REACH - further work on impact assessment
A case study approach
Final report

July 2005
KPMG Business Advisory Services
REACE1/RR/mh
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Abstract

Objective of the study

From March 2004 to April 2005, KPMG carried out a business impact assessment of REACH, the proposed new European legislation for the management of chemicals in the EU (October 2003). This was done within the framework of a Memorandum of Understanding (MoU) between the European Commission (DG Enterprise and DG Environment) and industry (UNICE/CEFIC).

The study was monitored by a multi-stakeholder group that included trade unions, environmental and consumer NGOs and that was chaired by the European Commission. The goal of the study was to examine the mechanisms of business decisions under REACH throughout the value chain. This was done through a series of ‘case studies’ around certain preparations in four sectors: automotive (paints, engine oils, metal working fluids), electronics (printed circuit board assembly preparations), flexible packaging (inks, varnishes and adhesives) and (in)organics (steel, non-ferrous metal, paper and cement). The insight gained from the study is intended to provide input for the legislative process. The process was kept fully transparent to all parties involved who contributed to the study in a constructive manner.

The study was not intended to quantify direct or indirect costs from a macro-economic perspective, but to develop a better understanding of the mechanisms through which registration under REACH may impact on the following areas: availability of substances and materials, the competitive position of EU companies in global supply chains, innovation, business benefits and recycling and recovery in the (in)organics sector.

The findings from three of the sector studies have been subject to external verification by independent experts hired by the European Commission, with positive results. External verification could not be organised for the electronics sector report within the timeframe of the study, nor has a full sectoral validation taken place in a workshop setting. Instead, a meeting with representatives of the downstream users was arranged.

Main findings of the study

1) Critical substances are not likely to disappear under REACH for economic reasons

Substances that are critical for the performance of products of downstream users are not likely to disappear from the market because of REACH testing and registration costs. Chemical suppliers are well aware that withdrawal of substances from the market would lead to costly reformulation and re-engineering downstream for formulators and downstream users. Taking the process costs of your customer into account in business decisions is a prerequisite for being active as a supplier in the sectors studied.

Besides these market considerations, registering instead of withdrawing substances might also be the most favourable option for chemical suppliers from an economical point of view. Several specialty chemical suppliers are formulators themselves. They sell most of their substances as formulations or ‘packages’ with a certain functionality. By registering most of their substances under REACH they can prevent costly reformulation of many of their own products.
Registration of a large part of the portfolio will, however, increase the product cost, especially for substances manufactured or imported in lower volumes. In the case studies, eleven substances have been identified where the registration costs exceed the expected future profits for these particular substances and ten of those are produced or imported in quantities lower than 100 tpa.

Although the registration costs are ‘one-off’ costs and not recurring, they may represent a substantial part of a company’s profit in any one year. It will also affect companies with limited financial resources. Companies will therefore look for options to reduce these costs. There are two strategies that companies seriously consider: forming consortia with other companies registering the same substances (1) and/or rationalising the portfolio before registration (2). This rationalisation of product portfolios will be done after discussions with the customer and will focus primarily on substances of less critical importance to customers and of less strategic importance within the portfolio.

In general, the mechanism described above leads to critical substances and preparations remaining available for downstream users. However, some key preconditions have to be met for the mechanism to work for each individual company. If not, there is a risk that critical substances may end up being withdrawn after all. Firstly, there has to be appropriate transparency and communication in the supply chain; otherwise a chemical supplier may not be aware of the importance of their products downstream. Secondly, a company has to be able to fund the direct registration costs. If a company is not able to form consortia (for instance, because of confidentiality reasons), or has many substances that have to be registered (for instance, because the fraction of polymers, which are exempt from REACH, in the portfolio is low) or has difficulties to get external money (for instance, because it is an SME), the company might have difficulties doing so. The study showed that the registration costs can account for up to 20% of a smaller company’s annual turnover. Finally, the company should be able to absorb or pass on the costs. The preconditions described here are to be taken seriously as the study also pointed out that if critical substances were withdrawn, the impact downstream could be significant.

2) REACH costs have to be absorbed in the supply chain

Keeping most of their products on the market will lead to a significant increase of the product costs for chemical suppliers. For instance, the increase in product cost of pigments & additives as a result of REACH testing and registration can be up to 20%. Although the registrant has to meet these costs just once and not every year, these costs still have to be either absorbed or passed on. The case studies show that it is often difficult for suppliers to pass on the registration costs to the customer for existing products. Chemical suppliers and formulators expect, however, to be able to pass on the costs through new products, in combination with offering improved functionality. The necessary sales price increases will be less visible further down the supply chain. That is because the costs get diluted as other major components in the products that were studied are either exempt from REACH or expected to be less vulnerable as they are produced in larger volumes. This might be different for other products than the ones that were studied, but in general, direct REACH costs will have limited impact on the profitability of actors in the supply chain. However, downstream users are not always in a position to accept extra costs and even a low impact on profitability could be a serious issue given the overall pressure on profitability in globally operating industries.
3) At smaller companies (SMEs) stress factors accumulate

It is more difficult for SMEs to fulfil the preconditions to be able to cope with REACH than it is for larger companies. It is generally more difficult for smaller companies to fund the registration costs. Also, in general, it may be more difficult to pass on the cost downstream as a result of limited negotiation power. In addition, smaller chemical suppliers generally produce in the smaller volume bands (< 100 t p.a.), where most of the vulnerable substances in this study have been found.

4) Potential effects of portfolio rationalisation downstream

Though critical substances are not likely to be withdrawn from the market, registration under REACH will absorb a substantial part of chemical suppliers’ profits and, in addition, the SMEs amongst them will face funding difficulties. Chemical suppliers indicate that they will rationalise their product portfolios to limit the costs. They are expected to withdraw primarily non-critical substances before the registration deadlines. The main downstream concern is that substances earmarked for non-registration and withdrawal will be kept on the market as long as legally possible. This makes economic sense from a supplier’s point of view, but will result in a concentration of these withdrawals over limited periods of time just before the registration deadlines for the lower volume bands. As a consequence, any resulting reformulation work downstream will also need to be concentrated over short periods of time and cannot be synchronised with otherwise necessary product development. This can lead to capacity problems and, as a consequence, the temporary inability to supply customers. A simulation conducted by the Flexible Packaging sector showed that a small percentage of withdrawal of chemicals can give rise to a percentage wise much larger need for reformulation.

5) Concerns about the extent and timing of possible future restrictions under REACH

According to the REACH proposal, a substance may be subject to Community-wide restrictions if it is demonstrated that risks cannot be adequately controlled. Concerns have been encountered at downstream user level about the extent and timing of possible future restrictions under REACH. Recent cases of substance loss have been studied and they showed that withdrawal of substances can result in major costs because of reformulation and re-engineering, particularly if not synchronised with development and product cycles. This may divert resources from market-driven activities, thereby affecting the competitiveness of EU producers.

6) Companies do not plan to increase R&D budgets

Companies included in the study do not plan to increase their budgets for research and development (R&D). They will give priority to keeping existing substances and formulations on the market to avoid problems down the supply chain. The more rationalisation of the product portfolio can be limited, the more resources will remain for innovation in the chain.
7) Narrowly defined ‘identified use’ may reduce business flexibility

The concept in REACH of ‘identified use’ may, if defined to narrowly, slow down changes to manufacturing processes. It will make it more difficult to solve problems arising in production that require an immediate reaction (‘trouble-shooting’). That is because the new ‘use’ that fixes the problem has to be registered in advance, but it is difficult to foresee all the potential problems. The scale of the problem very much depends on the actual implementation of the concept of ‘identified use’, which is generally perceived as unclear by many of the companies.

8) Loss of confidential business information (CBI) is a threat for enterprises

Information on the composition of preparations and their use appeared to be highly sensitive at all levels: chemical supplier, formulator and downstream user. Under REACH, sensitive market information has to be disclosed during the registration process and comprehensive information about the composition of a preparation is required. Confidential business information is crucial for the competitiveness of the participating companies and for recovering their R&D investments.

9) REACH will facilitate risk management

Companies expect REACH to improve the availability and quality of information on substances and preparations, which will facilitate risk management. In some cases the benefits to business are perceived to be low because existing legislation already provides sufficient information (e.g. food contact materials). Companies do not expect REACH to bring additional business either.

10) REACH requirements impose a high level of uncertainty to recycling/recovery business

The case study covering (in)organics (metals, paper and cement) shows that REACH definitions and concepts are difficult to apply to the highly complex primary and recycling / recovery materials. This unclear scope, interpretation and application of REACH leave those industries with open-ended questions and planning uncertainty.

The composition of recyclables and recoverables is variable and the precise origin unknown; therefore, frequent testing would be necessary in order to meet REACH requirements. If they remain within the scope of REACH and these frequent analyses were required, their higher registration costs could push companies to shift back to the use of primary materials and fuels.
2  Background and issue of this study

2.1 Memorandum of Understanding

Since the REACH proposal was adopted by the Commission in October 2003, studies have been performed by several parties into the expected business impact of REACH. Nevertheless, discussions about the possible impacts of REACH continued. The European Commission and UNICE/CEFIC therefore agreed on a Memorandum of Understanding to undertake further work concerning the impact assessment of REACH (MoU, 3 March 2004).

It was agreed that the further work would be carried out through a series of business case studies. The actual workings of the REACH proposals would be illustrated in specific situations. This would allow for a detailed diagnostic examination of the reasons for particular impacts, allowing for the identification of potential remedies.

According to the MoU, a Working Group was established with the aim of monitoring the progress of the study. The Working Group consists of representatives from:

- The Commission (DG ENTR, DG ENV, ECFIN) and JRC.
- The industry: UNICE and CEFIC.
- The industrial sectors involved in the case studies.
- User or retailing sectors not included in the scope of the studies.
- Small and Medium-sized Enterprises.
- Environmental NGOs (EEB, WWF).
- Trade Unions (ETUC, CES EMCEF, DGB).
- Consumer organisation (BEUC).

The Working Group would give its views on the methodological approach and any interim and final reports. The aim is to gain broader support for the study by means of a mutually agreed and transparent methodology. The Group will communicate its views to the High-level Group.

According to the MoU, a High-level Group has been set up to oversee the work. It provides a forum for high-level dialogue between stakeholders and the Commission, Council (Presidency), and European Parliament, and gives overall direction to the exercise.

This study by KPMG Business Advisory Services B.V. covers two of the studies mentioned in MoU:

- Analysis of the potential impacts of REACH on business throughout the supply chain.
- Analysis of the potential impacts of REACH on innovation.
The study is commissioned by an industry consortium consisting of:

- Cefic (chemical industry).
- ACEA (car manufacturers).
- Flexible Packaging Europe (flexible packaging manufacturers).
- REACH Alliance (a group of sectors of (in)organic materials and products manufacturers, such as steel, non-ferrous metals, paper and cement).
- AEA and JBCE (representing US and Japanese manufacturers in the electronics sector).

2.2 Objective of the study

The objective of the study is to develop a better understanding of the mechanisms through which REACH may impact on:

- the availability of substances and primary (in)organic raw materials (such as ore) to companies acting in the EU market and related reformulation / re-engineering efforts;
- the relative competitive position of EU companies in global supply chains (e.g. profitability of company operation, market shares, product quality, ...);
- innovation (e.g. in terms of R+D expenditure, performance and direction of innovation, new substances, new chemical products);
- business benefits related to workers’ safety, environmental protection and product safety (e.g. reduction of compliance costs, prevention of liability claims, etc.);
- recycling and recovery in the (in)organics sector (e.g. competitive position of secondary raw materials and fuels compared to primary raw materials).

It was thus not intended to conduct a macro-economic impact assessment resulting in additional figures on loss in GDP or employment, as this was explicitly excluded from the scope of the MoU. Neither was it intended to generalise findings regarding deselection percentages, profit losses, etc. Also excluded from the scope was the assessment of the costs and consequences of authorisations.
3 Introduction to the REACH proposal

3.1 REACH proposal in short

REACH stands for Registration, Evaluation, Authorisation of Chemicals and consists of the following elements:

- **Registration** requires industry to obtain relevant information on their substances and to use the acquired data to manage them safely.

- **Evaluation** of dossiers and substances is done by authorities, they can ask for more information if necessary.

- Risks associated with uses of substances with properties of very high concern will be reviewed and, if they are adequately controlled, or if the socio-economic benefits outweigh the risks and there are no suitable alternative substitute substances or technologies, then the uses will be granted an **Authorisation**.

- **Restrictions** may consist of conditions for the manufacture or use of a substance or of the prohibition, if necessary. The restrictions procedure provides a safety net to manage risks that have not been adequately addressed by another part of the REACH system.

3.2 Reasons for proposing a new EU Chemicals policy

The current EU legislative framework for general industrial chemicals is an assembly of many different Directives and Regulations which have developed historically. There are different rules for ‘existing’ and ‘new’ chemicals.

The current distinction between so-called ‘existing’ and ‘new’ chemicals is based on the cut-off date of 1981. All chemicals that were put on the market before 1981 are called ‘existing’ chemicals. In 1981, they numbered 100,106 different substances. Chemicals introduced to the market after 1981 (about 3000) are termed ‘new’ chemicals.

While new chemicals have to be tested before they are placed on the market*, there are no such provisions for ‘existing’ chemicals. Thus, although some information exists on the properties and uses of existing substances, there is generally not sufficient information publicly available in order to assess and control these substances effectively.

* Directive 67/548 requires new substances to be tested and assessed for possible risks to human health and the environment before they are marketed in volumes starting at 10kg. For higher volumes, more in-depth testing, focusing on long-term and chronic effects, has to be provided.

The current allocation of responsibilities is also seen as inappropriate: public authorities are responsible for undertaking risk assessments of substances rather than the enterprises that manufacture, import or use the substances. Furthermore, current legislation requires only the manufacturers and importers of substances to provide information, but does not impose similar obligations on downstream users (industrial users and formulators).
Decisions on further testing of substances can only be taken via a lengthy committee procedure and can only be requested from industry after authorities have proven that a substance may present a serious risk. Final risk assessments have therefore only been completed for a small number of substances. Since 1993, only 141 high-volume chemicals have been identified for risk assessment and possible recommendations for risk reduction, of which only a limited number (27) have completed the process.

Finally, new chemicals have to be notified and tested starting from volumes as low as 10kg per year. This has been a barrier to innovation within the EU chemicals industry by favouring the use of existing substances over new ones.

3.3 How REACH is supposed to work

In the White Paper on the Strategy for a Future Chemicals Policy, published in February 2001 (COM (2001) 88), the Commission outlined the result of a review of the current system and its ‘new strategy for ensuring a high level of chemicals safety and a competitive chemicals industry through a system for the Registration, Evaluation and Authorisation of Chemicals – the REACH system’. This vision was laid down in a draft proposal for a regulation that was submitted to all interested parties by means of an internal consultation in May 2003. The responses have led to an adjustment of parts of the proposal. The second version (and final and approved Commission proposal) was submitted to the European Parliament and the Council. This version forms the starting point for this study. Below, some of the obligations of the proposal that are relevant for the context of the study are described.

3.3.1 Registration

A European Chemicals Agency (ECA or ‘Agency’) is created to manage the technical, scientific and administrative aspects of the REACH system, and to ensure consistency of decision-making at Community level.

Substances on their own or in preparations

There is a general obligation for manufacturers and importers of substances to submit a registration to the Agency for each substance manufactured or imported in quantities of 1 tonne or above per year. Failure to register means that the substance is not allowed to be manufactured or imported.

The Regulation exempts certain substances that are adequately regulated under other legislation, such as medicinal products, or that generally present such low risks as not to require registration, such as water. Polymers are also exempt from the requirement to register, since they usually are not very hazardous; however, the registration of polymers may be reviewed later.

Manufacturers and importers of substances will need to obtain information on the substances they manufacture or import and use this information to assess the risks arising from the uses and to ensure that the risks which the substances may present are properly managed. Registration documents the performance of this duty and requires manufacturers and importers to submit:
a technical dossier and

- a chemical safety report for substances in quantities of 10 tonnes or more.

The technical dossier contains information on the properties, uses and on the classification of a substance, as well as guidance on safe use. To find out the properties of the substances, the information requirements in the testing annexes vary according to the tonnage in which the substance is manufactured or imported, and to the needs of the chemical safety assessment. The tonnage ‘trigger’ is chosen ‘as it gives an indication of the potential for exposure’.

The chemical safety report (CSR) for substances manufactured or imported in quantities starting at 10 tonnes, documents the hazard classification of a substance and the assessment as to whether the substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB). The CSR also describes exposure scenarios for specific uses of substances classified as dangerous and for PBT and vPvB substances.

Exposure scenarios are sets of conditions that describe how substances are manufactured or used during their lifecycle and how the manufacturer or importer controls, or recommends to control, exposures of humans and the environment. The exposure scenarios must include the appropriate risk management measures that, when properly implemented, ensure that the risks from the uses of the substance are adequately controlled.

