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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

(FKZ 203 65 423)

Summary

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

An examination based on selected supply chains taking into account effects on competitiveness, innovation, environment, and health.

This study was funded by the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety and the Federal Environmental Agency[1], and investigates the effects of REACH for manufacturers of chemical substances and downstream users (formulators and their customers). Some of the potential impacts were studied more closely in two specific supply chains, **paints and varnishes** and **cleaning agents and detergents**. The project was carried out by the Fraunhofer ISI (Karlsruhe) and Ökopol (Hamburg) between October 2003 and October 2004. It was accompanied by an advisory board comprising representatives from industry, non-governmental environmental and consumer organizations, authorities and research institutes. Considerable efforts were made to address the concerns of all the stakeholders represented in the advisory board. However, a consensus could not be reached on a number of issues regarding procedures, methods applied, assumptions and the conclusions. The stakeholders, therefore, were given the opportunity to submit comments on the final report, which are documented in an annex.

Focus of the study

The study focuses solely on the registration component of REACH (including downstream user aspects). It analyses the factors driving the costs and benefits of REACH at company level in the selected supply chains. This includes a critical review of direct registration cost estimates and their impact on subsequent levels of the supply chain. Particular attention was paid to the balance between REACH-triggered **adaptation pressure** and the **adaptation capacity** of companies.

Furthermore, the study illustrates the potential environmental and health benefits by "testing" the REACH mechanisms against the causes of damages related to chemicals, and against the current regulatory basis related to existing and new substances. This shows how, and to which extent, REACH may improve chemical safety and knowledge management procedures. The study concludes with the discussion of a number of proposals for optimising REACH.

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1 Funding Code UFOPLAN 203 65 423

Methodology used

Since the analysis focuses on the micro-level (single companies), a case study approach was used. Following the line of regulatory impact assessments, a range of different methodologies and data gathering methods were combined. Document analysis (including legislative texts), literature research as well as information from and interaction with stakeholders in the advisory board were used throughout the study. For the analysis of environmental and health effects, both historic and current examples of damages caused by single chemicals were analysed with respect to their causes and extent, based mainly on interviews and literature research. As a core element in the supply chain analysis, 24 companies across different levels of the chain were interviewed with particular attention paid to formulators. These companies are distributed as follows:

- **Supply chain analysis of detergents and cleaning agents**: one importer, one producer of surfactants, seven manufacturers of preparations (two of them for domestic use), four users of preparations (three industrial, one professional user).
- **Supply chain analysis of paints and varnishes:** one importer of additives, two producers of substances (additives and pigments), six manufacturers of paints for industrial use, six users of paints and varnishes (five industrial, one professional user).

Small, medium-sized and large companies were represented at the substance producers' and formulators' level. At the users' level, mainly large industrial users were interviewed. The interviews were based on a common guideline with some modules specific to the supply chain or to certain types of companies. In order to identify the potential additional impacts of REACH, baseline developments, e. g. with respect to the "normal" withdrawal and/or replacement of substances in the market, and globalisation trends were among the topics addressed in the interviews. Furthermore, the interviewees were also consulted in two workshops.

The study describes to which extent more general conclusions can be drawn from the selected cases. However, the study does not extrapolate data to more aggregate levels. Thus, no macroeconomic aspect is investigated, nor is substance withdrawal quantified.

