004): Aus dem Leben gegriffen – Die gesamtökonomische Bedeutung der KMUs im Chemikalienmarkt; 21.09.2004 (unveröffentlicht)

Greim, H. (2003): Peer Review von ICCA-Stoffen im BUA. In: Mitteilungen der Fachgruppe Umweltchemie und Ökotoxikologie, Gesellschaft Deutscher Chemiker, 9 (1).

Grenzmann, C.; Marquart, R.; Revermann, C.; Wudtke, J. (2004): FuE-Datenreport 2003 / 2004 - Forschung und Entwicklung in der Wirtschaft. Bericht über die FuE-Erhebungen 2001 und 2002, Essen: Wissenschaftsstatistik gGmbH im Stifterverband für die Deutsche Wissenschaft.

Grupp, H. (1997): Messung und Erklärung des technischen Wandels. Grundzüge einer empirischen Innovationsökonomik., Berlin, Heidelberg, New York: Springer.

Hauthal, Hermann G.; G. Wagner (Ed.) (2003): Reinigungs- und Pflegemittel im Haushalt. Augsburg: Verlag für chemische Industrie H. Zoilkowsky GmbH.

Hippel, E. v. (1988): The sources of innovation, New York: Oxford University Press.

HVBG (2004): Hauptverband der gewerblichen Berufsgenossenschaften (HVBG), Berufskrankheiten-Dokumentation (BK Dok)

IHO (2003): Jahresbericht 2002/2003.
http://iho.de/aktuellethemen/jahresbericht2002.html

IKW (2004a): Wasch-/Putz-/Reinigungsmittel-Markt Deutschland (zu Endverbraucherpreisen) in Mio. EURO. Internet 14.1.2004

IKW (2004b): Ein Jahrhundert verbrauchsnahe Innovationen der Waschmittel-Industrie. Foliensatz 2004

JRC (2003): European Commission - Joint Research Center; Assessment of additional testing needs under REACH; September 2003

Kennedy, M. M. (1979): Generalizing from single case studies. In: Evaluation Quarterly, 3 (4), S. 661-678.

Kinkel, S. (2003): Dynamische Standortbewertung und strategisches Standortcontrolling - Erfolgsmuster, kritische Faktoren, Instrumente, Frankfurt am Main: Peter Lang.

Kinkel, S. (Ed.) (2004): Erfolgsfaktor Standortplanung - In- und ausländische Standorte richtig bewerten, Berlin: Springer.

Kinkel, S.; Jung Erceg, P.; Lay, G. (2002): Auslandsproduktion - Chance oder Risiko für den Produktionsstandort Deutschland? - Stand, Entwicklung und Effekte von Produktionsverlagerungen im Verarbeitenden Gewerbe, Karlsruhe: Fraunhofer ISI.

Kinkel, S.; Wengel, J. (1998): Produktion zwischen Globalisierung und regionaler Vernetzung - Mit der richtigen Strategie zu Umsatz- und Beschäftigungswachstum, Karlsruhe: Fraunhofer ISI.

Köln, Gesundheitsamt: Ergebnisberichte Schadstoffuntersuchungen (2000 – 2003), http://www.stadt-koeln.de/bol/gesundheit/schadstoffuntersuchungen/index.html

Lahl, U. (2003): Kurs halten - Die politische Entscheidungsfindung zum neuen europäischen Chemikalienrecht geht in eine entscheidende Phase. In: Müllmagazin, 4, S. 8-15.

MERCER (Ed.) (2003): Study of the impact of the future chemicals policy - Final Report: UIC.

MERCER; NERA (Ed.) (2004): Study of the impact of the future chemicals policy - Additional study following the regulation proposal of 29th October 2003: UIC.