Exposure scenarios need to be developed to cover all ‘identified uses’, which are the manufacturers’ or importers’ own uses, and uses which are made known to the manufacturer or importer by his downstream users and which the manufacturer or importer includes in his assessment. Relevant exposure scenarios will need to be annexed to the safety data sheets that will be supplied to downstream users and distributors.

To reduce costs for industry and authorities, it is possible for registrants to form consortia, in which case information on the properties of the substance and its classification is submitted by one member of the consortium on behalf of the others.

Registration deadlines for substances depend on the tonnage ranges at which they are manufactured or imported per manufacturer or importer. The tonnage ranges > 1000 tpa, 100-1000 tpa and 1-100 tpa have to be registered within 3, 6 and 11 years after entry into force of REACH respectively. Substances that are carcinogenic, mutagenic or toxic for the reproduction (CMR substances) have to be registered within the 3-year time period.

Substances in articles

For the registration of substances in articles (e.g. manufactured goods, such as cars, textiles, electronic chips), a special regime applies. REACH requires certain substances that have been incorporated into articles to be registered according to the normal rules if those substances meet criteria for classification as dangerous and are intended to be released from the article during normal and reasonably foreseeable conditions of use. For substances that are not intended to be released, but may be released incidentally to the use of the article, a simple notification is required, on the basis of which the Agency may request a registration. The volume thresholds are as for any substance manufactured in, or imported into, the EU and apply per article type. The registration deadline is 11 years plus three months after the entry into force of the Regulation.
Information in the supply chain

The primary tool for information transfer is the already established safety data sheet (SDS) for all dangerous substances. The provisions of the current Safety Data Sheets Directive (91/155/EEC) are carried over to the REACH Regulation. As more information will be available as a result of registrations, the amount and quality of the data in the safety data sheets will increase. Where chemical safety assessments are performed according to the registration requirements, relevant exposure scenarios will be annexed to the safety data sheet and will thus be passed down the supply chain.

Downstream users (including formulators) are required to consider the safety of their uses of substances, based primarily on information from their suppliers, and to apply appropriate risk management measures. Downstream users will need to communicate effectively with their manufacturers or importers, to get the information they need in the safety data sheet supplied to them. In particular they will have to check that their use(s) are ‘covered’ by the safety data sheets, i.e. that they use a substance within the conditions described in the exposure scenarios in the Annex to the SDS, and apply these conditions.

To get the right information, downstream users have the right to make their uses known to their manufacturers or importers so that the manufacturers or importers can include these uses in their chemical safety assessments as ‘identified’ uses. The relevant exposure scenarios developed for these uses will need to be annexed to the safety data sheets.

A downstream user can also choose to keep his use confidential or decide to use a substance outside the conditions described in an exposure scenario communicated to him. In these cases, he will have to perform a chemical safety assessment himself: the downstream user chemical safety assessment consists of developing the exposure scenarios for his intended uses and, if necessary, a refinement of the supplier’s hazard assessment.

3.3.2 Evaluation

Evaluation of dossiers as well as substances under REACH is done by the Member State authorities. Evaluation may lead authorities to the conclusion that action needs to be taken under the restrictions or authorisation procedures (see below).

3.3.3 Authorisation & restrictions

For substances of very high concern, authorisation is required for their use and their placing on the market. Downstream users may use a substance for an authorised use provided they obtain the substance from a company to which authorisation has been granted, and they keep within the conditions of that authorisation. Such downstream users will need to notify the Agency that they are using an authorised substance.

Any substance on its own, in a preparation or in an article may be subject to Community-wide restrictions if it is demonstrated that risks are not adequately controlled. Thus, the restriction provisions act as a safety net. Interested parties will have an opportunity to comment and the Agency will provide opinions on any proposed restriction.
4 Approach of the study

4.1 The contributing sectors

The study has been carried out through a series of case studies of commonly used categories of preparations and materials and their suppliers in four industry sectors:

1. automotive;
2. (in)organic materials;
3. flexible packaging;
4. electronics.

4.2 Selected supply chains and materials for the case studies

In each of the four industry sectors mentioned above, in cooperation with the sector organisations, and discussed in the Working Group, two to four cases have been defined around one commonly used class of end-use materials of ‘critical’ importance at downstream user level (Table 4.1). In the context of the study, ‘critical’ refers to a substance, preparation or material essential for the technical performance of the product or process it is used in.

<table>
<thead>
<tr>
<th>Sector</th>
<th>DU</th>
<th>End-use materials selected for case studies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automotive</td>
<td>2 car manufacturers</td>
<td>Engine oil / metal working fluid/paint</td>
</tr>
<tr>
<td>(In)organic sector</td>
<td>4 (In)organic producers</td>
<td>Steel/paper/cement/zinc</td>
</tr>
<tr>
<td>Flexible packaging</td>
<td>2 Converters</td>
<td>Inks/varnishes/adhesives</td>
</tr>
<tr>
<td>Electronics</td>
<td>2 Printed Circuit Board assemblers</td>
<td>Assembly preparations</td>
</tr>
</tbody>
</table>

Table 4.1: Selected end-use materials for the case studies per sector

The selection of cases was based on the following criteria:

- Core aspects of REACH registration can be studied.
- Substantial relative economic significance for the value chain.
- Fundamental part of final product of the value chain.
- Company actor’s awareness of REACH requirements and willingness to contribute.
**Terminology**

The terminology used for the actors in the supply chain differs per sector. In the table below, the terminology used is reflected per sector. ‘Chemical supplier’ is equivalent to the material provider in the (in)organics sector, unless stated otherwise.

<table>
<thead>
<tr>
<th>Automotive, electronics and flexible packaging sector</th>
<th>(In)organic sector</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical supplier (CS)</td>
<td>Material provider (MP): Provider of raw materials to the (in)organic producer.</td>
</tr>
<tr>
<td>Formulator (F)</td>
<td>not applicable</td>
</tr>
<tr>
<td>Downstream user / converter (DU)</td>
<td>(In)organic producer (IP): producer of (in)organic materials by using raw materials</td>
</tr>
</tbody>
</table>

*Table 4.2: Differences in terminology per sector*

In total 10 case studies were carried out (see Table 4.1), one DU involved in each case study (see table below).

<table>
<thead>
<tr>
<th>Level</th>
<th>Automotive</th>
<th>(In)organics</th>
<th>Flexible Packaging</th>
<th>Electronics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical suppliers / mat. providers</td>
<td>3</td>
<td>5</td>
<td>4 (+ 5 for extra check)</td>
<td>2</td>
</tr>
<tr>
<td>Formulators</td>
<td>4</td>
<td>n.a.</td>
<td>4</td>
<td>2</td>
</tr>
<tr>
<td>Downstream users / (in)org producers</td>
<td>2</td>
<td>4</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

*Table 4.3: Number of participating companies per sector and supply chain level*

In the table below, the division of the participating companies in large companies, smaller companies (SMEs) and importers is given. All participating SMEs are independent companies. Two of them (one formulator and one chemical supplier) are highly innovative, which means that they continuously develop new preparations and substances and that these cover almost their entire portfolio.

<table>
<thead>
<tr>
<th>Level</th>
<th>Larger companies</th>
<th>SMEs</th>
<th>Of which importer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical suppliers/ material providers</td>
<td>11</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Formulators</td>
<td>6</td>
<td>4</td>
<td>-</td>
</tr>
<tr>
<td>Downstream users / (in)organic producers</td>
<td>10</td>
<td>-</td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>27</td>
<td>6</td>
<td>5</td>
</tr>
</tbody>
</table>

*Table 4.4: Distribution of large, smaller (SME) and importing companies participating per supply chain level*
4.3 Issues agreed upon in advance

4.3.1 Testing costs

The standardised costs for testing and registration to be used in this study were agreed in the Working group meeting of 8 December 2004 (excluding EEB and WWF). For the registration costs, the ECB and RPA study results\(^1\) have been used, with the addition of registration and evaluation fees and adaptations due to the absence of the Chemical Safety Report requirement for low volumes. Regarding the testing costs, this study uses the ECB scenarios with preference for the so-called ‘minimum QSAR’ scenario, as the real contribution of computer-based alternatives for testing is still debated in scientific circles.

<table>
<thead>
<tr>
<th>Individual registration costs (minimum QSAR)</th>
<th>Total test cost</th>
<th>Registration costs</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>V 1-10 tonne</td>
<td>8.702</td>
<td>5.900</td>
<td>14.602</td>
</tr>
<tr>
<td>VI 10-100 tonne</td>
<td>151.573</td>
<td>11.150</td>
<td>162.723</td>
</tr>
<tr>
<td>VII 100-1000 tonne</td>
<td>243.467</td>
<td>38.630</td>
<td>282.097</td>
</tr>
<tr>
<td>VIII &gt; 1000 tonne</td>
<td>278.213</td>
<td>44.950</td>
<td>323.163</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Consortia registration costs (minimum QSAR)</th>
<th>Total test cost</th>
<th>Total registration cost pre-reg and fees (per firm)</th>
<th>Total per firm - 2 firms</th>
</tr>
</thead>
<tbody>
<tr>
<td>V 1-10 tonne</td>
<td>8.702</td>
<td>24.000</td>
<td>633</td>
</tr>
<tr>
<td>VI 10-100 tonne</td>
<td>151.573</td>
<td>29.250</td>
<td>633</td>
</tr>
<tr>
<td>VII 100-1000 tonne</td>
<td>243.467</td>
<td>59.130</td>
<td>3.167</td>
</tr>
<tr>
<td>VIII &gt; 1000 tonne</td>
<td>278.213</td>
<td>86.450</td>
<td>3.167</td>
</tr>
<tr>
<td>Number of firms</td>
<td>2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Considerations

1. Testing cost:
   - Scenarios of the ECB studies
   - Scenario with minimum use of QSAR’s

2. Registration costs: use RPA study as basis and make following adjustments:
   - Annex V no longer require a CSA and CSR. Only overhead administrative costs will be needed
   - Registration and evaluation fees are added.

3. Distinguish between individual registration and consortium registration (two firms).

Table 4.5: Standardised testing and registration costs applied in this study

4.3.2 Methodology

From the suggested and agreed-upon (not by EEB/WWF) production processes (Table 4.1), preparations, substances or materials of critical importance (to the performance of that production process or to the quality of the product as a result of that process), were selected. These preparations and substances have been investigated throughout the supply chain.

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KPMG developed a spreadsheet to be used during data collection and for documenting the findings at company level throughout the supply chain. It has been discussed and amended by the Working Group several times with input from all the stakeholders. At the 8 December 2004 Working Group meeting, the Working Group finally endorsed the methodology spreadsheet (excluding EEB and WWF).

The spreadsheet integrates the methodology for establishing substance vulnerability under REACH and the questions to be asked during the interviews at the various supply chain levels. In the table below, a summary is given of the spread sheet. Where relevant, timing aspects were studied for the various issues.

<table>
<thead>
<tr>
<th>Sheet</th>
<th>Function</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Summary</td>
<td>Summarises all findings of the impact sheets at plant level</td>
</tr>
</tbody>
</table>
| 2. Context | Provides information on:  
  - the characteristics of the company (large or small; manufacturer or importer; chemical supplier, formulator or downstream user),  
  - the economical strength of the company and  
  - the business environment in which it operates. |
| 3. NPV (for chemical suppliers only) |  
  - Net Present Value (NPV) method which identifies vulnerable substances.  
  - A substance is regarded vulnerable if the testing and registration costs exceed its net present value of expected future profits.  
  - Because the due date and thus timing of registration may vary per substance, all cash flows are made present to the year 2005.  
  - The NPV method is not used in the (in)organic sector. |
| 4. Impact on: - Availability |  
  - These sheets aim to define the impact on ‘availability, competitiveness, innovation, benefits and recycling/recovery’.
| 5. - Competitiveness |  
  - The impact of REACH is determined against the ‘baseline’ scenario (i.e. expected normal evolution without REACH) |
| 6. - Innovation |  
  - The impact is determined for the selected critical substances and for the total portfolio. |
| 7. - Benefits |  
  - Recycling & recovery ((in)organics only) |

Table 4.6: The various sheets in the methodology spreadsheet and their function

The investigation at the selected companies took place at two levels:

1. **General level**

   - Asking for context, issues, decision-making process.
   - Asking for expected impact of REACH on whole portfolio.
2. Preparation and/or substance level

- How and why REACH will (will not) impact the selected critical preparations/substances.

- Events in the past with other preparations/substances.

The findings gathered at company level can therefore constantly be checked against or challenged by those gathered at substance level. The questions obtained at the two different levels are distinguishable in the methodology spreadsheet by a colour code: ‘green’ for company level and ‘orange’ for substance level (see table below).

<table>
<thead>
<tr>
<th>Level</th>
<th>Question</th>
<th>Parameter</th>
<th>Answer</th>
<th>Timeframe</th>
<th>REACH</th>
<th>Comments</th>
<th>Evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>F</td>
<td>MP I R&amp;D expenses</td>
<td>per year</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>CS</td>
<td>What are the companies total R&amp;D expenses per year?</td>
<td>EUR</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>DU</td>
<td>What are the companies total R&amp;D expenses per product group?</td>
<td>EUR</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

Sample

Level (CS, F, DU) to which the question applies

Question

To be expressed as (units)

Table 4.7: Sample of the methodology spreadsheet

Limitations

This case study also has some limitations:

- the amount of substances/materials studied is limited; cumulative effects are not considered;
- the number of suppliers investigated in each supply chain is limited;
- only financial/economic impact (not extent of restriction for toxicological reasons) studied;
only direct cost for registration of (in)organics was studied (while direct and indirect cost for other cases);

direct and indirect impacts of authorisation not included/quantified for all case studies.

Literature
The study was carried out in accordance with the case study approach described in literature by Eisenhardt (1989). This implies that:

- the study is focused on useful cases, rather than randomly selected cases;
- multiple data collection methods are used;
- qualitative and quantitative data are combined;
- there is overlap of data collection and analysis;
- the focus is on the search for ‘why’ behind relationships;
- there is within case analysis as well as cross-case pattern search;
- the researchers will operate with an ‘open mind’ without preconceived ideas.

While the general approach of this study have been explained in this chapter, in the next chapter the working process is described in more detail.

5 Working process

The companies at each supply chain level (CS, F, DU) are typically visited twice, as is represented in the table below. The first visits took place in the order downstream user (DU), formulator (F) and chemicals supplier (CS). These were called the ‘bottom-up interviews’. These interviews consisted of:

- a kick-off meeting to explain the study and methodology;
- the gathering of company and market context data;
- selecting critical materials and their suppliers to focus on; and
- determine vulnerability of these substances at CS level.

One or more weeks later, a second interview was held with the companies in the order CS, F, DU. These were called the ‘top-down interviews’. At these interviews, the relevant staff (purchase manager, HSE manager, marketing & sales manager, production manager) of the companies were available and they typically involved:

- analysing the market situation*;
- determining the reaction towards and the impact of REACH; and
- gathering supporting evidence for this.

*For this purpose, the F and DU were confronted with the reaction of their supplier (e.g. withdrawal or price increase of substances or preparations). In cases where vulnerability at CS level does not occur or the company does not permit the information to be passed on downstream, a scenario was used in order to show the potential impact of a certain level of withdrawal or price increase. Potential findings and conclusions of these scenarios are clearly identified as such.
Table 5.1: Working process of this study: materials and suppliers are selected bottom-up and the reaction and impact are determined top-down the supply chain. CS: chemical supplier; F: formulator; DU: downstream user.

The working process was the same for each sector and is explained below. However, specific elements can vary per sector, for instance, because of sector specific wishes for certain additional information or sector specific confidentiality constraints. Further sector specific details can be found in the Annexes.

5.1 ‘Bottom-up’ in the supply chain

1. At downstream user level, determine suppliers. The selected end-use materials (Table 4.1) generally are complex preparations (such as paint) containing up to 30 substances. The supply chains of these end-use applications are too complex to analyse completely within the scope of this study.

   - Therefore, at downstream user level, one or two classes of these materials are selected to focus on (such as base coat and clear coat paint).

   - Also, just one or two suppliers (formulators) of these materials were selected to be asked to participate in the study. The selection was made based on the same criteria as those used for selecting the cases:

     - Core aspects of REACH registration can be studied (possibility of deselection, innovation, benefits).
     - Relative economic significance for the value chain.
     - Fundamental part of final product of the value chain.
     - Company actor’s awareness of REACH requirements and willingness to contribute.
2. **At formulator level, the critical substances and suppliers are determined.** At formulator level, one or more functional categories of substances (Inorganic sector: supply materials at the level of the IP) of ‘critical’ importance were selected in the preparations. For this functional category of substances (example: ‘antifoam additives’ for paint), the suppliers are identified and asked to participate in the study. In the context of the study, ‘critical’ refers to a substance, preparation or material essential for the performance of the product or process it is used in.

3. **Involving companies.** The selection of suppliers was done in a rather pragmatic way since much depends on the willingness of the companies to contribute to the study. Confidentiality undertakings were drawn up with the companies to ensure that the necessary sensitive business information could be made available to KPMG.