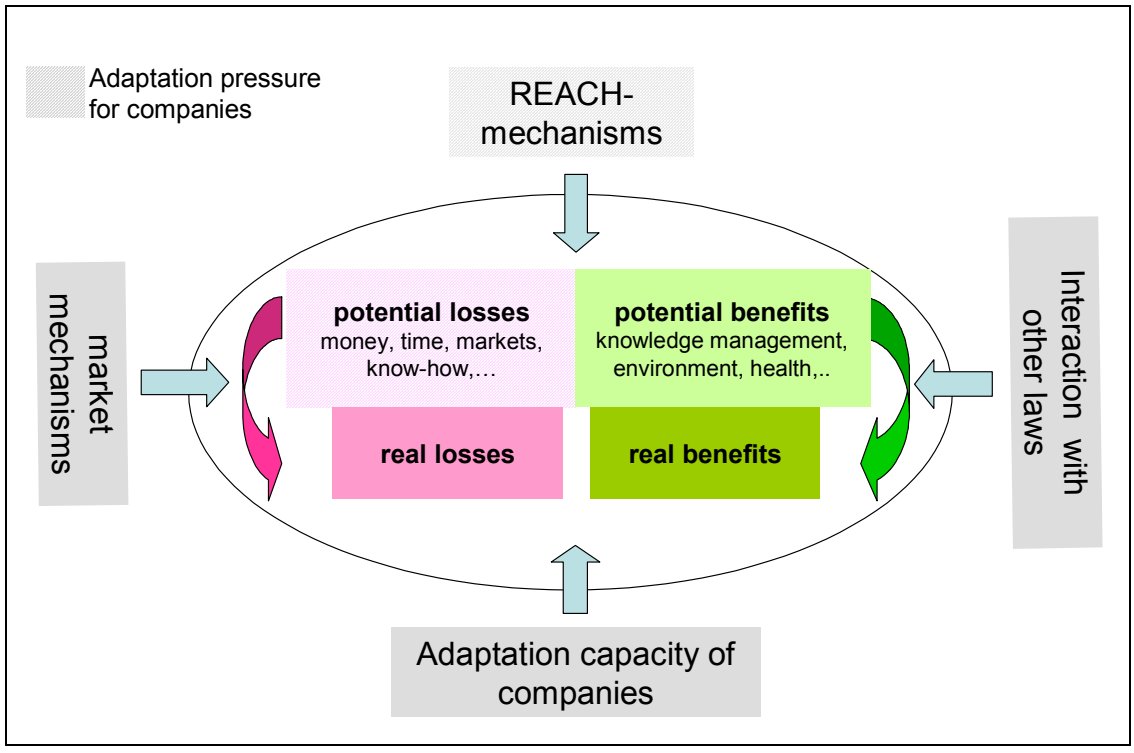
Main findings

The study deepens the understanding of the REACH mechanisms, the responses triggered in the market and the potential benefits. It starts from a model of REACH effects (see Figure 1). The "REACH mechanisms" refer to the duties and procedures originating from the draft legislation for the different actors in a supply chain, e. g. the manufac-

turers' duty to register their substances. These mechanisms may trigger a range of *potential* effects including potential benefits (e. g. improved knowledge of substances) and potential losses (e. g. loss of confidential know-how). The type and magnitude of the resulting *real* effects depend on the market mechanisms under which companies operate, e. g. trends in demand and competition. They are further influenced by the interaction of REACH with other laws which determines, for example, to what extent the REACH system can effectively raise the level of knowledge about substances. The REACH mechanisms and related potential losses generate an adaptation pressure for companies which is met by a certain adaptation capacity at company level. The relation between adaptation pressure and capacity also influences the benefits and losses actually realised.

The following sections provide an overview of the main findings by subject area. The results inspired suggestions about how to further optimise REACH and may be a useful contribution to the various processes at EU level related to the preparation and implementation of the REACH system.

Figure 1: A model of REACH effects



Direct registration costs and their determinants

The study in hand makes use of the cost scenarios which were also the basis for the *Extended Impact Assessment* of the European Commission in 2003. However, the cost scenario for the 1-10 t/a band was modified to adapt it to the last changes in the drafting process related to the reduction of information requirements for this tonnage band (no exposure assessment, no biodegradation testing, no test on algae growth inhibition, no second test related to mutagenicity). Table 1 shows the figures used in this study. In Table 2, these figures are broken down into costs (in the sense of investment expenditures) per kilo of a substance based on the production volume in one year.

Table 1: Registration costs according to RPA[2] and JRC (modified)[3]

	1-10 t/a	**10-100 t/a**	**100-1000 t/a**	**>1000 t/a**
Average scenario (Euro/substance)	13,100	83,750	201,130	252,450
Testing costs in this	7,700	73,100	163,000	208,000
Minimum scenario (Euro/substance)	12,100	51,150	166,130	229,450
Testing costs in this	6,700	40,500	128,000	185,000
Maximum scenario (Euro/substance)	14,100	162,650	282,130	322,450
Testing costs in this	8,700	152,000	244,000	278,000

Table 2: Specific registration costs

	1-10 t/a	**10-100 t/a**	**100-1000 t/a**	**>1000 t/a**
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

2 RPA (2003): 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. The costs for risk characterisation are reduced for substances between 1-10 t/a, because no exposure assessment is required. Costs include registration fees (of 400 EUR per substance [< 100 t/a] and 8000 EUR per substance [> 100 t/a]).

3 JRC (2003): Assessment of additional testing needs under REACH. European Commission - Joint Research Center; September 2003. Because of the reduction of test requirements, the costs of Annex V are lower than estimated by the JRC.

Based on the analysis of the cost studies by JRC (2003) and RPA (2003),[4] the following cost assumptions and drivers were identified as being particularly relevant:

- the standard information requirements of Annexes V and VI, whose fulfilment can hardly be influenced by testing strategies and the definition of exposure scenarios by the registrants;
- criteria for the acceptance of existing (but not standard) test data, criteria to apply techniques like read-across, quantitative structure-activity relationships (QSARs) and group assessments;
- the design of instruments for exposure assessment and availability of workable methods to justify waiving based on exposure considerations;
- the extent to which relevant studies of substance properties already exist at company level, for example those covered by the VCI voluntary commitment of 1997 on ensuring a minimum data set for all substances handled in a company at a volume of more than 1 ton per year;
- the availability of validated non-test based techniques to predict substance properties, in particular at that point in time when registration of substances with a production volume below 100 t per year starts (from 2012);
- the decision of a company whether to generate missing information and how to do it in the given time frame between 2004 and 2017, including the decision to withdraw substances (from certain applications) and possibly replace them with a substance requiring lower testing efforts;
- the number of manufacturers and importers of one substance who could potentially share existing data and the costs of additional studies;
- the companies' approach to sharing data and cost with each other regarding information on hazard-related properties.