Monheim, Gebäude- und Liegenschaftsmanagement: PCB-Problem in Schulen und anderen städtischen Gebäuden, http://www.monheim.de/stadtprofil/schulen/pcb/

Netherlands Water Association (2004): Andre Bannink, Vewin_Netherlands Water Association, persönliche Mitteilung

NONS (1996): European Inspection Project on the Notification of New Substances, final report, Ministry of Housing, Spatial Planning and Environment (VROM), The Netherlands, July 1996

Nordbeck, R.; Faust, M. (2002): European chemical regulation and its effect on innovation - An assessment of the EU's White Paper on the strategy for a future chemicals policy, Leipzig: UFZ Centre for Environmental Research.

Nordbeck, R.; Frohwein, T. (2003): Kosten und Nutzen der zukünftigen EU-Chemikalien-Regulierung - Der Streit der Gutachter. In: Ökologisches Wirtschaften, 2003 (6), S. 6-7.

OECD (Ed.) (2003): Best practices on regulatory impact analysis in OECD countries - Regulatory governance initiative in South East Europe. Sofia / Bulgaria, 23. Januar 2003, Paris: OECD.

Pearce, D.; Koundouri, P. (2003): The social cost of chemicals - The cost and benefits of future chemicals policy in the European Union. A report for WWF-UK, Godalming / UK: WWF-UK.

Porter, M.; van der Linde, C. (1995): Green and competitive - Ending the stalemate. In: Harvard Business Review on Business, 73 (5), S. 120-134.

Rehfeld, D.; Legler, H.; Schmoch, U.; Krawcyk, O.; Nordhaus-Janz, J.; Öz, F. (2004): Chemische Industrie - Neuorientierung, Innovationskraft und Wettbewerbsfähigkeit, München, Mering: Rainer Hampp Verlag.

RPA (Ed.) (2001): Regulatory Impact Assessment of the EU White Paper: Strategy for a Future Chemicals Policy. Final Report. Prepared for the Department of the Environment, Transport and the Regions. Loddon: Risk and Policy Analysts Limited.

RPA (Ed.) (2003a): Assessment of the impact of the new chemicals policy on occupational health - Final report prepared for the European Commission Environment Directorat-General, Loddon: Risk and Policy Analysts Limited.

RPA (Ed.) (2003b): Availability of low value products and product rationalisation - Assessment of the business impacts of new regulations in the chemicals sector - Phase 2, Loddon: Risk and Policy Analysts Limited.

RPA (Ed.) (2003c): Revised business impact assessment for the Consultation Document (Working Paper 4) - Assessment of the business impacts of new regulations in the chemicals sector - Phase 2, Loddon: Risk and Policy Analysts Limited.

RPA (Ed.) (2003d): Emission Scenario Document – Chemicals used in the Coating Industry: Paints, Lacquers and Varnishes, June 2003 (Draft), Loddon: Risk and Policy Analysts Limited.

RPA; BRE Environment (Ed.) (2003): The impact of the new chemicals policy on health and the environment - Final report prepared for the European Commission Environment Directorat-General, Loddon: Risk and Policy Analysts Limited.

RPA; Statistics Sweden (Ed.) (2002): Assessment of the business impact of new regulations in the chemicals sector - Final Report (June 2002) prepared for European Commission - Enterprise Directorate-General, Loddon / UK: RPA Risk & Policy Analysts Limited.

Rühl, R.: Das Nutzenpotential von REACH – Abschätzung für ein Teilsegment. Beitrag zu „Vorsorgende Strategien in der chemischen Industrie: Wie lassen sich die Innovationsanreize der EU-Richtlinie aufgreifen?", Evangelischen Akademie Loccum, 16. – 18. Januar 2004

Schnuch, A.; Geier, J.; Lessmann, H. und Uter, W. (2004): Untersuchungen zur Verbreitung umweltbedingter Kontaktallergien mit Schwerpunkt im privaten Bereich. UBA Texte 01/04, Forschungsbericht 299 61 219, UBA-FB 000574

SENSE – European inspection project: "Solid Enforcement of Substances in Europe", final report (1998); report on the follow up activities (1999). Ministry of Housing, Spatial Planning and Environment (VROM), The Netherlands

Serup-Hansen, N.; Gudum, A. and Soerensen M. M. (2004): Valuation of Chemical Related Health Impacts, Environmental Project Nr. 929 2004, Ministry of Environment, Environmental Protection Agency, Denmark.