4. **At chemical supplier level, determine the vulnerable substances.** The vulnerability of the selected critical substances was determined using the NPV (net present value) method, which compares the costs of registration of a substance to the expected future profits.

- In the context of the study, a substance is regarded ‘vulnerable’ if the REACH registration costs exceed the net present value of expected future profits.

- If possible, a larger sample of the portfolio has been put through the NPV method, to get an impression of the overall vulnerability of the portfolio and to be able to study the reaction of the chemical supplier towards possible vulnerable substances.

- Because not all substances are marketed as such, but in combination with other substances (‘package’), an estimation of the profit margin was necessary. The profit margin as a percentage of the end product of the chemical supplier is assumed to be the margin of the substance under investigation. Besides that mechanisms of REACH effects to these substances are studied.

- The NPV method is not applicable to the (in)organics sector, because withdrawal of the selected materials will not take place. Here scenarios are used to assess the direct cost effects of the different possible interpretations of REACH (see box below).

---

**Note on the (in)organic sector**

In the (in)organic sector, the scope is the raw materials and fuels derived either from nature or from recycling and or recovery and not the end-use materials downstream.

At the start of the study, the primary and secondary raw materials and alternative fuels had already been selected (iron ore, recovered paper, paper pulp, zinc concentrate, old tyres, blast furnace slag and fly ashes for cement). **The focus is on ‘how’ REACH should be interpreted and ‘what if’ those interpretations did take place.**

The interpretation of REACH for the (in)organic sector is perceived as being not clear to the sector. Therefore, scenarios are used to assess the direct cost effects of the possible different interpretations of REACH. The scenarios are compiled in close cooperation with the (in)organic producer and the material provider.

Finally the company responsible for registration selected a **vulnerable and likely** scenario (which is its task according to REACH requirements; at present no clear guidance available). ‘Vulnerable’ stands for ‘with high direct cost’. ‘Likely’ stands for ‘a likely interpretation of REACH’ in the eyes of the registrant). The scenario selected could be either the worst-case scenario in terms of the highest direct costs for testing and registration of the material and/or the scenario that is the most likely for the registrant. With these scenarios, the mechanism of REACH was studied.
5.2 ‘Top-down’ in the supply chain

1 At chemical supplier level, determine impact and reaction. The economical vulnerability of a substance is just one of the criteria a chemical supplier might apply when determining its response to the REACH requirements. Profitability and market considerations can also be of importance and therefore these have also been analysed. Determined are:

- The impact on the company (availability, competitiveness, innovation, benefits, etc.).
- The reaction (likelihood of withdrawal, the possible extent of price increase or the likelihood of replacement by an alternative).
- The market situation (in order to understand or predict the response of the formulator in the selected cases).

Note on Flexible packaging sector

In order to facilitate the information exchange between the formulator and the chemical supplier in the flexible packaging case, additives and pigments are divided in functional categories. If the chemical supplier objects to telling the formulator that a certain product might be de-selected, a similar product from the same functional category can be taken. Furthermore, rather than selecting one substance in one preparation in the flexible packaging case, several categories of additives were selected that are commonly used in different functional groups (inks, varnish and adhesives).

6. At formulator level, determine the impact and reaction. The Formulator will be confronted with the reaction of its supplier, depending on the agreed level of confidentiality (otherwise a certain level of withdrawal and price increase was assumed to be able to study the mechanisms). Determined was:

- The impact on the company (availability, competitiveness, innovation, benefits, etc.).
- The reaction (likelihood of withdrawal, the possible extent of price increase or the likelihood of replacement by an alternative).
- The market situation (in order to understand or predict the response of the formulator in the selected cases).

7. At downstream user level, determine impact and reaction. The DU will be confronted with the reaction of the formulator, depending on the agreed level of confidentiality (otherwise a certain level of withdrawal and price increase was assumed to be able to study the mechanisms). Determined was:

- The impact on the company (availability, competitiveness, innovation, etc.).
- The reaction towards the formulator.
- The market situation (in order to understand or predict the response of the DU in the selected cases).
The CS might indicate that although withdrawal of the selected investigated critical substances is not to be expected, some rationalisation of their portfolio could take place because the size of the one-off registration cost of REACH is relatively high compared to yearly portfolio. In that situation, the possible effects of withdrawal of critical substances on formulators and downstream users are assessed using documented examples of substance withdrawal in the past or by simulation. This is done to gain insight into the underlying mechanism and into possible effects of unavailability of critical substances.

8. **Performing additional checks at alternative companies.** Besides the companies that had originally been planned to be part of the case study, some alternative companies were contacted at a later stage.

- Some alternative chemical supplier companies were contacted that supply the same products to formulators as the CSs in the case. These CSs were asked to give their opinion about the likelihood of deselection of certain products. This information was used as check for the results found during the formal CS visits. In case the information from these CSs differs from the findings at the formal CS, it is mentioned separately from the findings.

- As it appeared during the study that a large part of the suppliers identified at downstream user level were large companies, downstream users were asked to suggest additional small and medium-sized companies (SMEs) to be added to the study. At these SMEs all paragraphs of the methodology spreadsheet were studied; those that were of particular importance to the company were studied in detail.

5.3 **Processing data**

9. **Checking data integrity.** Findings and supporting evidence collected during the interviews were put in the methodology spreadsheet. Systematic checks on completeness and integrity of the data were performed by a KPMG quality control staff member.

- As the companies were asked to give information about a hypothetical situation in the future (REACH 2007-2018), it is inevitable that a major part of the information is of a judgemental nature. In order to put this information into perspective, the information was internally matched against:
  - the context in which the company operates (market situation, sector outlook, etc.);
  - the expected baseline situation (without REACH);
  - the impacts of comparable situations in the past; and
  - the impacts on one or more selected products.

- If necessary, the company was asked to supply missing information after the interview. However, the study depends on the willingness of the participating companies to supply data. This means that questions could remain unanswered by the company with or without a reason.

- Finally, the completed methodology spreadsheet was sent to the participating company for a final check.
10. **Compilation of company data and analysis.** Based on all the company interviews within a sector supply chain, an analysis was carried out of the mechanisms observed and the conditions under which these mechanisms occur. The characteristics of the companies involved (for example, size of the company and position in the supply chain) were taken into account during this exercise.

11. **External verification.** For each of the interviews within the single case studies, the findings were compiled in a ‘summary sheet’ at company level. This summary sheet, as well as the underlying data sheets, was subject to external verification by independent experts hired by the European Commission. Company names, substance names and company documents were not disclosed to the verifiers for reasons of confidentiality. The verification work was carried out according to the ‘Rules and Procedures for Verification’ endorsed by the Working Group on 1 March 2005. No external verification of the findings in the Electronic sector study has taken place due to delays in the completion of the assessment.

12. **Validation in sector workshops and a validation workshop.**

   Sector workshops* were used to:
   - validate the draft findings in the case studies at sector level (and between different sectors in the case of (in)organics);
   - make sure that they are well understood and cross checked; and
   - find out whether they can be recognised as being representative for comparable cases.

   The function of the validation workshop was to do this across all of the sectors studied. The members of the Working Group participated in the Validation workshop.

* The sector workshops were attended by the independent EU experts (‘verifiers’). A full sectoral validation workshop for the Electronic sector study has not taken place; instead a meeting with representatives of the Electronic sector downstream users was arranged.
6 Consolidated findings

This chapter contains the consolidated findings about all the sectors studied: automotive, (in)organics, flexible packaging and electronics. The findings of the first three sectors mentioned have been subject to external verification and sector validation. Due to time constraints, this was not done for the electronics study, however, the findings in the electronics were collected according to the same working method and with the same team of researchers as in the other sectors.

The following codes have been used to indicate to which sectors the findings can be traced back.

<table>
<thead>
<tr>
<th>Code</th>
<th>Sector</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. AM</td>
<td>Automotive</td>
</tr>
<tr>
<td>2. IO</td>
<td>(in)organics</td>
</tr>
<tr>
<td>3. FP</td>
<td>flexible packaging</td>
</tr>
<tr>
<td>4. EL</td>
<td>electronics</td>
</tr>
</tbody>
</table>

The different levels in the supply chain are indicated with CS, F, DU for chemical supplier, formulator and downstream user respectively. The presentation of the findings below follows the structure of the methodology spreadsheet, that is:

Main areas of investigation:
1. Availability of substances and primary & secondary raw materials.
2. Competitiveness.
3. Innovation.
5. Recycling and recovery.

6.1 Availability of substances and primary & secondary raw materials/fuels

6.1.1 Level of vulnerability at chemical supplier level

A total of 164 individual substances were studied at company entities ranging in size from 20 (SME European office) to 1000 (plant of larger company) employees. Chemical suppliers that were investigated typically produced/imported in the 1-1000 tpa range. The table below presents the vulnerable substance found per sector.

<table>
<thead>
<tr>
<th></th>
<th>NPV assessed substances</th>
<th>Critical substances</th>
<th>Vulnerable and critical</th>
<th>Total vulnerable</th>
</tr>
</thead>
<tbody>
<tr>
<td>Automotive</td>
<td>50</td>
<td>22</td>
<td>1*</td>
<td>8</td>
</tr>
<tr>
<td>Flex. Packaging</td>
<td>24</td>
<td>22</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Electronics</td>
<td>4</td>
<td>4</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

*Table 6.1: vulnerable substances found at chemical supplier level per sector

*substance is component of a multi-substance package, which as a whole is not vulnerable.
The selected substances/preparations that are ‘critical’ at formulator/downstream user level and that have been followed upstream, appeared to be ‘not vulnerable’ using the NPV method.

To get an impression of the overall vulnerability of the portfolio, the researchers additionally assessed a larger part of the portfolio using the NPV method. Among these substances, there might be critical as well as non-critical substances (this was not assessed). For reasons of confidentiality, assessing a larger part of the portfolio turned out to be possible only at some companies. One of these companies was an SME manufacturer/importer in the automotive sector where a significant part (> 50%) of the portfolio was assessed. The percentage of vulnerable substances (related to the total portfolio) was found to be 17%. All except one of the substances found vulnerable are in the lower than 100 tonnage band. One vulnerable substance was found to be manufactured in the 100-1000 tpa volume band, however this substance is a component of a multi-substance package, which as a whole is not vulnerable.

**Vulnerability found at SMEs**
- Vulnerable substances were found at two out of a total of two SME chemical suppliers studied (one importer/producer outside EU and one producer in the EU):
  - AM: large part of portfolio of 1 SME man./importer tested: 17% vulnerable substances;
  - FP: 1 substance tested, 1 vulnerable.
  - EL: 1 substance tested, 1 vulnerable.

The level of vulnerability at two larger CSs studied is difficult to quantify because only a limited part of the portfolio could be assessed (< 5%). Taking into account that one of these companies produces in higher volumes, and the other one has a larger fraction of polymers in its portfolio (which are exempt from REACH), it can be assumed that the level of vulnerability is lower than that found at the SME.

**Larger CS: indications of low vulnerability, but difficult to quantify:**
- because substances tested represent only a small fraction of portfolio (< 5%);
- but reasons to assume that it is lower than for SME: larger volumes, more polymers;
- AM: 20 tested 1 vulnerable.
- FP: 23 tested, none vulnerable;
- EL: 3 substances tested, 1 vulnerable.

### 6.1.2 Level of substitution, reformulation, withdrawal

In many instances, chemical suppliers in the sectors studied do not market the substances they manufacture as ‘single substances’, but combine them into ‘packages’ with a certain functionality. Typically, one particular substance is used in many packages. Chemical suppliers therefore prefer to register such a substance to prevent reformulations of many packages.

Simply substituting one substance by another (to lower the total registration costs) is not seen as a feasible alternative by chemical suppliers. Substitution is likely to change the properties of the package as a whole, thus requiring the same efforts to maintain functionality as in the case of reformulation.
Formulators also prefer registration to reformulation (preferably by the chemical supplier, in some cases by themselves). It is advantageous to them to keep the chemical composition of their existing products as it is. The products often have been developed according to costumer, sectoral or governmental standards, and changing a formulation can lead to significant downstream user re-approval costs. Moreover, if a formulator indicates it will no longer supply a certain preparation in exactly the same composition to the DU, the DU often also asks competitor suppliers to propose an alternative, giving them new opportunities to compete.

**CS and F in principle prefer registration above substitution/reformulation.**
- Several substances typically used in many formulations (AM, FP, EL).
- Changing a formulation leads to significant DU approval costs (AM, FP, EL) and often gives competitors new opportunities to compete (AM).

Besides the cost-driven considerations described above (prevent reformulation and re-approval costs), a more general determination to try maintaining the portfolio has been found at all supply chain levels, especially in the automotive and the flexible packaging sector, but also in the electronics sector. The mechanism behind this is that for downstream users in the sectors studied, it is very important that existing preparations are kept on the market. Their processes and the quality of their end products rely heavily on the properties and quality of these preparations.

Some downstream users recently started communicating this signal towards their suppliers (formulators); others are planning to do so in the short term. Some formulators have already also done this towards their suppliers.

Suppliers were found to be sensitive towards this signal coming from customers. Continuity of supply, trust, quality and customer communication are important prerequisites for suppliers active in these sectors, especially in the automotive sector.

In general, it can be concluded that while making decisions about taking a substance from the market or keeping it in the portfolio, the NPV outcome is just one of the arguments; market considerations, customer relations and profitability of substances are very important too. It should be noted, however, that the mechanism described above can only fully take place if there is appropriate transparency, communication in the supply chain and CS and F can fund and absorb or pass on REACH costs. If not, there is a risk that critical substances may after all end up being withdrawn.

**CS and F will try to maintain portfolio**
- Market considerations are very important (AM, FP, EL).
- Continuity of supply, trust, quality and customer communication are important prerequisites for suppliers (especially AM).
- Pressure from downstream to maintain critical substances/preparations (AM, FP).

Context:
Precondition 1: appropriate transparency and communication in the supply chain.
Precondition 2: CS and F can fund and absorb or pass on REACH costs.
For the (in)organics it has been found that:

- Withdrawal of primary raw materials (minerals, ores) is unlikely as there are no alternatives.
- Depending on the specific situation for the alternative raw material or fuel (current autonomous price evolution, market position of the (in)organics producer vis à vis his supplier), the sector indicated that there could be a switch back from the alternative materials to primary raw materials and fuels, due to higher registration costs for secondary materials/fuels than for primary materials.
- Present guidance on interpretation and way of registration under REACH is insufficient.

<table>
<thead>
<tr>
<th>IO: Impact on raw materials</th>
</tr>
</thead>
<tbody>
<tr>
<td>withdrawal of primary raw materials unlikely.</td>
</tr>
<tr>
<td>a shift from secondary raw materials back to primary raw materials / fuels could occur.</td>
</tr>
</tbody>
</table>

### 6.1.3 Funding direct costs

Assuming that the chemical suppliers will maintain their portfolio and succeed in passing on* or absorb the registration costs, still, in absolute terms, the amount of money required for registration turned out to be significant for an individual company. For one SME chemical supplier (importer) in the automotive sector, it amounted up to 20% of annual turnover. For one chemical supplier in the electronics sector, that imports (and probably has to register) 10% of the total portfolio in volume, for the majority of the imported substances, the one-off registration cost is 100% or more of the profit margin of that substance.

Companies indicated that they will therefore look for options to reduce these costs. Two options were put forward the most:

- Form consortia with other companies registering the same substance(s) (no option if securing confidential business information is more important).
- Rationalise part of the portfolio if ‘one-off’ registration cost is a substantial part of profit, if substances are of limited strategic importance, at the end of the life-cycle, less critical downstream (with some reduction in profit). They indicated that they will do this only after discussion with the customer.

<table>
<thead>
<tr>
<th>In absolute terms, the amount of money required for registration can be significant for the registrant.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measures planned by companies to reduce costs are:</td>
</tr>
<tr>
<td>• Consortia forming (AM, FP, EL).</td>
</tr>
<tr>
<td>• Rationalise part of portfolio where one-off registration cost is a substantial part of profit, substances are of limited strategic importance, at end of life-cycle, less critical downstream and after discussion with costumer (AM, FP, EL).</td>
</tr>
</tbody>
</table>

Larger companies think these measures offer sufficient opportunities to lower and consequently fund the registration costs. For SMEs, however, access to money is generally more difficult, and

---

* (In)organic producers and material providers have to absorb the direct costs of REACH, notably those who are active in a global market and cannot influence world product prices.
the direct costs might still be difficult to fund. This may increase the need for and extent of the rationalisation described above.

Taking these measures into account, it will still be difficult for SMEs to fund the direct costs (AM, FP, EL).

6.1.4 Consequences of substance loss

In many instances, communication between the different actors in the supply chain about the continuity of supply has already started, be it before or as result of this study. Suppliers indicated towards their customers that they will try to maintain their portfolio. However, suppliers normally do not give absolute guarantees about what their portfolio will be in the future.

Therefore, the uncertainty remains at some companies at formulator level about the actual timing and likelihood of withdrawal of substances by their chemical suppliers. Formulators are particularly sensitive to this uncertainty as they experience pressure from upstream, as well as from downstream.