There is a high degree of uncertainty attached to all these factors and quantification thus results in very broad scenarios. Some of the cost drivers were analysed in more detail and proposals were derived on how to link the costs of registration more closely to the potential risk of a substance and its uses.

4 Op. cit.

Potential benefits for chemical safety

Based on the analysis of existing standard instruments under the current chemicals legislation and the company interviews in the two supply chains, a number of potential benefits of the REACH system could be identified:

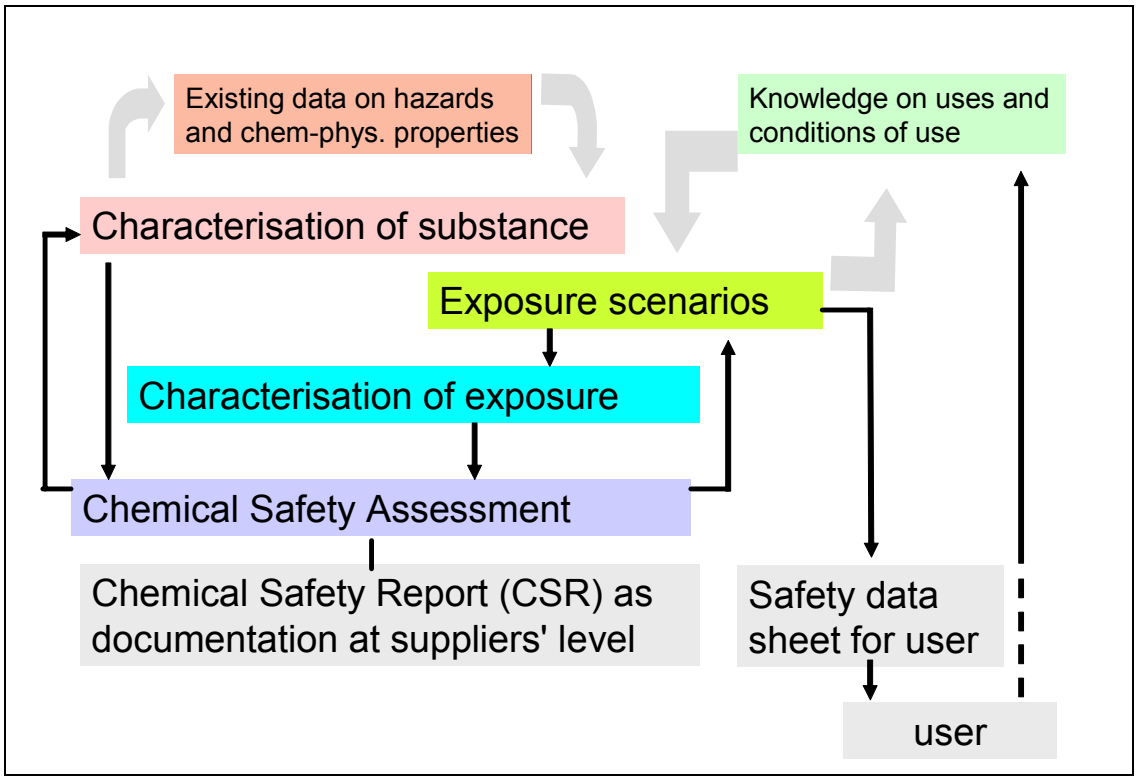
- REACH will improve the knowledge about properties of existing chemical substances related to environment and health. This is especially true for those substances, for which proper hazard assessment has not been possible so far due to the lack of relevant standard information. Formulators and industrial users will benefit from this information, since the share of substances not yet assessed in their raw material portfolio will decrease. At the same time, the competitive advantage for manufacturers of substances not classified as dangerous due to a lack of data will also diminish. Companies aiming to improve the safety of products and processes will be able to choose from among substances which can be accurately compared with regard to their properties.
- However, to a large extent, the interviewed companies do not expect these REACH mechanisms to result in business benefits. More concretely, none of the companies expects that customers will be willing to pay a higher price for “safe products” with proper documentation according to the REACH standard.
- REACH introduces a common and tiered system for the evaluation of existing information and the generation of additional information where needed on substance properties and exposure patterns. The iterative and flexible nature of the Chemical Safety Assessment (CSA) makes it possible to fill the existing information gaps in a targeted and harmonised way (see Figure 2). However, the instruments needed to implement this concept are not yet available. In addition, handling the flexibility related to information requirements and the new distribution of responsibilities between authorities and industry requires a common process of operationalising the new approaches and practising them in joint projects (see RIP[5] and SPORT[6]).
- Exposure assessment and the definition of conditions for safe use throughout all the relevant life cycle steps will be a pre-requisite for registration and hence for the continued marketing and use of a substance. This sets a strong incentive for substance manufacturers and importers to improve the exposure related parts of their safety data sheets and thereby support small and medium-sized users, in particu-

5 REACH Implementation Projects

6 Strategic Partnership on REACH testing

lar. At the same time, downstream users will be obliged to (i) either meet the conditions of safe use as defined by the supplier or (ii) contact the supplier and provide more specific information on the actual type and conditions of use or (iii) formally take the responsibility for carrying out their own safety assessment and for defining the conditions of safe use. This mechanism will provide an incentive for downstream users to make information on use and exposure available to suppliers.