SRU - Rat von Sachverständigen für Umweltfragen (Ed.) (2003): Zur Wirtschaftsverträglichkeit der Reform der Europäischen Chemikalienpolitik - Stellungnahme Juli 2003, Berlin: SRU.

SRU - Rat von Sachverständigen für Umweltfragen (Ed.) (2004a): Meeresumweltschutz für Nord- und Ostsee - Sondergutachten (Bundestagsdrucksache 15/2626), Berlin: Deutscher Bundestag.

SRU - Rat von Sachverständigen für Umweltfragen (Ed.) (2004b): Umweltgutachten 2004 - Umweltpolitische Handlungsfähigkeit sichern, Wiesbaden: SRU.

Statistisches Bundesamt (2003): Produktion im Produzierenden Gewerbe 2002. Fachserie 4, Reihe 3.1. Wiesbaden TEGEWA (2004): Textilhilfsmittelkatalog 2004/2005. Frankfurt am Main: Deutscher Fachverlag.

UK WIR – UK Water Industry Research (2003): The economics of achieving good water status with water industry measures: an assessment of the scale and scope of potential costs associated with the Water Framework and related directives (Report Ref No. 03/RG/07/3) (www.ukwir.org).

Umweltbundesamt (Ed.) (1998): Innovationspotentiale von Umwelttechnologien. Heidelberg: Physica-Verlag.

Umweltbundesamt (Ed.) (2004): "Dicke Luft" im Wohnzimmer - Ein guter Grund für einen neuen Umgang mit chemischen Stoffen (Themendienst 01/2004), Berlin: Umweltbundesamt.

UNEP – United Nations Environment Programme (1998): Environmental Effects of Ozone Depletion: 1998 Update, van der Leun, J.C., Tevini, M. Tang, X. and Worrest, R. C. (eds.), Nairobi.

United Nations (Ed.) (2003): The Road from Johannesburg - World Summit on sustainable Development. What was achieved and the way forward. New York: United Nations.

VCI (1997): Freiwillige Selbstverpflichtung der deutschen Chemischen Industrie zur Bewertung von Stoffen (insbesondere Zwischenprodukten) für die Verbesserung der Aussagefähigkeit; 1997;

VCI (Ed.) (2003a): Auswirkungen der REACH Verordnung auf Produzenten und Importeure von Chemikalien. Foliensatz Dr. Fink vom 3.12.2003;

VCI (Ed.) (2003b): Chemiewirtschaft in Zahlen - Ausgabe 2003, Frankfurt: Verband der Chemischen Industrie e. V.

VCI (Ed.) (2004a): Chemie Report Spezial - EU-Chemikalienpolitik: Das REACH-System muss praktikabler werden, Frankfurt: Verband der Chemischen Industrie e. V..

VCI (Ed.) (2004b): Expositionskategorien - Mensch und Umwelt gezielt schützen. Frankfurt: Verband der Chemischen Industrie e. V..

Wagner, Günter (1993): Waschmittel. Stuttgart: Ernst Klett Verlag.

Waibel, H.; Fleischer, G. (1998): Kosten und Nutzen des chemischen Pflanzenschutzes in der deutschen Landwirtschaft aus gesamtwirtschaftlicher Sicht. Universität Hannover, 1998

Wolf, O.; Delgado, L. (2003): The impact of REACH on innovation in the chemical industry, Sevilla: JRC-IPTS.

Yin, R. K. (1989): Case study research - Design and methods. Revised Edition, Newbury Park, London, New Delhi: Sage Publications.