Uncertainty and concern observed at formulator level about the availability of critical substances and the timing and likelihood of withdrawal (AM, FP, EL).

On the one hand, the formulations they produce are technically highly dependent on the substances that get delivered from upstream and, on the other hand, they feel the pressure from (sometimes powerful) downstream users to maintain their portfolio.

There is also concern at formulator level that chemical suppliers in complex supply chains, that are not transparent, will be unable to take into account the consequences for small or unknown users (or uses) when taking the decision to either register or rationalise a substance. In the electronic sector it was found that formulators purchase sometimes very small quantities (<1 tpa) for specific uses. Formulators are worried that the chemical supplier will not register these low-volume products in their portfolio. However, from the case study it appeared that many of these ‘low-volume’ substances are supplied also to other sectors and consequently are produced in much higher volumes (sometimes >100 tpa).

IF withdrawal of critical substances took place, the impact downstream will be significant* in a relevant amount of situations (depending on the substance)

I.e. order of magnitude higher compared to direct costs of registration.

Reasons:
• Loss of only a few critical substances may result in large-scale re-formulation (simulation FP); (one company indicated already having rationalised its purchase portfolio; critical substances therefore form a bigger part in this portfolio, which may result in higher impact).
• Reformulation and re-engineering require extensive and often time-consuming testing and approval procedures of the product (reliability, safety, etc.) (AM, FP, EL).
• Re-formulation and re-design may require fundamental changes at process and/or product level with a large cost increase for EU-based companies (AM).
This uncertainty is also triggered by the awareness at formulator level that if withdrawal of critical substances takes place, the impact for them and downstream users may be significant (a higher order of magnitude compared to the direct costs of registration).

Formulators typically use a particular critical substance in many of their formulations. So the loss of only a few critical substances would affect a large part of their portfolio, resulting in large-scale re-formulation. In itself that would already be a significant impact. On top of that, however, newly-formulated preparations require extensive testing and approval procedures at both formulator and downstream user level. In some instances they even require fundamental changes at process and/or product level (with a large associated cost increase for EU-based companies).

### 6.2 Competitiveness

#### 6.2.1 Direct costs for chemical suppliers and formulators

The average increase in product costs for a company strongly depends on the amount of substances that have to be registered in relation to the whole portfolio and the level of consortia forming that is possible. The cost price increase has been established for four CSs of additives and pigments, assuming consortia forming of two companies (consortia of more than two companies could not be taken into account, as agreed in the testing cost approach, paragraph 2.3.1). It appeared that the increase in product costs ranges from 6 to 20%; see box below.

<table>
<thead>
<tr>
<th>Increase in product cost of pigments &amp; additives for chemical suppliers as a result of testing and registration can be up to 20% (one-off) on the whole portfolio</th>
</tr>
</thead>
<tbody>
<tr>
<td>FP: 6% (on whole portfolio) with consortia and available information; 20% without consortia (for selected products).</td>
</tr>
<tr>
<td>AM: 6% for a larger company without consortia; 17% for an SME with consortia.</td>
</tr>
</tbody>
</table>

These figures are one-off costs, meaning that the registrant has to make the costs just once, not every year. Example: if a company wants to pass on these costs to the customer, it has to increase the price of all substances by 20% for one year, or the company might prefer to increase the price by 4% (on top of inflation) for 5 years.

These costs get diluted if passed on down the value chain. Additives make up 10% (paint, PCB assembly preparations) to 30% (engine oil) in the value of a preparation; for pigments in ink, it can be more.

<table>
<thead>
<tr>
<th>The direct costs get diluted down the value chain if passed on (AM, FP, EL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>…as additives make up 10% (paint, PCB assembly preparations) to 30% (engine oil) in the value of a preparation (for pigments in ink, it can be more).</td>
</tr>
</tbody>
</table>

Cumulative effects might occur from other (not studied) substances; however, other major components would be exempt (resins) or less vulnerable (solvents).
It should be noted, however, that cumulative effects can occur from other (not studied) substances. Although for the end-user products studied (Table 4.1), additives and pigments are the most critical and potentially vulnerable under REACH. That is because major other components are either exempt from REACH (resins) or expected to be less vulnerable as they are produced in larger volumes (solvents).

**6.2.2 Impact of direct costs on profit**

For chemical suppliers and formulators

CS and F expect to either absorb or pass on the direct costs. Passing on costs is seen as a feasible option by the companies in some situations. Product price increases at these levels have become quite common as solvent prices have risen tens of percentages over the past few years, due to world oil prices. However, this is a global effect, whereas REACH is a regional effect.

It should be noted that increasing the price for existing products (‘just for environmental reasons’, as a formulator stated it) might be very difficult for formulators. Downstream users in the automotive sector, for example, are used to demanding, and getting, year-over-year price reductions on existing preparations. Therefore, formulators expect to pass on costs (also those of existing products) on new products, in combination with offering improved functionality. Passing on costs may be more difficult for SME companies and where global competition and international sourcing is particularly strong.

<table>
<thead>
<tr>
<th>CS and F expect to absorb or in some situations pass on the direct costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Formulators expect to pass on costs (also at least partially those of existing products) on new products, in combination with offering improved functionality (AM).</td>
</tr>
<tr>
<td>• Passing on costs may be more difficult for SME companies (FP) and where global competition and international sourcing is particularly strong (EL).</td>
</tr>
<tr>
<td>• Passing on costs is not feasible in (in)organics (IO).</td>
</tr>
</tbody>
</table>

For downstream users

The direct REACH cost of the end-use materials studied (Table 4.1) will have a limited impact on the profitability of the downstream users. That is because the impact at formulator level is already found to be limited (see earlier in this report) and these costs get further diluted from F to DU level. It must be noted, however, that the cost can be different for other materials (critical and non-critical; not in the study) and costs will accumulate. Furthermore, there are several reasons why even a small impact on profitability causes problems to the downstream user, as is shown in the box below.
Direct REACH costs of selected materials will have limited impact on the profitability of the downstream users

- The impact at formulator level is already found to be limited (AM, FP, EL).
- From F to DU level, these cost get further diluted (AM, FP, EL).

**Context:**
- Even a low impact on profitability could be a serious issue given the overall pressure on profitability in global operating industries (AM, EL).
- Profit margin in the sectors studied are currently low (or even negative) (AM & FP).
- Small price changes can lead to changes in international sourcing in globally operating industries (AM).
- It can be different for other materials (not in the study), and costs may accumulate.
- Difficult for DU to pass on costs to end user, if operating on a global market (AM, several IO sectors, EL).

For (in)organics
Definitions and the way of registration in REACH are perceived by the sector as being difficult to interpret when applied to the (in)organic sector. Therefore, different scenarios are used in this study for the interpretation of REACH. This approach has been discussed in the Working Group. The scenarios are defined by the registrant, according to its task under REACH obligations. The impacts found vary, depending on the scenario defined.

**Strong uncertainty felt in (in)organic sector as to how (if at all) to apply REACH**

- Due to multiple interpretations of REACH regarding the IO, different scenarios are used in this study (exempt or not exempt from REACH) of which the results differ substantially. Cost price increases for (in)organics vary depending on scenario chosen.

If the raw materials (primary and secondary and alternative fuels) are not exempt from the scope of REACH, the following can be concluded:

- It is difficult for the IP (IO) to pass on direct costs from the registration of the raw materials to the customer. It is a global market (and the IP cannot influence the market price) and, in the worst-case scenario, the impact on the profitability of the IP is high.
- MP (within the EU) and IP are affected by REACH in terms of competitiveness due to the extra costs associated with the registration and that fact that they cannot pass on the costs to their customers.
- SMEs in (in)organic sector typically produce over 1000 tpa, facing the same level of REACH registration costs as their larger competitors.

**6.2.3 Impact on market share**

Companies do not always have detailed information about their present market share as it very much depends on what is defined as ‘the market’. In general, companies do not expect to lose market share because of REACH alone. Others have no concrete idea about how their market share will develop and what the possible impact of REACH on market share will be. In certain
sectors (AM), the concern was raised at the sector workshop of article producers having higher costs and more stringent requirements than importers of articles.

**Companies (at all levels) do not expect to lose market share or simply don’t know**

**Context**
Concern is raised among article producers of having higher costs and more stringent requirements than importers of articles.

### 6.2.4 Impact on portfolio

As already indicated in paragraph 6.1.2, companies at all levels want to maintain their portfolio.

**Companies want to maintain their portfolio. They will do all in their power to minimise the impact of REACH (AM, IO, FP, EL).**

**However, complicating factors are:**
- Uncertainty about raw materials/base chemicals availability for some CS/IP (AM, FP, IO).
- The extent to which rationalisation of substances of limited strategic importance can be properly and timely discussed with the customer; this depends on transparency in the supply chain (AM, FP, EL).
- Ability of SMEs to form consortia and fund direct costs (AM, FP, EL).

Whether they will succeed in this, depends on several factors, which may or may not be fulfilled.

- For chemical suppliers, it is important that all the raw chemicals which they need to manufacture their own (fine) chemical products, remain available.
- For all supply chain levels, it is important that the supply chain is sufficiently transparent to ensure timely information about possible rationalisation of substances.
- Finally, for companies relying on SME suppliers, it is important that these SMEs manage to form consortia and fund the costs of registration. (paragraph 6.1.3).

### 6.2.5 Impact on delocalisation

Delocalisation just because of REACH is unlikely. Many of the companies manufacturing in the EU have invested heavily in EU production facilities and from the analysis of the market situation it appeared that (especially in the automotive and the flexible packaging sector) the proximity to the customer is important for chemical suppliers and formulators.

However, REACH may add to delocalisation pressures, especially for commodities (delocalisation in this context can also mean shifting part of their portfolio to own facilities outside the EU or using contract manufacturers).

Moreover, even small price changes can lead to changes in international sourcing in globally operating industries.
**Delocalisation just because of REACH is unlikely**

- Capital has been invested here (production facilities).
- Proximity of customers is important (AM & FP).

**Context:**

- However, REACH may add to delocalisation pressures, especially for commodities, (depending on the availability of primary and secondary raw materials in the EU). 
- Small price changes can lead to changes in international sourcing in globally operating industries (AM). 
- Delocalisation in the (in)organics sector was only studied for steel (IO).

### 6.2.6 Impact on workability

Formulators indicated that they will need extra manpower for various activities associated with REACH (listed in the box below). Given the level of expertise required, companies may encounter difficulties to fill these vacancies.

Downstream users and formulators have concerns regarding the issues of ‘identified uses’. Besides restricting their general flexibility of using substances, downstream users fear that the concept of identified uses will make trouble-shooting difficult (defined as a reaction to a production process problem leading to suboptimal or a stop in production). That is because the new ‘use’ that fixes the problem has to be registered in advance, while it is difficult to foresee all the potential problems.

Also, the definition of ‘identified use’, for instance the level of detail that is required, is generally perceived as unclear by many of the companies studied.

**Extra manpower needed at CS and F for:**

- Registration (mostly CS), identifying uses, communication up and down supply chain. 
- Adapting Material Safety Data Sheets. 
- Exposure assessments (content requirements and amount uncertain to companies). 
- Registration of primary and secondary raw materials (IO).

**Flexibility at DU reduced by narrow ‘identified uses’ (AM, EL)**

- The concept of identified uses will make trouble-shooting (reaction to process problem leading to suboptimal or a stop in production) difficult due to need for prior registration (difficult to foresee all the potential problems of all the applications in advance). 
- The definition (level of detail required) of identified uses is uncertain.

Some chemical suppliers and formulators have strong concerns about REACH forcing them to disclose confidential business information. This relates to sensitive market information that has to be disclosed during the registration process (especially about the use of certain substances/preparations and comprehensive information about the composition of the preparation).
In the electronic sector, finding companies willing to participate to the study turned out to be problematic, as confidential business information (CBI) appeared to be a major issue in this sector.

Formulators in the electronic sector indicated they will not share detailed information about specific applications with their suppliers. They consider this as confidential information, especially in the first years of the life-cycle of a preparation, when it has not yet become a commodity and gives a competitive advantage to the formulator as well as to the downstream user. One of the formulators indicated that if this information will have to be disclosed, some new and strategic products will be at risk. Information on the composition of preparations was regarded to be highly sensitive and protection of CBI important with regard to the pay back for R&D investments. Disclosure would result in competitive disadvantages or loss of market shares.

This confidentiality issue could become a barrier in the communication between the formulator and the chemical supplier, thus making it more difficult for the formulator to achieve the proper registration of all substances and their uses. The sharing of confidential business information will also be an issue between formulators and their downstream users. The impact of the issue of confidential business information depends heavily on how detailed the exposure scenarios have to be under REACH.

The issue of confidential business information did not turn out to be relevant for the (in)organics sector.

Possible future legal substances limitations under REACH
There are strong concerns about the extent and timing of possible future restrictions under REACH, in particular insofar as EU and non-EU industry will be affected differently (process chemicals and rules on substances in imported articles), and the timing of restrictions is not in line with lead-times and product cycles of effected product and processes.

Several chemical suppliers and formulators see intellectual property / confidential business information at risk (CS/F), because of communication/disclosure requirements under REACH.
This implies:
- Sensitive market information.
- Information on specific use of substances/preparations.
- Information on preparation composition.

Context:
- Extension of information requirements from hazardous substances to all substances implies disclosure of complete formulation composition.
- Confidential business information crucial for competitiveness and recovering R&D investments (AM, FP, EL).
- Access to confidential business information made easier to free riders (AM).
- Optimum communication up and down the supply chain only possible without confidentiality concerns.

As timing is not foreseeable it may trigger reformulations or re-engineering of running series (models under construction), which will entail high costs that cannot be recovered (AM).
In the case of accumulated restrictions, the time available for finding alternatives and earn back investments will be limited, and there are various examples of this.

As described earlier in this report, critical substance loss requires long adaptation times and many resources, as has been more specifically indicated in the box below.

<table>
<thead>
<tr>
<th>Worries about the extent and timing of possible future legal substances limitations under REACH (AM, IO, FP, EL).</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Importance: for products with long lead-time; re-engineering of ‘running series’ (models under production) expensive (AM).</td>
</tr>
<tr>
<td>• Restricted access to certain raw material sources limiting competitiveness (IO).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>If occurring at a high rate, impact may be high (AM, FP, EL).</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Longer term testing is needed to ensure reliability.</td>
</tr>
<tr>
<td>• Limited amount of time available to companies to find alternatives and earn back investments; capacity problems expected.</td>
</tr>
<tr>
<td>• Reformulation will take away resources from innovation and customer-oriented R&amp;D, which may have negative implications further down the chain (e.g. developing new products and processes).</td>
</tr>
</tbody>
</table>

| Documented examples where substance bans resulted in high costs and reformulations (AM&FP). |

6.3 **Impact on innovation**

Companies indicate that they will not increase R&D expenses. Because reformulation due to economic withdrawal is not expected* to occur on a large scale (see earlier in this report), the diversion of R&D resources towards reformulations will be limited.

Some companies indicate some delay in time-to-market as their R&D department is also involved in registration activities. Companies that manufacture part of their substances as polymers indicated they might shift innovation towards polymers.

At the sector workshop, some concerns were expressed about the workability of the exemption for product and process-oriented R&D, given that information on the R&D project needs to be communicated to the agency.

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* The diversion of R&D resources away from customer-oriented R&D following the loss of substances for legal reasons may be strong, because unexpected alternatives have to be found, which are not necessarily in line with R&D orientation.
No increase in R&D expenses expected (AM, FP).

Limited diversion of R&D resources due to REACH implementation (AM, FP, EL)

- ...because of limited economical withdrawal of critical substances.
- Some indicate delay in time-to-market (CS: from 2 yrs at present to 2.5 yrs under REACH for non-polymeric substances), others do not or simply don’t know (AM & FP).
- … but potentially high diversion in the case of multiple restrictions.

Shift of innovation towards polymers (AM, FP).

### 6.4 Impact on benefits

Many companies in the automotive and flexible packaging sector indicated that they already have quite some knowledge about substances, because of other legislation that applies, such as the ELV Directive and the food contact law respectively, and/or because high brand value makes testing of the final product necessary in any case.

Still, REACH is expected to improve the availability and quality of information on substances and preparations compared to the present situation, which will make it easier to control risks. One company mentioned that REACH may trigger beneficial rationalisation of the portfolio. In (in)organics, little benefits were recognised.

**In general, some benefits recognised:**

- Better information (AM, IO, FP, EL).
- Risk management easier (AM, EL).
- Rationalisation (1x at FP, 1x at EL).
- Positive influence on the reputation (EL).

Sectors indicate already having quite some knowledge on substances because of other legislation: end-of-life vehicles (AM) and food contact law (FP).

**(In)organics sector expects little benefits**

'as the current environmental and workforce legislation deals adequately with their materials'.