Figure 2: Knowledge management in the iterative Chemical Safety Assessment



- Apart from the incentives to hand on available information from lower to upper levels in the supply chain, the REACH-mechanisms will lead to a better product safety documentation. This makes the allocation of responsibility more transparent in cases of liability claims.

- However, the potential benefits will only materialise if the small and medium-sized companies are motivated and capable of introducing the new system. Many of the companies already have difficulties now in complying with the requirements related to *safety data sheets* and the classification and labelling of products. In the companies interviewed for this study, the employees responsible for product safety had to manage quite a large number of products: 40 to 600 products in the supply chain of detergents and cleaning products, and 820 to 6000 products in the paints' supply chain (see Table 3). There is not much scope to increase the capacity of these

companies in terms of the number of staff. Hence, there is a need for practicable IT-based instruments, on the one hand, and staff training on the other. In the long term, the current complexity of substance-related requirements in various pieces of legislation (regarding chemicals, health, and environment) should be reduced through policy integration at EU- and member state level.

- 5 examples were analysed in order to “test” REACH for its theoretical effectiveness in preventing costs related to adverse health or environment effects: PCB contamination of public buildings, chemicals in the raw water of water utilities, health damage at the workplace, contact allergies in the general public, and the depletion of the ozone layer by CFCs. The overall results of this "test" were:
    - REACH may prevent damage costs through the standard information requirements for each substance. These include a systematic evaluation of the properties of substances, such as skin sensitisation or degradability, and defining exposure scenarios accordingly. Definition and communication of exposure scenarios by the manufacturer may prevent substances of being used in an unsafe manner. However, the extent of cost prevention cannot be predicted since REACH will only affect some of the causes at the root of the damage. REACH will prevent damage costs to the extent that information is missing or is not understandable to those causing the damage by their decisions or behaviour.
    - Non-standard effects of chemicals (new types of effects) will not be discovered during registration. Thus, cases such as today’s PCB- and HCFC-related costs would probably not have been prevented by a REACH-system in place at the end of the 1960s. At this point in time neither the interaction between HCFCs and ozone nor persistence and liability to bioaccumulate of PCBs were among the classification criteria for dangerous substances. Nevertheless, there is a significant difference between today’s situation and knowledge at that time: New types of adverse effects may be also discovered in future, but the extent of adverse impacts will be lower. The standard evaluation of degradability, liability to bioaccumulate and use patterns will at least prevent a problem becoming only visible when tens of thousands of tons of a substance have already accumulated in the environment without any chance of recovery.

Innovation effects of REACH

Allocating notifications of new substances to the two supply chains considered shows that, in the past, the number of new substances was low in both cases, with slightly

more new substances being developed in the paint chain. The observed rate is likely to be insufficient to replace *existing* substances being withdrawn from the market. REACH will lower the registration requirements for the development and the market introduction of new substances up to a production volume of 10 t/a. However, it was doubted in the interviews whether the relaxation in these low tonnage bands would constitute an innovation impulse. This was related to the interviewees' assumption that commercially relevant market volumes lie above 10 t per year and that therefore the manufacturer will have to fulfil the requirements of the current base set for new substances (equivalent to REACH Annex VI, except the endpoints related to repro-toxicity) in any case.

In both chains, client-specific knowledge about applications of chemicals already forms the basis for innovation today, with this type of knowledge being particularly prevalent among formulators. Therefore, REACH is not likely to significantly increase the formulator's knowledge of customer's needs and hence will only constitute a small innovation impulse. In contrast, substance producers could obtain additional innovation impulses through increased knowledge about exposure patterns and uses. However, this may be restrained by the formulators' concern of confidential knowledge being leaked to potential competitors. A possible solution to this conflict of interests may lie in the development of more general categories for describing the uses and exposure scenarios relevant for the specific supply chain.

A comparison of R&D intensities at the level of manufacturers of substances and formulators reveals that the share of R&D in turnover is below the average of the chemical industry in the supply chain of detergents and cleaning products (see Table 3). This indicates that their innovation capacity and therefore the adaptation capacity to REACH are below average as well. In the paint and varnish chain, R&D intensity – and correspondingly the capacity to adapt to REACH – is higher. It reaches the chemical industry's average or even the high R&D shares typical for specialities. However, the higher adaptation capacity in the paint chain must be seen in relation to the adaptation pressure, which is also higher here (see below).