### 6.5 Impact on recycling and recovery

It is unclear to the participating companies in the study and the companies participating in the (in)organics sector workshop whether all secondary raw materials / fuels are exempt from the scope of REACH or whether they are totally or partly included in the scope of REACH.
Recycling of recovered paper
Recovered paper is assumed to be waste and exempt from REACH and, therefore, there will be no effects. The material provider will continue to supply the paper mill with recovered paper. If, however, recovered paper is assumed not to be exempt from REACH, the strict REACH requirements could negatively influence the European trend of high-quality recycling and recovery. Frequent analysis of recovered paper would have to take place, which could have a negative effect on the use of recovered paper.

Energy recovery and materials recycling in cement production
Due to the limited expected price increase (due to direct costs of REACH), fly-ash and blast-furnace slag is still likely to be used as a secondary raw material. However, the potential impacts can be considerably more important given that companies generally use different alternative raw materials from several suppliers.

It is unclear to the participating companies in the (in)organics study and the companies participating of the sector workshop whether all secondary raw materials/fuels are exempt from the scope of REACH or whether they are totally or partly included in the scope of REACH.

Under the precondition that waste is assumed not to be exempt from REACH, strict REACH requirements could limit the European trend of high-quality recycling and recovery*.

*The broken information chain (the link between the material/substances used in the first-time production of an article is lost once the final consumer discards the article and the article is collected for recycling/recovery) in the recycling/recovery of secondary raw materials/fuels complicates registration.
7 The Automotive case study

7.1 Sector background

Automobile sales are closely linked to the economic circumstances. At present, carmakers are looking for price cuts and try to remain competitive by offering a vehicle ‘facelift’ – new body and possibly interior – every four years, and a whole new vehicle every eight years. Delays in bringing a new product onto the market may leave an opening for competitors and increase the risk of losing market share. New technology is equally important as new models in attracting customers. Safety, fuel-cell technology and engine management systems are technology areas that are believed to lead in innovation over the next years.

The market is characterised by strong competition, both in Europe (import competition) and on the world market. Auto companies are increasingly investing in China. An important reason for that is to tap to the vast Chinese market, but some view China as a manufacturing opportunity and a source of profitable exports at some stage in the future.*

Carmakers have come to rely on suppliers to share the cost of developing components, which reduces capital requirements (the development of a new model can cost more than one billion euros), but tightens the links between the companies. Suppliers are particularly vulnerable in this product lifecycle since they are involved virtually from conception and make investments in the design, development and retooling. Furthermore, carmakers demand, and get, year-over-year price reductions on existing business. Depending on the specific carmaker, suppliers often win new business on the basis of the highest value part – that is, the supplier offering the most features or an ability to set the carmaker’s vehicles apart from the competition at the lowest cost, will win the business. Other supplier selection criteria include the ability to deliver new technology to next-generation vehicles, top-quality customer service, and an excellent delivery track record. Prerequisites include electronic communications and co-located customer support staff.

The carmaker market may be technologically challenging for suppliers but not very profitable. European suppliers and OEMs are operating with low profits and high cost pressure at the moment, and a trend for investments in low-cost destinations. Suppliers in the selected cases also deliver to other markets, such as industrial markets and workshops, which may be more profitable.

(* KPMG International, 2005; 2005 KPMG Global Auto Executive survey; Automotive Momentum vol. 1, nr. 1; Publication number 211-276.)

7.2 Selected supply chains and materials for the case study

Selecting supply chains at downstream users

In cooperation with sector organisation ACEA, and discussed in the multi-stakeholder Working Group monitoring the progress of the study, two cases have been defined around two important parts of a car: the bodywork and the car engine.
At each one of those, some preparations have been identified that are essential for the technical properties or performance of the bodywork and the engine or the associated manufacturing processes. The other criteria applied were that these preparations had to be commonly used, are of significant economical importance for the supply chain and are suitable for studying the core aspects of REACH registration.

The choice was finally made for paint, engine oil and metal working fluid. According to the same criteria, a few specific commercial products were selected to follow up the supply chain (see table below).

<table>
<thead>
<tr>
<th>Case</th>
<th>Critical preparation selected</th>
<th>Nr of commercial products selected</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bodywork</td>
<td>Paint</td>
<td>2</td>
<td>A base coat and a clear coat</td>
</tr>
<tr>
<td>Engine</td>
<td>Engine oil</td>
<td>2</td>
<td>‘Soluble’ engine oil</td>
</tr>
<tr>
<td>Engine</td>
<td>Metal Working Fluid (MWF)</td>
<td>2</td>
<td>‘Soluble’ MWF</td>
</tr>
</tbody>
</table>

*Table 7.1. Critical preparations selected for the automotive case study*

Consequently, the suppliers (formulators) of the selected paint and oil products were identified and asked to participate in the case study. The selection of formulators was done in a rather pragmatic way since much depended on the willingness of the companies to contribute to the study. Eventually, four formulators of paint or oil were willing to participate. Confidentiality undertakings were drawn up with these companies to ensure that the necessary sensitive business information could be made available to the researchers.

*Selecting critical substances at formulator level*

At formulator level, some critical components in paint, engine oil and metal working fluid had to be identified to be followed further upstream to the chemical supplier. It was decided (according to the same criteria described earlier) to focus on additives that are used in these preparations.

The other main components were left out of the scope because they are either exempt from REACH (resins) or produced in large volumes (solvents and mineral oil), making them less vulnerable to economical withdrawal and thus less suitable for studying the key aspects of REACH. Pigments were not expected by the paint formulator to be seriously affected by REACH, as most of the special pigments used were introduced after 1981 and have already been notified according to the present chemicals legislation (regulation 67/548).

The additives selected were of the categories: viscosity regulators, rheology modifiers, wetting and dispersing additives, detergents, anti-wear agents, antioxidants, metal deactivators and rust & corrosion inhibitors. Not all substances are marketed as single substance by the chemical supplier, but sold in combination with other substances (as a “package”).
Again, the selection of suppliers of additives to be interviewed was done in a rather pragmatic way; eventually, three chemical suppliers were willing to contribute to the study. These were two relatively large manufacturers and one SME importer.

**Assessing the vulnerability of substances at chemical supplier level**

Also at chemical supplier level, confidentiality undertakings were drawn up with the companies to ensure that the necessary sensitive business information could be made available.

The vulnerability of the selected critical additives was determined using the NPV (net present value) method, which compares the costs of registration of a substance to the expected future profits. In the context of the study, a substance is regarded ‘vulnerable’ if the REACH registration costs exceed the net present value of expected future profits.

Additionally, a larger sample of the portfolio has been put through the NPV method at two companies, to get an impression of the overall vulnerability of the portfolio. One of those companies delivered the necessary data in time for verification and could be taken into account in this report.

**Simplified supply chain**

<table>
<thead>
<tr>
<th>Chemical supplier</th>
<th>Additive manufacturer CS 1</th>
<th>Additive manufacturer CS 2</th>
<th>Additive manufacturer / importer CS 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical substances: additives (viscosity regulators, rheology modifier, wetting and dispersing additive, rust &amp; corrosion inhibitors, …)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Formulator</th>
<th>Paint manufacturer F1</th>
<th>Paint manufacturer F2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical preparations: base coat paint, clear coat (paint), soluble engine oil, soluble metal working fluid (MWF)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Downstream user</th>
<th>Car manufacturer (body work) DU1</th>
<th>Car manufacturer (engine) DU2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical articles: body work, car engine.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Small or medium sized company

Nr. of critical preparations / substances selected for the case study (left)

Nr. of other substances accessed (right)

Table 7.2: Simplified representation of the supply chains studied in the Automotive case study.

In the end, in total, two downstream users, four formulators and three chemical suppliers were selected and willing to participate to the study (see Table 7.2). Besides the companies that had originally been planned to be part of the case study, some alternative companies were contacted at a later stage.
As only one SME importer happened to be among the companies selected, one alternative SME importer has been visited to check the validity of the results. This SME importer supplies additive packages to formulators of lubricant oils. The issues found here, appeared to be similar as those documented for the SME importer already in the study. As the company was not a part of the supply chain under study and no NPV calculations could be made, the company is not shown in the table.

**Determining the impact and the reaction down the supply chain**

Having assessed the vulnerability of the selected substances, the chemical suppliers were asked what their reaction will be under REACH: withdraw the substances from the market, present an alternative substance or increase price. Besides for the selected substances, this has also been asked for the whole of the portfolio in order to gain insight into the decision making process.

Next, one level downstream, the formulators of paint and oil were confronted with the reaction of their suppliers of additives. For reasons of confidentiality, the level of withdrawal and price increases were presented by the researchers as possible scenarios. The additional advantage of working with scenarios is that the researchers are able to study the reaction of formulators on withdrawal of substances, even when chemical suppliers indicated that in this particular case withdrawal is not to be expected. This way of working should increase the insight into the mechanisms behind REACH.

At the same time, the impact on the company in terms of availability of substances, competitiveness, innovation, benefits, etc. was assessed. Also, the formulators were asked what their reaction will be under REACH: withdraw the selected paints and oils from the market, present an alternative or increase price. Besides for the selected preparations, this has also been asked for the whole of the portfolio in order to gain insight into the decision making process.

Finally, at downstream user level, the car makers were confronted with the reaction of their paint and oil suppliers according to the same working method of using scenario’s and the impact on the company in terms of availability of substances, competitiveness, innovation, benefits, etc. was assessed.

The suppliers of paint and oil might indicate that withdrawal or reformulation of the selected products as a result of substance loss is not to be expected. To still be able to get insight into the consequences of substance loss for downstream users, additionally some documented examples of substance withdrawal in the recent past have been studied.

**Verifying and validating the data**

The data gathered by the researchers were subject to an external verification by independent experts hired by the European Commission. Company names, substance names and company documents were not disclosed to the verifiers for reasons of confidentiality.

A sector workshop was held to validate the draft findings in the case studies at sector level and to find out whether they can be recognised as being representative for comparable cases. The sector workshop was attended by representatives of most of the companies (chemical suppliers,
formulators and downstream users) that participated in the study, as well as experts from some other companies active in the sector.

7.3 **Findings of the Automotive Case Study**

When discussing the findings of the nine companies involved in the automotive case study, we distinguish findings for the following areas: vulnerability, availability, competitiveness, innovation and benefits. In each area, we will discuss the findings for chemical suppliers, formulators and downstream users where relevant. Remarks that were made during the sector workshops have been added indicated as such.

7.3.1 **Vulnerability of substances at chemical supplier level**

Of the, in total, 78 substances assessed at three chemical suppliers (one smaller and two larger ones), the data of 50 of them were delivered in time for external verification and were taken into account in this report.

The six additive products that were investigated and that were identified as being ‘critical’ for the paint and oil formulators, contain 22 substances in total of which 1 appeared to be vulnerable. This means that for one critical substance, the REACH testing costs exceed the net present value (NPV) of the expected future profit. However, this substance was part of a package containing also other substances, making the package as a whole ‘not vulnerable’.

<table>
<thead>
<tr>
<th>Tonnage band (tpa)</th>
<th>NPV assessed substances</th>
<th>Critical substances</th>
<th>Vulnerable and Critical</th>
<th>Total Vulnerable</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-10</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>10-100</td>
<td>20</td>
<td>1</td>
<td>0</td>
<td>6</td>
</tr>
<tr>
<td>100-1000</td>
<td>17</td>
<td>12</td>
<td>1*</td>
<td>1*</td>
</tr>
<tr>
<td>&gt; 1000</td>
<td>11</td>
<td>9</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>50</strong></td>
<td><strong>22</strong></td>
<td><strong>1</strong>*</td>
<td><strong>8</strong></td>
</tr>
</tbody>
</table>

*substance is component of a multi-substance package, which as a whole is not vulnerable.

To get an impression of the overall vulnerability of the portfolio, a larger part (more than half) of the portfolio of one SME manufacturer/importer was assessed additionally. This exercise yielded another 7 vulnerable substances, assuming that the company forms two-firm consortia to share the testing costs. Forming consortia was indicated by the company to be a likely strategy. Expressed as percentage of vulnerable substances related to the total portfolio this was found to be 17%.

The level of vulnerability at two larger CSs studied is difficult to quantify because, in one instance, only a limited part of the portfolio has been assessed (< 5%) and, in another instance, the required figures were not available on time to test vulnerability with the NPV methodology. Taking into account that one of these companies produces in higher volumes and the other has a relatively large fraction of polymers in its portfolio (which are exempt from REACH), it can be assumed that the level of vulnerability is lower than that established for the SME manufacturer/importer company.
Almost all of the vulnerable substances found were in the lower than 100 tonnage band. One had an annual volume of a little above 100 tpa and one substance had an annual volume of lower than 10 tpa. It must be noted that not many of the substances tested were in the smaller than 10 tpa range: two all together (see Table 7.3).

### 7.3.2 Availability of substances for downstream users

Having found some vulnerable substances, the question now is, what will chemical supplier do with these substances: register or withdraw from the market; and: what is the mechanism behind this decision making process? The case studies show that the likelihood that additives are withdrawn that are critical for paint and oil formulators or car makers is low, assumed that the necessary raw chemicals remain being available to the chemical suppliers.

**Chemical suppliers**

All three chemical suppliers indicated that they would not automatically withdraw substances that appear ‘vulnerable’. Market considerations are very important. The background for this finding is that continuity of supply, trust, quality and customer communication are important prerequisites for specialty chemical suppliers operating in the automotive sector.

Chemical suppliers are aware that withdrawal of additives will force formulators of paint and oil to reformulate their products and that any reformulation of an existing product causes disruption and additional cost to businesses in the supply chain. The new product would usually be required to undergo a series of tests to confirm that it performs to customer specifications (and the specifications of those further down the supply chain). Requalification of a product is expensive and moreover, it often gives competitors new opportunities to compete.

Besides these market considerations, registering instead of withdrawing substances might also be the most favourable option for chemical suppliers from an economical point if view. Two of the three chemical suppliers in the case study are formulators themselves. They sell most of their substances as formulations or ‘packages’ with a particular functionality. Typically, one particular substance is used in many packages. This practise is widely encountered at specialty chemicals suppliers. By registering most of their substances under REACH they can prevent costly reformulation of many of their own products.

**Formulators**

Formulators of paint, engine oil and metal working fluid normally have day-to-day contact on technical and economic issues with their chemical suppliers. REACH has in many instances already been put on the agenda. Formulators indicated to the researchers that they will communicate very clearly to their suppliers that the availability of critical substances is of key importance for their business and for that of their customers (car makers).
**Downstream users**

A change in formulation requires retesting the product, not for the paint and oil formulator, but also for the car maker. Indeed, if this change affects the manufacturing process or final product itself, the required resources are significant. Given their size, the downstream users in the study are in a strong position vis-à-vis their suppliers, which is why they should be able to avert economic deselection by early communication upwards in the chain (see table below). In the cases studied, the impact of economic deselection on the downstream users is therefore expected to be low.

![Diagram](image)

*Table 7.4. Mechanism in which two-way communication ensures that critical substances remain being available for downstream users.*

Key preconditions that have to be met for this mechanism to work are that there is appropriate transparency and communication in the supply chain, that the chemical supplier is able to fund the direct registration costs and that the chemical supplier is able to absorb or pass on the costs. This will be elaborated further in the next paragraph (“competitiveness”).

**Input from the sector workshop**

During the sector workshop, the analysis that economic deselection may often be avoided was seen as plausible by downstream user firms as far as substances are concerned that are critical for large downstream users, but – given the complexity of and the lack of transparency in supply chains – questioned when it comes to the smaller uses, in particular by smaller companies that were outside the scope of the studies. Furthermore, the participants emphasised that this mechanism can only fully take place if there is proper transparency and communication in the supply chain and chemical suppliers and formulators can absorb or pass on REACH costs.
7.3.3 Competitiveness

Chemical suppliers

Keeping most of their products on the market will lead to a significant increase of the product costs for chemical suppliers. REACH increases the total product price of additives for paint and oil by on average 10% (one-off costs) on the total portfolio. The range found for the three chemical suppliers in the case study is from 6 to 17%, depending on the portion of non-polymeric (to be registered) substances in the portfolio.

Still, the impact of REACH on the competitiveness of larger chemical suppliers will be limited. That is because the chemical suppliers in the study expect to pass on the costs downstream. They have done this earlier with the risen oil and solvent prices over the past few years. However, it should be noted that these cost increases took place globally, which is not the case for REACH.

The funding of the amount of money needed for registration, however, is a concern for some companies. It appeared from the automotive case study that an SME manufacturer importer should in total spend 20% of its annual turnover on registration, taking two-firm consortia forming into account.

Formulators

For the paint and oil formulator, the cost price increase their products as a result of price increase of substances (additives) is low, although larger for oil than for paint. Additives make up 1% (paint) to 20% (engine oil) of the product in volume, so possible price increases of additives (direct costs) get diluted downstream. Major components other than additives are either exempt from REACH (such as polymeric resins) or expected to be less vulnerable as they are produced in larger volumes (such as solvents).