Substance de-selection

The decision of a substance manufacturer to register a substance is based on economic and strategic considerations. Manufacturers' expectations as to their registration choices differ: based on an analysis of his portfolio, the interviewed manufacturer of surfactants reckons that, under REACH conditions, he would refrain from registration for 40 % of his substances. In 5 % to 10 % of the cases this would result in the substance disappearing from the market completely. In the other cases, market concentration would result. The manufacturer of pigments had not yet carried out a detailed port-

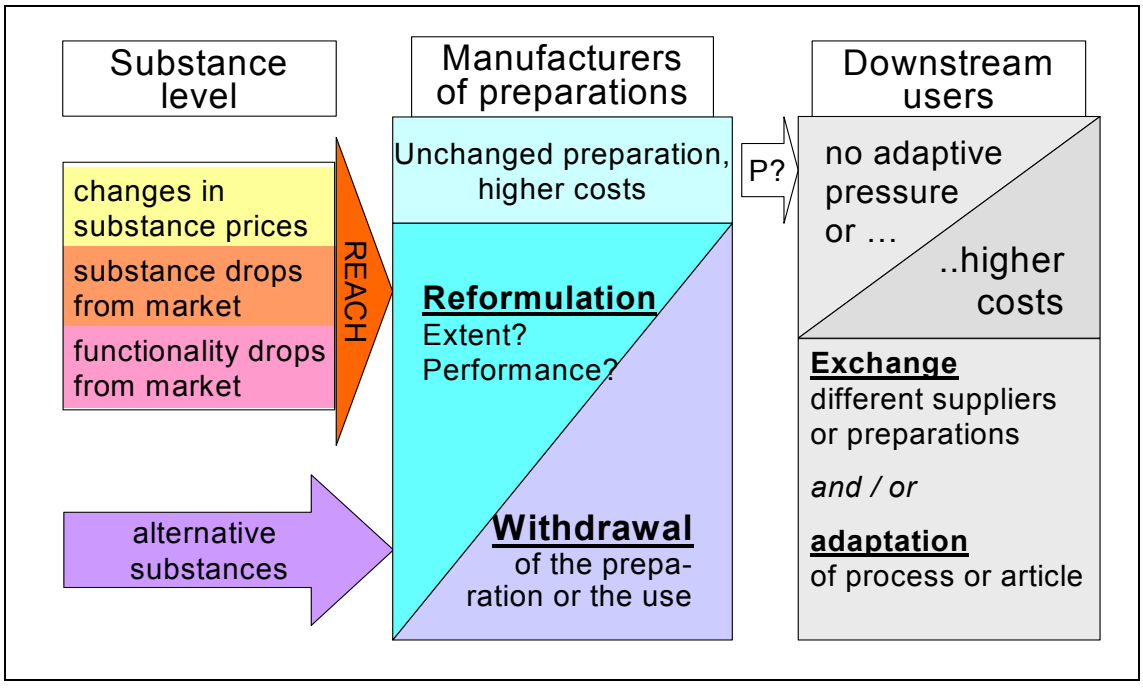
folio analysis to identify substances likely or not likely to be withdrawn. The manufacturer of additives for paints takes it for granted that he will continue to offer his clients all the current functionalities of his additives.

The registration procedure under REACH may contribute – to a smaller or larger degree - to substance de-selection from companies' portfolios. The diversity of substances and functionalities available in the market may also decrease. If de-selection is linked to the **risks** of a substance's use, then a major objective of REACH will already have been achieved during the registration phase. In contrast, if the de-selection takes place mainly due to risk-independent data requirements and hence is purely **cost-**driven, then REACH would fail to achieve a major goal and would actually weaken the innovation basis of formulators. The balance between risk-driven and risk-independent de-selection depends on how the REACH system is designed.

Consequences of substance de-selection for formulators and downstream users outside the chemical industry

In the case of a substance or functionality dropping out of the market, formulators and downstream users outside the chemical industry have to adapt to this change (see Figure 2).

Figure 2: Adaptation mechanisms to REACH in the supply chain



For formulators, this may mean the reformulation of their products with possible effects on performance, or the withdrawal of a product. Since formulators of paints rely on a

larger substance portfolio in absolute terms, and also on a larger number of formulas, they are likely to be more strongly affected by the de-selection of substances compared to the formulators of detergents and cleaning products (see Table 3).

With respect to substance de-selection, the current study indicates that formulators will have the capacity to cope with de-selection to a certain extent. This assessment is based on an indicator developed in the supply chain analyses, which measures today's rate of forced raw material exchange. Over a period of 10 years, this amounted to 5 - 7 % of the formulators' substance portfolio[7] in the *paint* supply chain, and to 10 - 20 % in the *cleaning products* supply chain. The total rate of substance exchange (including voluntary exchange of substances) is still significantly higher (see Table 3).

Indications of the costs occurring for the substitution of substances in the past range between 10,000 Euro and 150,000 Euro per substance. The time-to-market of preparations in both supply chains usually lies between 0.1 and 5 years (see Table 3). These figures indicate that the companies clearly have an interest to avoid (repeated) substance replacements. If REACH succeeds in providing more robust information about raw materials used in the *paint* or *cleaning agent* chain respectively, the need for repeated replacements as a result of new hazard information would decrease after the phase-in period of REACH. However, this benefit can only be realised if the same substance (including a similar degree of impurities) is registered with a consolidated hazard data set, even though various companies may be involved in the production and marketing of the substance. This aspect motivates the proposal made for *one substance-one registration* in the next section.

Downstream users may have to change suppliers or use new preparations. The new preparations need to be tested with respect to their performance in the production process or as part of the final product. This may have an effect on current production (e. g. delays) and may require the adaptation of production processes or articles. The *cleaning agent* chain is less affected in this respect, since the technical interdependence between chemicals and production processes is not as strong as in the paint chain.

Pass-along of registration costs in the supply chain

All interviewees were sceptical about the possibilities to pass on registration costs or other REACH-induced additional costs to subsequent levels in the supply chain. These

7 "raw material portfolio" since formulators often buy mixtures as inputs rather than single substances.

expectations are based among others on experiences from price negotiations with large customers or retail chains. Furthermore, the pessimism relates to the downstream users' general option to relocate production to sites outside Europe, e. g. in the automobile or electronics industry.

However, these expectations must be seen in the light of the follow-up costs that result if a substance or preparation is withdrawn from the market under the conditions of stable prices. In fact, formulators and downstream users outside the chemical industry may find themselves in a trade-off situation, facing the choice between follow-up costs for reformulation and the adaptation of processes and articles on the one hand, or higher chemical prices on the other. If the alternative to price increases is the withdrawal of a preparation, the downstream user may accept a price increase. It is therefore plausible that registration costs could be shifted to customers to a certain extent. In other cases similar to the paint chain, where chemicals and process technology are highly interdependent, this could also take the form of a strategic contribution to the registration costs on the part of formulators or downstream users.

For downstream users outside the chemical industry, the share of costs for paints or detergents and cleaning products is low in relation to total production costs for the companies interviewed (see Table 3). The same is true for the share of chemicals in total costs. This indicates a certain capacity to absorb higher prices for chemicals.

Effects on international competitiveness

Given the current general globalisation trends, it is difficult to empirically grasp the incremental effect of REACH in the future. The current study therefore focuses on identifying principal mechanisms which may influence the international competitiveness of companies under REACH.

At the substance level, EU manufacturers with safety documentation of high quality can improve their competitive position, since substance imports will face the same documentation and test requirements and may lose their price advantage. For importers of chemicals, the registration duty under REACH poses a problem. They often sell a substance sporadically with little opportunity to recover registration costs. In addition, the registration of all the components of a preparation may fail because of limited information about the formula. A REACH model with one registration per substance, where the importer can "buy in" to the registration dossier, may resolve this problem (see below).

Producers of industrial paints are increasingly acting on a global scale, independent of their size. While knowledge-based production steps (e. g. R&D or the production of specific additives) still remain in Europe, production and customer advisory services

are moving abroad. These developments are taking place independently of REACH. For SMEs involved in the production of detergents and cleaning products, non-EU markets are of less importance. This is reflected, e. g. in the low exports to such regions (see Table 3). In contrast, the large substance manufacturers and formulators interviewed in this supply chain, serve non-EU markets from production sites outside the EU. Production could be increased, if non-EU market demand grew under REACH.

Generally speaking, downstream users outside the chemical industry follow their markets and/or the global differentials in labour and material costs as well as in knowledge and qualification of the labour force. Given the low share of chemicals' costs in overall production costs at this level, delocalisation of production offers few advantages if it is motivated solely by the REACH-registration costs being passed on in the chain. Arguably, any rise in production costs in the EU, which is not reflected in increased innovation, turnover or profits, harbours the potential to reinforce existing delocalisation trends. However, this study could not identify any concrete, case-specific indication that REACH might be a substantial driver for such tendencies.

Adaptation pressure and capacity

The supply chain analysis shows that REACH poses certain challenges to companies. But it also becomes apparent that the companies have a number of mechanisms at their disposal on how to cope with these challenges and, within certain limits, adapt to the changes induced. Comparing the adaptation pressure and the adaptation capacity between the two supply chains shows the supply chain of *detergents and cleaning products* to be better-off, e. g. with respect to lower vulnerability to de-selection, higher personnel capacity for product safety management, lower interdependencies between chemicals and application technologies, and lower exposure to international competition. For the sub-sector of *household products* the adaptation pressure is reduced even further because substances fall into high volume tonnage bands (above 1000 t/a) and a lower number of preparations is marketed. However, the market prices and margins of surfactants are relatively low which raises the relative proportion of registration costs here (see Tables 2 and 3). The adaptation capacity for cleaning products, as indicated by the share of R&D in turnover, is lower than for the *paint* chain or the chemical industry in general. There are three common factors driving the balance between adaptation pressure and adaptation capacity in both chains. First, a relatively high share of dangerous substances requires a high number of exposure assessments. Secondly, the cost-driven withdrawal of substances is clearly relevant when comparing the registration cost level in Table 2 and the market price level in Table 3. Thirdly, new substances in tonnages above 10 t have played hardly any role so far.