If reformulation is necessary however, this causes indirect costs and the impact on the product price will be larger. For instance, the cost to redevelop major products can be up to EUR 0.5 million for paint to EUR 2 million for engine oil per product. For engine oil, this could increase the cost price of products by 10% (one-off).

Downstream users

Direct REACH costs related to paint, engine oil and metal working fluid will have a low impact on the profitability of the car maker. This is because the impact at formulator level is already found to be low and, in general, costs of chemical materials studied are relatively low. For example: the total costs of paint are smaller than 1% for a typical car. This can, however, be different for other materials and costs add up on.

Also, it should be noted, that even a low impact on profitability could be a serious issue given the overall pressure on profitability in the EU automotive industry. It is difficult to pass on costs to consumers given the global market. Furthermore, the automotive industry is global and sources globally.
Possible impact of restrictions
It is uncertain what the extent and timing of possible future restrictions under REACH will be. Several recent real-world substance prohibitions were studied and this made clear that the impact on the automotive industry may be high. This is because, in some cases, re-engineering is very difficult because of restrictions.

The main reasons for this are the complexity of the final product, the fact that any changes may require longer term testing to ensure reliability, safety, quality, etc., and the long lead-times and product cycles in the automotive industry. Cars have three to five years’ lead-time and a product cycle of about six years; spare parts have to be available for significantly longer. Some car parts have been designed specifically for use in conjunction with certain preparations (considering functionality and material compatibility). Given the capital-intensive production, re-engineering of ‘running series’ (models under production) is particularly expensive. This makes it important that there is enough time available to companies to find alternatives and earn back investments. Forced substitution may divert innovation from areas where economic operators expect the highest returns. The costs from forced substitution may affect the competitiveness towards outside EU competitors, which have less strict requirements to meet (art. 6 on substances in articles).

Input from the sector workshop
This point was seen as crucial by downstream users at the sector workshop. The findings on the possible impact of restrictions should be seen in the context of the strong overall pressures on the profitability of the EU Automotive industry due to global competition.

Market share, portfolio & delocalisation
In principle, chemical suppliers, and also formulators, want to keep their portfolio intact. The impression is that some products of less importance and less critically downstream may be rationalised after consultation of the customer in order to reduce the (absolute) registration costs.

As deselection for commercial reasons is found to be low, economical withdrawal will not impact market share or delocalisation of production of the downstream user.

Chemical suppliers and formulators do not expect to lose market share or simply don't know. Delocalisation because of REACH is not likely, capital has been invested here (production facilities) and the proximity of customers is important. However, REACH may add to delocalisation pressures.

Workability
Chemical suppliers and formulators indicated that they will need extra manpower for various activities associated with REACH, such as registration, identify uses, exposure scenarios, communication up and down the chain and adapting ‘safety data sheets’. For two chemical suppliers this was calculated to be an additional 2 full time equivalents (FTE) on total workforce of 300-600.
Downstream users have concerns regarding the issue of ‘identified uses’. Carmakers typically use a large number of substances. The way they are able to use these substances affects the flexibility of production. ‘Identified uses’ may restrict flexibility if they are overly narrow. This point is of general validity, but becomes particularly important when it comes to ‘troubleshooting’, i.e. finding solutions to problems that arise in production. Such problems can lead to the halt of production in the worst case and require a rapid response. Waiting for a new registration for such a ‘trouble-shooting use’ may have serious business consequences, because it is not possible to foresee all potential problems in advance.

Some chemical suppliers and formulators have strong concerns about REACH forcing them to disclose confidential business information. This relates to sensitive market information that has to be disclosed during the registration process, as well as the extensive information on the preparation composition that REACH requires. It will make it easier for third parties to determine how the products have been formulated, so lowering the barrier to new entrants.

**Input from the sector workshop**

During the sector workshop, these findings from the interview were mostly recognised by the participants. The participants (formulators) emphasised, however, that a formulator’s portfolio depends on the substance availability to the company, which may be affected by rationalisation by chemical suppliers. Furthermore, the ability of the formulators to pass on costs was questioned.

**7.3.4 Innovation**

The companies in the sector generally do not expect to increase their R&D budget. One company indicated that they expect some delay in time-to-market as their R&D department is also involved in registration activities. The expectations of companies about the scale of the impact range from unchanged to a limited increase in time-to-market of several months.

The reasons for this limited increase differ. At one chemical supplier it was found that the time-to-market will probably be prolonged from 2 years at present to 2.5 year under REACH for non-polymeric substances. Polymeric substances however appeared to be a substantial part of the portfolio of that chemical supplier, so the average increase in time-to-market is limited. Another chemical supplier indicated that the timing of innovation regarding additives for engine oil is mostly driven by industry specifications, government environmental regulations and changes in car maker specifications. So the time-to-market for this market segment is not expected to change under REACH.

One chemical supplier that manufactures part of its substances as polymers indicated that they might shift innovation towards polymers to circumvent registration (polymers are exempt from REACH).
Because reformulation as a result of economic withdrawal is not expected to occur on a large scale, the diversion of R&D resources towards reformulations will be limited. Restriction of substances (uses), however, might impact innovation to a larger extent if new technology has to be developed and longer term testing is needed to gain confidence and customer acceptance. This is true at chemical supplier, formulator, as well as downstream user level. One example studied at formulator level showed that a past restriction led to the company having to reformulate 80% of its portfolio, requiring 2-3 years of work for the company’s R&D staff.

Input from the sector workshop
During the sector workshop, these findings were mostly recognised by the participants. However, the chemical suppliers and formulators participants emphasised that availability of substances, which may by hampered by rationalisation, is of key importance to innovation. The sector workshop also underlined the positive importance of the exemption for product and process-oriented R&D, although concerns exist about its workability given that information on the R&D project has to be made available to public authorities.

7.3.5 Benefits
Potential benefits of REACH recognised at chemical supplier level are a better quality of ‘safety data sheets’ and better toxicological information for downstream users in higher tonnage bands, which makes risk management easier. During the sector workshop, these findings were mostly recognised by the participants. The participants emphasised that existing legislation (e.g. ELV Directive) already led to proper availability of information and that high brand values of car manufacturers make testing of the final product necessary in any case.

Input from the sector workshop
During the sector workshop, these findings were mostly recognised by the participants. In addition, a potential first-mover advantage was recognised if REACH became a global standard.
8 The (In)organic sector case study

8.1 Sector background

The (in)organic sector industry is represented by the REACH Alliance and comprises 12 industrial sectors in Europe, viz. cement, ceramics, glass, gypsum, iron & steel, lime, minerals, non-ferrous metals, ores, paper, pre-cast concrete and ready mixed concrete. These sectors are high volume materials providers and recover/recycle wastes, secondary raw material and fuels. Both the raw materials and the products of these 12 sectors are included in the scope of REACH proposal as it stands now.

The (in)organic sector is a highly cyclic sector and acting in a very competitive worldwide market. The raw materials (minerals, ores and secondary raw materials (recyclables)/fuels) of the material providers are a complex mixture of substances and highly variable in compositions. The volumes of raw material are usually more than 1000 tonnes per year. The (in)organic producers provide substances for a wide variety of product users and applications and mainly used as a commodity (steel, paper, etc.).

In this study, four sectors have been selected, namely; non-ferrous, paper, cement and the steel sector.

8.2 Context setting for the four selected sectors in the (in)organic sector

*Metal industry (ferrous (steel) and non-ferrous (zinc))*

Two materials of the metal industry are selected in this study: ferrous (steel) and non-ferrous (zinc). The main users of zinc and steel are the construction industry and the automobile industry.

Minerals and ore derived from mines are the primary raw materials for the production of zinc and steel. The primary raw materials are mainly imported from outside the EU, in this particular case, by EU companies (metals producers).

Base metal prices (raw materials and the products) are set daily on the London Metal Exchange (LME). This means that metal prices are fixed at worldwide level so limited opportunity to pass on costs to “users”. The current market is slowly restoring the distortions between the three players, mines, smelters and the users.

The world mine production in 2003 of zinc content is about 10 million ton, whereas the mine production of zinc content in the EU is about 1 million ton. The zinc (metal) production world wide is about 10 million ton and in the EU about 3 million ton.

The global production in 2003 from iron ore mines was 1120 million tonnes. Collectively, China, Japan and Korea account for 60% of global iron ore imports. In 2003, the crude steel production was 160 million tonnes in Europe (125 million tonnes for the EU-15) and 965 million tonnes crude steel production world wide. China is the largest producer at 220 million tonnes per year. The integrated steel production route (i.e. a blast furnace, followed by basic
oxygen steelmaking), which accounts for 60% of EU steel, uses iron ore as its primary raw material, while the electric arc furnace production route uses scrap steel as its primary iron-bearing material.

**Cement Industry**

Basically, cement is produced in two steps: first, clinker is produced from raw materials. In the second step cement is produced from cement clinker.

The raw materials to make *clinker* are delivered in bulk, crushed and homogenized. Four basic oxides in the correct proportions make cement clinker: calcium oxide, silicon oxide, alumina oxide and iron oxide. These elements are mixed homogeneously and will combine when heated. Hydraulic hardening of cement is due to the hydration of these compounds. The final product of this phase is called "clinker".

The second phase is handled in a cement grinding mill, which may be located in a different place to the clinker plant. Gypsum (calcium sulphates) and possibly additional cementitious (such as blast furnace slag, coal fly ash, natural pozzolanas, etc.) or inert materials (limestone) are added to the clinker. All constituents are ground leading to a fine and homogenous powder. The *cement* is then stored in silos before being dispatched either in bulk or bagged.

Waste is used in cement manufacturing as an alternative fuel and raw material, thereby providing a significant contribution to *recovery*. Alternative fuels are used in the clinker production. Currently the substitution of fossil fuel is 12.2 % (4.4 million ton waste) which is equivalent to the saving of 3.5 million tonnes of coal. Currently alternative materials used on both clinker and cement production result in 11.5 % direct saving of natural raw materials needs (35 Million tonnes).

**Paper industry**

The global demand (paper consumption) for all papers (paper and board of all grams) in 2003 is approximately 325 million ton. Whereas the total demands in Western Europe for papers is about 79 million ton. For the production of paper both virgin pulp (cellulose and mechanical pulp, which are primary raw materials) and pulp made from recovered paper (secondary raw material) can be used. The volume of virgin pulp consumption in Western Europe is about 42 million ton. For the production of paper 50% is produced with recovered paper. The Paper industry acts on a global market so limited opportunity to pass on costs to "users".

### 8.3 Case study background

#### 8.3.1 Selected materials

The business impact study for the (in)organic sector is focused on the accessibility of both primary and secondary raw materials for the producer due to the new proposed REACH legislation. Primary or secondary raw materials are used to produce a product. Primary raw materials are materials such as minerals and ores. Secondary raw materials or recyclables are raw materials such as recovered paper, and alternative fuels such as used tyres.

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4 Western Europe: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Portugal, Spain, Sweden and United Kingdom.

5 CEPI, European Pulp and Paper Industry Annual Statistics 2003
In close cooperation with the Working Group and REACH Alliance, four cases, including the (in)organic producers and the type of raw materials, were selected. The table below reflects the selected cases. Due to confidentiality reasons, the names of the participating companies are not shown.

Selected raw materials and participating actors

<table>
<thead>
<tr>
<th>Case</th>
<th>Raw material</th>
<th>Primary/secondary raw material/ fuels</th>
<th>Actor</th>
<th>(In)organic producer (IP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-ferrous case</td>
<td>Zinc concentrate</td>
<td>Primary</td>
<td>A Mine in EU</td>
<td>Zinc smelter</td>
</tr>
<tr>
<td>Paper case</td>
<td>Recovered paper</td>
<td>Secondary</td>
<td>A Service provider of old paper</td>
<td>Paper mill</td>
</tr>
<tr>
<td></td>
<td>Chemical pulp</td>
<td>Primary</td>
<td>A Supplier of chemical pulp</td>
<td></td>
</tr>
<tr>
<td>Cement case</td>
<td>Fly ash</td>
<td>Secondary raw material</td>
<td>A power plant</td>
<td>Cement company</td>
</tr>
<tr>
<td></td>
<td>Blast-furnace slag</td>
<td>Secondary raw material</td>
<td>A Steel company</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Old tyres</td>
<td>Secondary fuel</td>
<td>A Service provider of old tyres</td>
<td></td>
</tr>
<tr>
<td>Steel case</td>
<td>Iron ore</td>
<td>Primary</td>
<td>Imported from outside the EU therefore not applicable</td>
<td>Steel company</td>
</tr>
</tbody>
</table>

Compared to the number of raw materials used by the (in)organic producers, a limited number of raw materials/fuels has been investigated in this study. The (in)organic producers use much more different input (raw) materials and, therefore, the study of the impact of REACH is limited to the selected materials.

The impact of authorisation on the availability of primary and secondary raw materials has not been studied. This may be relevant in case raw materials should require authorisation.

8.3.2 Participating companies

Context information for participating companies in the study is reflected underneath:

<table>
<thead>
<tr>
<th>Context (based on the year 2003)</th>
<th>Zinc smelter</th>
<th>Material provider zinc smelter</th>
<th>Steel producer</th>
<th>Cement producer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actor</td>
<td>IP</td>
<td>MP</td>
<td>IP</td>
<td>IP</td>
</tr>
<tr>
<td>Annual production</td>
<td>600 000 ton zinc</td>
<td>385 078 t/y zinc concentrate</td>
<td>20 Mton t/year steel</td>
<td>2 572 Mt/y cement (NL)</td>
</tr>
<tr>
<td>Annual turnover</td>
<td>4677 Meuro (total whole company) 805 Meuro (BU Zinc)</td>
<td>1466 Meuro</td>
<td>8 Billion euro</td>
<td>72 Meuro (NL)</td>
</tr>
<tr>
<td>Employment</td>
<td>9640 (total company) 2863 (BU Zinc)</td>
<td>668</td>
<td>45000 (in EU)</td>
<td>540 (NL)</td>
</tr>
</tbody>
</table>

The context information about the participating paper mill is confidential and therefore not presented.
8.3.3 Scenarios

Multiple interpretations of REACH for the registration of the substance were possible for the selected materials (as described above) in the (in)organic sector study.

In order to understand the impact of REACH for selected raw materials, scenarios for different possible interpretations for the registration of the materials were used. The scenario approach was presented at the 22 June 2004 meeting of the Working Group.

According to REACH provisions, the registrant finally has to choose the way to register the substance. Therefore, the registrant in this (in)organic sector study also selected the way to register the substance. The way to register the substance is hereafter called the scenario. For the selection of one scenario per case by the registrant, two criteria were used:

- Likeliness: Is the scenario, according to the registrant, a likely* interpretation in practice?
- Vulnerability: Are there high direct costs for the registrant in this scenario?

By using these criteria for the selection of a scenario, the possible impacts and benefits could be investigated.

The variables for the scenarios are:

- Possible interpretations of REACH.
- Single-company registration or consortium registration of the substance/material.

The relevant possible interpretations of REACH for the selected materials in the (in)organic sector are described below.

<table>
<thead>
<tr>
<th>Definition in REACH</th>
<th>REACH requirement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Natural mineral, not chemically modified, and does not meet the criteria for dangerous substance/preparation (Annex 3 point 8)</td>
<td>Exempt from REACH</td>
</tr>
<tr>
<td>Waste and/or secondary material (raw material or fuel)</td>
<td>Totally or partly included or exempt from REACH</td>
</tr>
<tr>
<td>Preparation (single-company or consortium registration) (Article 3 point 2)</td>
<td>Registration of the substances (≥ 1 ton/year) in the preparation</td>
</tr>
<tr>
<td>One substance (single-company or consortium registration) (Article 3 point 1)</td>
<td>Registration as one substance</td>
</tr>
</tbody>
</table>

Below, only the selected scenarios are described and the findings based on those scenarios are reflected.
8.4 Findings of the (In)organics case study

8.4.1 General

The case studies in the (in)organic sector show that interpretations of REACH regarding the selected raw materials are not fully clear. The REACH requirements involve a high level of uncertainty when applied to the (in)organic sector as the definitions are difficult to interpret. Due to the variability in composition, the raw materials either have to be registered as one group of substances (if difference in composition will be accepted as still being one ‘substance’) or as different substances.

8.4.2 Non-ferrous case

The selected material in the non-ferrous case is zinc concentrate. The zinc concentrate is used by the zinc smelter (the (in)organic producer) and obtained in two different ways:

1. From a material provider in the EU a mine.

2. By importing the zinc concentrate from a supplier outside the EU.

The impact of REACH on the companies in the supply chain differs in the way of obtaining the zinc concentrate. In the first situation, where the zinc smelter buys zinc concentrate from the material provider inside the EU, the material provider has to register the zinc concentrate. In the second situation, the zinc smelter is the importer of zinc concentrate inside the EU and has to register the zinc concentrate. In both situations, the yearly volume of zinc concentrate exceeds the highest threshold for registration (> 1000 t/yr). The impact of REACH was studied for each of the two situations.