These aspects indicate the necessity of balancing the adaptation pressure to the adaptation capacity of the companies as much as possible. Several factors drive this balance: (i) the amount of registration costs which have to be invested independently of a substance's risk; (ii) the relation of REACH-triggered substance withdrawal to the baseline rate of forced substance exchange in the market; (iii) incentives for registrants of the same substance to submit one common substance data set; (iv) instruments allowing the existing capacities for health, safety and environmental management in the chain to be better exploited; and (v) increased knowledge about which substances are present in companies' portfolios and at chain level. The proposals below show how REACH could be designed in a way that strengthens the adaptive capacity of companies and lowers the adaptation pressure.

Table 3: Structure and selected indicators from the supply chain analyses[8]

Subject	Detergents and cleaning products	Paints and varnishes
Substance manufacturers	Surfactants (1) 35% of substances < 100 t/a	additives(1) and pigments(1) 75-90% of substances < 100 t/a
Formulators	7 companies	6 companies
Users of preparations	4 companies (3 industrial)	6 companies (5 industrial)
Level of market prices of substances (S)	0.7 – 3 EUR / kg	5 - 23 EUR/kg
Size of raw material portfolio[9] at formulators' level (F)	90 – 300 substances (or raw materials)	300 – 3000 substances (or raw materials)
Share of raw materials classified as dangerous (F)	60 – 100 %	30 – 80 %
Number of products per employee responsible for completeness and correctness of product safety information (F)	40 – 600 products	820 - 6000 products
New raw materials p.a. (% of the raw materials portfolio) (F)	1.7 – 5.6 %	1.1 – 7.4 %
R&D % of turnover (S, F, D)	<< 1-3%	3-7%
Number of preparations per million EUR of turnover (F)	1-28	10-100
Time-to-market at the level of formulators (F)	0.1 – 5 years	0.5 – 5 years

8 Capitals in brackets indicate the supply chain level: S=substance manufacturer, F= formulator, D= downstream user outside the chemical industry.

9 Raw material = substances, preparations and (pre)polymers meeting the polymer definition

Subject	Detergents and cleaning products	Paints and varnishes
Export of preparations to non-EU markets (F)	Rather low	Significant
Share of costs for detergents and paints in total turnover (D)	< 1 %	< 1 %
Ratio of voluntary replacement of raw material (as % of raw material portfolio, over 10 years) (F)	20 – 40 %	7 – 70 %[10]
Ratio of forced raw material substitution (as % of raw material portfolio, over 10 years) (F)	10 – 20 %	5 – 7 %

Suggestions on how to optimise REACH

A general observation made in the current study is that costs and benefits will greatly depend on the development of flexible and workable implementation instruments. Based on the impact mechanisms of REACH identified, a number of proposals were derived to reinforce the benefits of REACH and to limit the drawbacks. These proposals relate to modifications of the proposed REACH regulation as well as to guidance on and instruments for its implementation.

One registration per substance (OSOR)[11]

There are various well justified reasons for generating one single consolidated data set on hazard information under REACH for substances with the same identity (defined by CAS number, impurities and distribution of isomers), but produced or imported by different companies and at different tonnage bands:

- one consolidated data set would reduce the problem of conflicting information for the users of substances.
- The costs of additional testing would be reduced for each company, since all existing information can be used and additional testing is only carried out once. Importers and late registrants could “buy in” to an existing data set with low administrative expense. This model is particularly suited to those information requirements where testing is not related to specific exposure patterns.

10 In the supply chain of paints, the ratio also includes new raw materials without parallel removal of others from the portfolio.

11 One substance - one registration

- The impacts on competition related to “early” and “late” registration of the same substance in different tonnage bands would be reduced. Otherwise, for a number of years, the same substance produced by different companies at different tonnage bands would exist on the market with different levels of safety documentation.

An accurate definition of the identity of a substance is essential for this approach in order to avoid substances with high degrees of impurities being registered together with “clean” substances.

This proposal would only affect those areas where more than one producer and/or importer places the same substance on the EU market and where the costs of co-operation among competitors do not exceed the net cost savings for all. For example, OSOR would be effective for surfactants in cleaning agents and less effective for specific functional additives in paint. In addition, the effectiveness of the OSOR approach depends on whether the data sharing mechanisms cover all the hazard data and not just results from vertebrate studies.

Knowledge management on the basis of REACH Annexes I – IX

The registration costs for a company depend on the information requirements themselves and on the strategy chosen by the manufacturer to meet these requirements. This includes the definition of exposure scenarios for safe use and decisions for further testing if hazards are indicated based on screening information. But there is also a type of cost which is not driven by risks (resulting from hazards and intended use) and which cannot therefore be avoided by a safer design of products or changes in the conditions of use. In order to avoid substance withdrawal triggered by costs rather than risks, additional options should be explored of how to link the information requirements more closely to potential risks and how to reduce the testing costs. Examples for such options are:

- options to waive the tests for reproductive and development toxicity for substances from 10-100 t/a if an appropriate exposure assessment is available; and/or
- the use of non-test based techniques to predict the skin sensitising potential of the substance or the potential for adverse effects on reproduction and development.