Selected scenario

Zinc concentrate from inside the EU: Material provider has to apply REACH

According to the material provider, zinc concentrate is a natural mineral and is therefore exempt from REACH. Although no test have been carried out by the material provider, according to the material provider zinc concentrate does not meet the criteria for dangerous according the directive 67/548/EEC. But due to the uncertainty of this interpretation, the study is continued with other scenarios: as a preparation or as a substance (see table, numbers 3 and 4).
### Definition in REACH

1. **Natural mineral, not chemically modified, and does not meet the criteria for dangerous substance/preparation**

   Zinc concentrate is comprised of naturally occurring minerals that have been extracted from the host rock by size reduction and separation by froth flotation. Zinc concentrate is according the Mine not dangerous according to directive 67/548/EEC. Zinc concentrate has been transported by sea in bulk carriers for decades and has not been categorised as hazardous. The metals present in zinc concentrate are not readily bio available and the Mine believes that specific testing will show that the product is not harmful to the environment.

<table>
<thead>
<tr>
<th>Likely and vulnerable scenario?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes (according to material provider)</td>
</tr>
</tbody>
</table>

2. **Waste and/or secondary material (raw material or fuel)**

   Not applicable for zinc concentrate

   | No |

3. **Preparation (single-company or consortium registration)**

   i) The mine blends (mix) their output (raw materials) in order to deliver a consistent product (zinc concentrate) may in fact meet the current EU criteria for a preparation
   ii) Currently, (zinc) concentrates are treaded by industry as preparations.

   | Yes |

4. **One substance (single-company or consortium registration)**

   i) Zinc concentrate is derived from the mine and no substances are added and therefore zinc concentrate can be seen as one substance
   ii) Not applicable due the fact that for zinc concentrate not one CAS number, EINECS or ELINCS number.

   | Yes |

<table>
<thead>
<tr>
<th>Definition in REACH</th>
<th>Interpretation for zinc concentrate</th>
<th>Likely and vulnerable scenario?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Zinc concentrate is comprised of naturally occurring minerals that have been extracted from the host rock by size reduction and separation by froth flotation. Zinc concentrate is according the Mine not dangerous according to directive 67/548/EEC. Zinc concentrate has been transported by sea in bulk carriers for decades and has not been categorised as hazardous. The metals present in zinc concentrate are not readily bio available and the Mine believes that specific testing will show that the product is not harmful to the environment.</td>
<td>Yes (according to material provider)</td>
</tr>
<tr>
<td>2</td>
<td>Waste and/or secondary material (raw material or fuel)</td>
<td>Not applicable for zinc concentrate</td>
</tr>
</tbody>
</table>
| 3                   | Preparation (single-company or consortium registration) | i) The mine blends (mix) their output (raw materials) in order to deliver a consistent product (zinc concentrate) may in fact meet the current EU criteria for a preparation
   ii) Currently, (zinc) concentrates are treaded by industry as preparations. |
| 4                   | One substance (single-company or consortium registration) | i) Zinc concentrate is derived from the mine and no substances are added and therefore zinc concentrate can be seen as one substance
   ii) Not applicable due the fact that for zinc concentrate not one CAS number, EINECS or ELINCS number. |

**Table: Interpretations of REACH for zinc concentrate inside the EU and the likely and vulnerable scenarios**

The following assumptions have been made to specify the scenario’s in more detail. Due to the fact that the zinc concentrate of the material provider may vary in composition and the allowed ranges of the variation in composition are not clear in REACH, consortium forming may be inhibited. The registrant therefore selected the scenario of a single-company registration. Regarding the preparation scenario, the number of substances in the preparation depends on the type of rock and the volume. In this case study it is assumed that 5 common substances (with a volume \( \geq 1000 \text{ ton/year} \)) in the preparation have to be registered.

The yearly volume of zinc concentrate does exceed the highest threshold for registration. The direct costs for the registration of zinc concentrate as a preparation or as a substance are reflected underneath.

Direct costs: registration as a preparation and a substance.
**Scenario** | **Direct costs**<sup>6</sup> (euro)
---|---
3 | Single-company registration as a preparation of 5 common substances | 1.615.815
4 | Single-company registration as one substance | 323.163

Due to the fact the material provider can not influence the market price of zinc concentrate the costs has to be absorbed by the material provider. In order to understand the impact of REACH the worst case scenario (the most vulnerable scenario) for registration is selected by the registrant: single-company registration as a preparation of 5 common substances (scenario 3). The direct costs of REACH registration are assumed to be taken in 1 year based on the financial and market situation of 2003. It is unknown whether the price increase will be maintained in the next year(s).

**Zinc concentrate from outside the EU: Zinc smelter has to apply REACH**

Interpretations of REACH for zinc concentrate from outside the EU and the likely and vulnerable<sup>7</sup> scenarios:

<table>
<thead>
<tr>
<th>Definition in REACH</th>
<th>Interpretation for zinc concentrate</th>
<th>Likely and vulnerable scenario?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Natural mineral, not chemically modified, and does not meet the criteria for dangerous substance/preparation</td>
<td>Zinc concentrate can be seen as a natural mineral. But according to the zinc smelter some components in zinc concentrate do meet the criteria for dangerous like lead sulphide.</td>
</tr>
<tr>
<td>2</td>
<td>Waste and/or secondary material (raw material or fuel)</td>
<td>Not applicable for zinc concentrate</td>
</tr>
<tr>
<td>3</td>
<td>Preparation (single-company or consortium registration)</td>
<td>i) The mine blends (mix) its output (raw materials) in order to deliver a consistent product (zinc concentrate) may in fact meet the current EU criteria for a preparation ii) Currently, concentrates are treaded by industry as preparations.</td>
</tr>
<tr>
<td>4</td>
<td>One substance (single-company or consortium registration)</td>
<td>Zinc concentrate is derived from a mine (outside the EU) and no substances are added and therefore zinc concentrate can be seen as one substance</td>
</tr>
</tbody>
</table>

The following assumptions have been made to specify the scenario’s in more detail. According the zinc smelter the zinc concentrate can be seen as a preparation or as a substance (number 3 and 4).

Regarding the registration as a preparation, the number of substances in the preparation depends on the type of rock and the volume. In this scenario it is assumed that 10 common substances in the preparation have to be registered. Although the composition may vary it is assumed in this scenario that the registration of an average composition of zinc concentrate consortium forming wit EU mines and smelters could be possible.

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<sup>6</sup> Direct costs calculated in corporation with the company and based on the agreed test and registration costs.

<sup>7</sup> See paragraph 8.3.3 for explanation of 'likely' and 'vulnerable'.
The zinc smelter imports from different material providers (more than 50) all over the world. Due to the fact that the zinc concentrate of the different material providers may vary in composition and the allowed ranges of the variation in composition are not clear in REACH, single-company registration of each different composition of the zinc concentrate per material provider could be a likely and vulnerable scenario. The yearly volume of zinc concentrate does exceed the highest threshold for registration. In the table underneath the two scenarios (number 3 and 4) are described and per scenario the direct costs for registration and testing are reflected.

**Direct costs: registration as a substance and a preparation**

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Direct costs 8 (euro)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 <strong>Consortium registration</strong> as a preparation (of 10 common substances) with a consortium of 12 partners (EU mines and smelters)</td>
<td>380,000</td>
</tr>
<tr>
<td>4 <strong>Single-company registration</strong> as a substance per quality (50 different qualities of concentrate imported from outside the EU)</td>
<td>16,160,000</td>
</tr>
</tbody>
</table>

In this case the zinc smelter selected both scenarios and therefore the impact of REACH for both scenarios has been investigated. The direct costs of REACH registration are assumed to be taken in 1 year based on the financial and market situation of 2003. Unknown if the price increase will be maintained in the next year(s).

**Findings**

The results are based on the selected scenarios:

<table>
<thead>
<tr>
<th>Type raw material</th>
<th>Scenario</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zinc concentrate from material provider</td>
<td>Single-company registration as a preparation of 5 common substances</td>
</tr>
<tr>
<td>Zinc concentrate imported by zinc smelter</td>
<td><strong>Consortium registration</strong> as a preparation (of 10 common substances) with a consortium of 12 partners (EU mines and smelters)</td>
</tr>
<tr>
<td></td>
<td><strong>Single-company registration</strong> as a substance per quality (50 different qualities of concentrate imported from outside the EU)</td>
</tr>
</tbody>
</table>

**Availability**

Zinc concentrate is a mineral derived from nature and, therefore, withdrawal of zinc concentrate is not likely.

REACH-related direct costs will not influence the availability of zinc concentrate for the material provider in the EU as they are not likely to cause a significant increase in the cost of zinc concentrate for both the importer and the material provider in the EU (see under ‘competitiveness’).

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8 Direct costs calculated in corporation with the company and based on the agreed test and registration costs.
Registration costs will need to be paid by the (in)organic producer or the material provider if located in the EU. The price of the zinc concentrate is determined by the London Metal Exchange (LME) and cannot be influenced by the material provider. This means that the material provider or the zinc smelter has to absorb the costs caused by REACH:

- 25% of the zinc concentrate is purchased from the material provider inside the EU; there will be no impact for the zinc smelter;
- 75% of the zinc concentrate is imported from outside the EU; the zinc smelter has to bear all the costs of registration.

Regarding the direct costs of REACH for the scenario (number 4) of single-company registration of 50 qualities of zinc concentrate imported from outside the EU, the access to unregistered raw materials could be limited because registration costs for low volume contracts (<3000 ton) cannot be amortised. Due to limited access to unregistered raw materials, there is less possibility to benefit from advantageous treatment charges, which could result in higher prices for zinc smelter. The zinc smelter indicated that he expects that with a limited access of unregistered materials and in a situation of a tight supply market conditions, REACH could even have a high impact on the availability of zinc concentrate (not quantified).

**Competitiveness**

Significant profitability (EBIT) impact is expected with a reduction of 10% for the material provider and 80% for the zinc smelter in the situation of a registration of 50 different qualities by the zinc smelter. For the consortium registration scenario no significant impact on the profitability is expected. The REACH related total product cost for the zinc smelter will increase by approximately with 2% for the single-company registration and 0.05% for the consortium registration scenario.

**Innovation (benefits)**

Zinc is a commodity, whereas zinc concentrate is a necessary raw material (substance) to produce zinc. Therefore, REACH is unlikely to increase the R&D research to new substances (raw materials) to produce zinc. Because the material is a natural product in concentrated form, there are limited possibilities to change the composition.

**Benefits to HSE**

Zinc concentrate is already classified as CMR material; therefore, HS&E risk management measures have already been taken. Furthermore, zinc concentrate has been in common use for a long time. The material (zinc concentrate) has only one use: raw material for zinc metal production. There may be benefits from REACH in terms of transparency of classification in the level playing field in the EU.
8.4.3 Paper case

Two materials were selected in this case: *recovered paper* and *chemical pulp*, both used by the paper mill. The interpretation of REACH for both selected materials is presented below.

**Selected scenario**

The interpretation of REACH for both selected materials is reflected underneath.

Interpretations of chemical pulp and the likely and vulnerable scenarios:

| Definition in REACH | Interpretation for chemical pulp | Likely and vulnerable scenario? |
|---------------------|----------------------------------|---------------------------------
| 1 Natural materials, not chemically modified, and does not meet the criteria for dangerous substance/preparation | Chemical pulp is a *natural material* derived from wood. Even tough chemicals are used in the production process of chemical pulp, the polymeric cellulose fibres are not chemically modified. | Yes |
| 2 Waste and/or secondary material (raw material or fuel) | Not applicable | No |
| 3 Preparation (single or consortium registration) | Not applicable | No |
| 4 One substance (single or consortium registration) | Not applicable | No |

Interpretations of recovered paper and the likely and vulnerable scenarios:

| Definition in REACH | Interpretation for recovered paper | Likely and vulnerable scenario? |
|---------------------|----------------------------------|---------------------------------
| 1 Natural materials, not chemically modified, and does not meet the criteria for dangerous substance/preparation | Not applicable | No |
| 2 Waste and/or secondary material (raw material or fuel) | Recovered paper is disposed of old paper and can been defined as waste and exempt from REACH | Yes |
| 3 Preparation (single or consortium registration) | Recovered paper can be seen as a preparation of different substances | No |
| 4 One substance (single or consortium registration) | Recovered paper can be seen as an article | No |

The two selected materials are both assumed by the company to be exempt from REACH registration and therefore the study is not continued regarding these materials as such. However, and this also according to the REACH proposal, the use of these raw materials could result in the necessity of analysing and possible notification of substances in the paper *product* (article) from the paper mill. Magazine paper is an article and notification is necessary according to REACH if certain criteria according to article 6.2 of REACH are met. To understand the impact of REACH, the study is therefore continued by studying the impacts of using recovered paper as raw material for magazine paper.
The total amount of paper produced by the paper mill is in the range of hundreds of thousands to millions of tonnes per year. This means that dangerous substances (such as metals) arising from natural origin easily exceed the quantity threshold of 1 ton/year, even though the concentrations of dangerous substances in paper products are low.

Due to the broken information chain\(^9\), the precise composition of the recovered paper is unknown. Therefore, each role of paper produced from recovered paper would have to be tested for dangerous substances in order to meet REACH requirements. As this was found to be impossible to deal with in practice, a scenario is used where analyses for dangerous substances are done per day of production.

**Findings**

The results are based on the selected scenario:

<table>
<thead>
<tr>
<th>Scenario</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notifications of substances in magazine paper (‘article’). Due to the broken information chain for registration analyses for dangerous substance (in ppm level) per day of production are needed.</td>
</tr>
</tbody>
</table>

**Availability**

Both selected raw materials (chemical pulp and recovered paper) are assumed to be exempt from REACH (chemical pulp is assumed to be a natural material and recovered is assumed to be waste) and therefore REACH has a low impact on the availability of the raw materials chemical pulp and recovered paper.

**Competitiveness**

For the selected scenario (for registration of the magazine paper analyses per day of the production is needed), the costs are EUR 7 million/yr, causing a high impact on the profitability of the paper mill. The expected high impact on profitability can add to a possible shift of production (using more virgin fibre) or delocalisation decisions.

**Innovation**

The paper mill indicated that REACH is unlikely to increase the R&D research into new substances (raw materials) to produce magazine paper.

**Benefits to HSE**

There is currently no information deficit regarding the HSE aspects of the use of magazine paper with a certain purpose, such newspapers, magazines, etc. The yearly cumulative amount of dangerous substances (such as metals arising from nature) in all paper produced (hundreds of thousands to millions of tonnes) easily exceed the 1 ton/year quantity threshold, whilst the

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\(^9\) The broken information chain: Only the collector of the secondary raw material is known and not the source or the exact supplier of the original paper products, which are disposed of and as such have become waste. This is the broken information chain. As a result, the exact composition of the waste is not known.
concentration is very much below the dangerous one\textsuperscript{10}. However, frequent analyses enforced by REACH would not change the HSE exposure on daily consumers and, as such, would not provide any additional benefits for the environment or human health. Furthermore, in the current situation, chemical legislation is not applicable to magazine paper and therefore no SDS is required for magazine paper.

In the situation that recovered paper needs to be registered by the material provider, information about the composition of raw materials in the recovered paper are necessary for registration and would therefore become available for to the paper mill as well.

\textit{Recycling of recovered paper}

Recovered paper is assumed to be exempt from REACH by the material provider and therefore there will be no effects. The material provider will continue the supply the paper mill with recovered paper.

If, however, very frequent analyses of recovered paper were required, this could have a negative effect on the use of recovered paper and could result in a shift from secondary raw materials back to primary raw materials.

\textbf{8.4.4 Cement case}

In the cement case, three materials of critical importance were selected:

- Fly ash: Originates from the production of electricity and an alternative to clinker in cement production.
- Blast-furnace slag: Originates from the production of iron and an alternative to clinker in cement production.
- Old tyres: old rubber tyres from cars, trucks, etc. is an alternative to fossil fuel in clinker production.

The yearly volume of fly ash and blast-furnace slag exceeds the highest threshold for registration (> 1000 t/yr)*.

* The volume of old tires purchased from the supplier that was chosen is lower than 1,000 t, but the volume of old tires from the second supplier of old tires for the cement plant studied, exceeds the 1,000 t threshold by more than an order of magnitude.

\textsuperscript{10} Always 100 to 1000 fold below the limit of dangerous concentration.
Selected scenario

Fly ash

Interpretations of fly ash and the likely and vulnerable scenarios:

<table>
<thead>
<tr>
<th>Definition in REACH</th>
<th>Interpretation for fly ash</th>
<th>Likely and vulnerable scenario?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Natural mineral, not chemically modified, and does not meet the criteria for dangerous substance/preparation</td>
<td>Not applicable</td>
<td>No</td>
</tr>
<tr>
<td>2 Waste and/or secondary material (raw material or fuel)</td>
<td>Fly ash is a by product from the production of electricity and is a secondary raw material.</td>
<td>Yes, in the scope of REACH and needs to be registered</td>
</tr>
<tr>
<td>3 Preparation (single or consortium registration)</td>
<td>Fly ash is a waste derived during the production of electricity and could therefore be seen as a preparation of two or more substances.</td>
<td>No. Despite the interpretation this is not a likely and vulnerable scenario according the materials provider</td>
</tr>
<tr>
<td>4 One substance (single or consortium registration)</td>
<td>Fly ash is a by product and could be seen as one substance.</td>
<td>Yes, in the scope of REACH and needs registration</td>
</tr>
</tbody>
</table>

According to the material provider, two scenarios are vulnerable: either fly ash could be seen as waste and is exempt from the scope of REACH (nr. 2) or fly ash is a substance (nr. 4).