Both strategies require more development in the next few years since the instruments are not yet readily available. Which of the two strategies will turn out to be more effective cannot be predicted at the moment.

For substances with a production volume below 10 tons per year, the current information requirements do not provide a sufficient basis for the systematic identification of

hazards and risks. Without significant additional burdens, the potential of REACH to identify risks could be increased by the following modifications:

- the minimum information requirements (Annex V) should include the endpoints related to acute toxicity and biodegradation.
- The required substance information is insufficient to classify substances with regard to long-term or repeated exposure. In order to derive appropriate risk management measures, types of uses should be specified in the registration which result in long-term or repeated exposure.

Use and exposure categories

The type and conditions of use related to substances in paints, cleaning agents or other preparations vary widely across the market. In order to facilitate communication on uses and exposure up and down the supply chain, a categorisation system is needed. Nearly all the companies interviewed proposed “exposure categories” as a strategy to make REACH workable. Such a system must

- provide a “standard language” on exposure across all levels in the supply chain,
- ensure that details on uses can be kept confidential in order to prevent unwanted leaks of know how,
- ensure that sufficient flexibility is maintained with regard to the modification of uses,
- localise a clear responsibility for every actor in the chain concerning his contribution to the safe use,
- enable the grouping of similar exposure cases into one category determined, for example, by route of exposure, location of exposure, duration and frequency of exposure, expected level of exposure, risk management measures.

The current Annex I of REACH leaves room for using categories in exposure assessment. However, it does not suggest any standard system. Several systems to classify use patterns and potential exposure are already in use such as, e.g. i) the industry and use categories in the EU Technical Guidance Document on Risk Assessment (TGD), ii) generic emission scenarios for certain sectors, processes or products (as agreed at OECD level) or iii) standard control measures related to the type of workplace, activity

and hazard of a substance (TRGS 430[12] and COSHH essentials[13]). Thus, these systems could be further developed for practical use under REACH.

Development of instruments and methods (RIP process)

The companies interviewed during this study did not see the flexibility incorporated into the Annexes I and V to IX in the current REACH proposal as an opportunity to implement the objectives of REACH in a pragmatic way. They were clearly concerned about being exposed to different interpretations by authorities in dossier evaluation. Also, companies expect authorities to always request complete data of the highest quality. In return, authorities expect companies to avoid the disclosure of information and additional testing wherever they can.

The instruments needed to implement some of the key tasks under the REACH system are not yet available. This applies, for example, to the instruments related to exposure assessment and the integration of risk management into chemicals' safety assessment. There is also a need to develop rules on how to interpret the flexibility with regard to the use of existing data, sufficiently validated QSARs, group assessment or waiving.

If authorities and industry co-operate in developing workable solutions for the implementation of REACH, this will also create the confidence needed to shift responsibility from the authorities to industry. Companies would provide the experience of acting in the market; authorities would contribute their experience related to risk assessment, knowledge of databases and assessment methodology. Hence, it is to be recommended that the *REACH Implementation Projects* (RIP) should start soon and involve both companies and authorities. Progress should be communicated within the networks of the parties involved. Such processes should continue in parallel to the implementation of REACH in a way that newly gained experiences could be used to further develop the instruments step-by-step. Based on experience from the first registration and evaluation phase (the first five years after REACH has been enforced), the various techniques to predict hazards and risks could then be further developed (e.g. QSARs and exposure modelling).

Information about REACH for companies

During the interviews it became obvious that the companies at all three levels of the supply chain need more precise information on the specific requirements relevant to

12 Technical rules or guidance on hazardous substances (GER)

13 Control of substances hazardous to health (UK)

them, and on the role they are to play in the overall REACH system. At formulators' level, there is a considerable degree of misunderstanding related to i) the need to carry out safety assessments at downstream user level, ii) how uses and exposure scenarios will be defined and iii) the type of know-how to be potentially disclosed. There was also a high degree of uncertainty related to the various REACH processes at EU level and the best way to prepare for REACH in the current situation. One of the difficulties in developing realistic expectations regarding the potential impacts of REACH at formulators' level relates to the fact that the number of substances to be potentially registered by the substance manufacturers is unknown at the different tonnage bands. It may therefore be beneficial for formulators, as well as for producers of substances, if the knowledge about the type and number of substances to be registered for a particular chain were to be increased at company or association level already now. The same applies to the definition of the relevant standard exposure situations for substances during the use of preparations. This would enable substance manufacturers to cover the relevant uses and exposure scenarios for their preparation from the beginning.

In the light of these insights, it becomes clear that companies need accurate and reliable information addressing their specific role in the future REACH system and how they can begin to prepare for REACH now. In turn, this requires neutral and reliable information produced under the responsibility of public authorities and practical support being given to the companies by the industrial associations.