The material provider of fly ash, however, chose not to participate in this study due to an internal discussion regarding the interpretation and definition according to REACH of fly ash.

Nevertheless, the study is continued at the cement producer (or (in)organic producer), without the information of the materials provider. For scenario 4 it is assumed that the direct costs of REACH are passed on (based on the volume) to the cement producer.

The yearly volume of fly ash exceeds the highest threshold for registration. The direct costs of REACH registration are assumed to be taken in 1 year based on the financial and market situation of 2003. Unknown if the price increase will be maintained in the next year(s).

Underneath the direct costs for the selected scenario are reflected.
Direct costs: registration as a substance and a preparation:

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Direct costs(^{11}) (euro)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2 Waste</td>
<td>0</td>
</tr>
<tr>
<td>4 Registration as one substance</td>
<td>323,163</td>
</tr>
</tbody>
</table>

The direct costs of REACH registration are assumed to be taken in 1 year based on the financial and market situation of 2003. Unknown if the price increase will be maintained in the next year(s).

Blast furnace slag

Interpretations of blast furnace slag and the likely and vulnerable scenarios:

<table>
<thead>
<tr>
<th>Definition in REACH</th>
<th>Interpretation for blast furnace slag</th>
<th>Likely and vulnerable scenario?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Natural mineral, not chemically modified, and does not meet the criteria for dangerous substance/preparation</td>
<td>Not applicable</td>
<td>No</td>
</tr>
<tr>
<td>2 Waste and/or secondary material (raw material or fuel)</td>
<td>Not applicable. Blast furnace slag is a by product and not waste</td>
<td>No</td>
</tr>
<tr>
<td>3 Preparation (single or consortium registration)</td>
<td>Blast furnace slag is derived during the production of iron and could therefore be seen as a preparation of two or more substances.</td>
<td>Yes</td>
</tr>
<tr>
<td>4 One substance (single or consortium registration)</td>
<td>Blast furnace slag is a by product and could be seen as one substance.</td>
<td>Yes</td>
</tr>
<tr>
<td>5 Intermediate</td>
<td>Blast furnace slag is considered an intermediate. The MP and IP are located on the same site (earlier one organisation) and there fore blast furnace slag could be seen as an intermediate</td>
<td>Yes</td>
</tr>
</tbody>
</table>

According to the material provider (participating steel producer in the study) three scenarios are likely and vulnerable. Regarding the preparation approach, six common substances are assumed to be registered.

Direct costs: registration as a substance and a preparation of blast furnace slag:

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Direct costs (euro)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 Single-company registration as an intermediate**</td>
<td>16,500*</td>
</tr>
<tr>
<td>4 Consortium registration as one substance</td>
<td>75,000 – 90,000*</td>
</tr>
<tr>
<td>3 Consortium registration of 6 substances in the preparation</td>
<td>445,000 – 540,000*</td>
</tr>
</tbody>
</table>

\(^*\): Direct costs estimated specific for blast furnace slag by another external consultant of the material provider.

\(^{**}\): The approved standard direct costs did not include direct costs for intermediates, therefore the direct cost estimated by the external consultant are used.

\(^{11}\): Direct costs calculated in corporation with the company and based on the agreed test and registration costs.
The direct costs estimated by this study and those of an external consultant the material provider hired, are for the substance and preparation scenario in the same range. In order to understand the impact of REACH the worst case scenario (the most vulnerable scenario) for registration is selected by the registrant: consortium registration of 6 substances in the preparation for further study and with the direct costs of 540,000 euro.

The direct costs of REACH registration are assumed to be taken in 1 year based on the financial and market situation of 2003. Unknown if the price increase will be maintained in the next year(s).

Old tires

Interpretations of *old tires* and the likely and vulnerable scenarios:

<table>
<thead>
<tr>
<th>Definition in REACH</th>
<th>Interpretation for old tires</th>
<th>Likely and vulnerable scenario?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Natural mineral, not chemically modified, and does not meet the criteria for</td>
<td>Not applicable</td>
<td>No</td>
</tr>
<tr>
<td>dangerous substance/preparation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 Waste and/or secondary material (raw material or fuel)</td>
<td>Old tires are parts of disposed of cars, trucks etc.</td>
<td>Yes</td>
</tr>
<tr>
<td>3 Preparation (single or consortium registration)</td>
<td>Not applicable</td>
<td>No</td>
</tr>
<tr>
<td>4 One substance (single or consortium registration)</td>
<td>Old tires could be seen as an article.</td>
<td>No. According the material provider of old tires this is not a vulnerable scenario.</td>
</tr>
</tbody>
</table>

According to the material provider of old tyres, old tyres are waste and are exempt from the scope of REACH. Due the uncertainty about this interpretation, and in order to study the impact of REACH on recovery of secondary materials, the study is continued for the scenario that, due to REACH, no old tyres are available as a secondary fuel. For this scenario, only the impact on recovery has been studied.

**Findings**

The results are based on the selected scenarios:

<table>
<thead>
<tr>
<th>Type raw material</th>
<th>Scenario</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fly ash</td>
<td>Registration as one substance</td>
</tr>
<tr>
<td>Blast furnace slag</td>
<td>Consortium registration of 6 substances in the preparation</td>
</tr>
<tr>
<td>Old tires</td>
<td>Due to REACH, no old tyres are available as a secondary fuel.</td>
</tr>
</tbody>
</table>

**Availability**

Fly ash and blast-furnace slag are by-products of other production processes and their availability is not expected to be influenced by REACH. Therefore, no withdrawal or reformulation is expected of either raw material.
**Competitiveness**

Direct costs of REACH could increase the price of *fly ash* by approx. 3% for the year REACH is implemented (uncertain whether the price increase will be maintained in the following year(s)). REACH-related direct costs could probably increase the price of *dry blast-furnace slag* (<5%) for the year REACH is implemented. The possible price increase of fly ash will increase the total product cost by approx. 4% for fly-ash cement and 2% for the total cement portfolio (of the company as a whole). The possible price increase for blast-furnace slag will increase the total product cost slightly (<5%) for the material provider (steel producer). The REACH-related direct costs increases associated with fly ashes and blast furnace slag are expected to have a limited impact.

**Innovation**

REACH is unlikely to increase the R&D research into new substances (raw materials) to produce (fly-ash and blast-furnace) cement.

**Benefits to HSE**

Currently, the cement producer as market leader already supplies the required HSE information in the supply chain. Therefore, REACH is not expected to influence the HSE information or HSE situation for users of the end-product (cement), according to the cement producer. The implementation of REACH, according to the cement producer, will not have an impact on the environment with regard to the production of fly-ash cement.

REACH may have a positive influence on balancing the level playing field regarding HSE information in the industry.

**Recycling and recovery**

Due to the limited expected price increase (due to direct REACH costs), fly ash and blast-furnace slag are still likely to be recycled.

However, if recycling of both raw materials is not possible because of REACH, there will be an environmental impact in terms of the emission of CO₂, energy use and the substitution by primary raw materials. The advantage of fly ash in comparison to clinker is a reduction of CO₂ emission of 0.2 ton CO₂/ton cement and a reduction primary raw material (marl) of 0.4 ton/ton cement and a reduction of energy of 1 GJ/ton cement. The advantage of blast furnace slag in comparison to clinker is a reduction of CO₂ emission of 0.6 ton CO₂/ton cement and a reduction primary raw material (marl) of 1.1 ton/ton cement and a reduction of energy of 2.5 GJ/ton cement.

If, due to REACH old tyres will no longer available as a secondary fuel the substitution of secondary fuel (old tyres) by fossil fuels, the CO₂ emission (0.1 ton CO₂/ton cement) will increase. Furthermore, disposal of old tyres instead of recovery will cause an increase in the total land-filled waste disposal.
8.4.5 Steel case

The steel producer (or the (in)organic producer) selected one critical substance: iron ore. The iron ore is imported from outside the EU. Therefore, the steel producer has direct registration obligations under REACH.

Selected scenario

Interpretations of iron ore and the likely and vulnerable scenarios:

<table>
<thead>
<tr>
<th>Definition in REACH</th>
<th>Interpretation for iron ore</th>
<th>Likely and vulnerable scenario?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Natural mineral, not chemically modified, and does not meet the criteria for dangerous substance/preparation</td>
<td>Iron ore is naturally-occurring mineral and chemical modified and does not meeting the criteria classification as for dangerous.</td>
<td>Yes</td>
</tr>
<tr>
<td>2 Waste and/or secondary material (raw material or fuel)</td>
<td>Not applicable</td>
<td>No</td>
</tr>
<tr>
<td>3 Preparation (single or consortium registration)</td>
<td>Not applicable</td>
<td>No</td>
</tr>
<tr>
<td>4 One substance (single or consortium registration)</td>
<td>Iron ore is processed (physical treatment) and the key question is, is this chemical modification? Iron ore is currently not classified as a ‘dangerous substance’. However, iron ore may contain impurities, not analysed at present in small percentages (and may be reduced by processing), large volumes of imported iron ore mean that the absolute volume of impurities could be large. And, therefore, authorisation may be needed. But authorisation is excluded from the scope of the study. A difference in the chemical composition could theoretically require a separate registration per supplier</td>
<td>Yes</td>
</tr>
</tbody>
</table>

According to the steel producer, two scenarios are vulnerable: either iron ore could be seen as natural material (number 1) and is exempt from the scope of REACH or iron ore is a substance (number 4).

Three types of iron ore can be distinguished: lump, pellets and pellet feed concentrate. The pellet feed concentrate is an intermediate.

The yearly volume of iron ore exceeds the highest threshold for registration. The direct cost of testing and registration for iron ore according to both the KPMG and the external consultant, RPA, are shown below.
Direct costs: registration as a substance and a preparation

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Direct costs$^{12}$ (euro) KPMG study</th>
<th>Direct costs$^{13}$ (euro) External consultant steel producer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Natural material</td>
<td>0</td>
</tr>
<tr>
<td>4a</td>
<td>Consortium registration as one substance (share borne by the steel producer)</td>
<td>442,400</td>
</tr>
<tr>
<td>4b</td>
<td>Consortium registration per current supplier (6 supplier) (share borne by the steel producer)</td>
<td>820,600</td>
</tr>
</tbody>
</table>

The direct costs of REACH registration are assumed to be taken in one year, based on the financial and market situation of 2003. It is not known whether this price increase will be maintained in the next year(s).

For this study the registrant (the steel producer) selected finally the scenario: consortium registration per current supplier.

Findings

The results are based on the selected scenario:

<table>
<thead>
<tr>
<th>Type raw material</th>
<th>Scenario</th>
</tr>
</thead>
<tbody>
<tr>
<td>Iron ore</td>
<td>Consortium registration per current supplier (6 supplier) (share borne by the steel producer)</td>
</tr>
</tbody>
</table>

Availability

Direct costs of REACH to register ore will not increase the overall cost of iron ore significantly and are not likely to reduce the availability of iron ore and/or steel.

Competitiveness

REACH-related direct cost increases associated with iron ore will not significantly impact the cost of iron ore products. The possible cost increases will be passed on as far as the market situation allows, otherwise will be absorbed.

REACH-related direct costs are still substantial and equate to the current cost-saving programmes implemented by steel producers aimed at saving comparable amounts. REACH-related costs are therefore an additional cost burden.

Innovation

Steel is a commodity, whereas iron ore is a necessary material to produce steel and, therefore, REACH is unlikely to increase the R&D research into new substances.

$^{12}$ Direct costs calculated in co-operation with the company and based on the agreed test and registration costs.

$^{13}$ The external consultant of the steel producer, RPA, specified the direct costs for iron ore. For the calculation of the direct costs the external consultant has been taken into account those three types of iron. The direct costs for an intermediate are assumed to be lower. The average direct costs used in the KPMG study do not take into account the different types of material; instead average direct costs are used.
Benefits to HSE

Currently, there is no deficit of health information in relation to steel sector products. However, there may be some benefits from REACH in terms of suppliers providing steel companies with better hazard information. There is no evidence to suggest that health risks associated with the steel industry’s raw materials are not already adequately known.

8.5 Input from the sector workshop

This paragraph reflects the conclusions and recommendations of the REACH Alliance\(^\text{14}\) sector workshop held on 7 March 2005 and are endorsed by the attendees of the workshop.

**General**

Overall, the participants in the REACH Alliance sector workshop do not disagree with the findings and conclusions of KPMG on the four cases of the (in)organic business case, provided that several limitations are taken into account (such as a few selected materials in limited parts of the supply chain).

Uncertainty and question marks exist regarding the interpretation of the application of REACH to the raw materials used in the sectors of the REACH Alliance, regarding both the terminology as well as the way the definitions for ‘waste’, ‘substance’ and ‘preparation’ are applied to (inorganic) raw materials.

Clarification of REACH (including guidance) is needed by the sectors of the REACH Alliance and, in order to be effective, such clarifications should be shared by the Commission and the Member States.

**Impact on competitiveness**

The sectors in the REACH Alliance are affected by REACH in terms of competitiveness due to the extra costs associated with the registration under REACH.

Because the study looked at a limited number of input materials/fuels, there will be a cumulative effect on the competitiveness due to the use of many more input materials in a real situation.

As even smaller companies in the (in)organic sector will typically exceed the highest threshold for registration (>1000 ton/year), the test and registration costs are expected to be comparable to those for the large companies in the sector. The impact of REACH on smaller companies could be more significant than on the large companies.

**Impact on availability**

Although all sectors are affected in their competitiveness, it is unlikely that the raw materials of the (in)organic sector will be withdrawn from the market mainly due the fact that they are used in high volumes and they are essential for the production of ‘commodities’. Because of possible price effects of REACH for waste collectors and, therefore, for recovery of alternative materials

\(^{14}\) REACH Alliance is an alliance of 12 different sectors of (in)organic materials. In the KPMG study this sector is called the (in-)organic sector.
or fuels in the inorganic chemistry, it is possible that some alternative materials/fuels will no longer be available for use in the industry.

**Impact on recycling and recovery**

There is a trend of increased recycling and recovery in the EU. REACH is not intended to have a negative influence on the high-quality recycling and recovery of secondary raw materials and fuels in the current situation and in the future. The broken information chain\(^\text{15}\) is a common concern for the industry and requires additional analysis of input material for registration. Depending on the requirements for these analyses, this could negatively impact the recycling/recovery of alternative feedstock. Depending on the specific situation for the alternative raw material or fuel, there could be a switch away from the alternative materials to primary raw materials and fuels.

**Benefits to innovation and HS&E**

Benefits of REACH for HS&E and innovation are low. HS&E issues are already covered by existing regulations. As a result of REACH, better information could be provided down the supply chain in some cases. But the HS&E benefits found in the KMPG study are in no relation to the very high additional costs due to the implementation of REACH.

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\(^{15}\) The broken information chain means that the secondary raw material is a waste that is disposed of by consumers (companies, etc). Only the service provider (or the waste collector) of the secondary raw material is known and not the source or the exact supplier of the waste to the service provider. Therefore, the exact composition of the waste is not known and the information chain is broken.
9 The Flexible Packaging case study

9.1 Sector background

Flexible Packaging Converters

Flexible Packaging mainly compromises printed multi-layer material based on plastic film, paper or aluminium foil. The packaging material is not rigid and in general takes the shape of the packed product. Some examples (also see figure 9.1) of flexible packaging are: coffee bags, sweets wrappers, chips bags, lids for dairy containers and sleeves for PET bottles. Approximately 80% of flexible packaging is used for food packaging.

Flexible packaging materials consist of: substrates (plastic, aluminium and paper), inks, varnishes and adhesives. The total EU production value is approximately EUR 10 billion. The average flexible packaging converter has 135 employees and profitability of 4.5% (EBIT). In the EU the annual production of flexible packaging is 15 billion m². The extent of import and export of flexible packaging material is limited (respectively 1.3% and 6.2%) because the local presence of the flexible packaging converter provides added value for the customers (packer-fillers). Most packer-fillers are large multinational companies, such as Unilever and Kraft-foods.

Over the last five years the flexible packaging market has consolidated. Whereas five years ago the top 6 converters accounted for 20% of the market this is currently increased to 30% of the world flexible packaging market. The largest converters are: Alcan Packaging, Amcor Flexibles, Bemis, Constantia Group, Huhtamaki, Nordenia, Sealed Air Cryovac and Printpack.

The majority of flexible packaging is used for food packaging and therefore raw materials (plastics) need to comply with food contact legislation. In practise many raw materials are tested for toxicological properties; this is the responsibility of the converter but performed in close cooperation with suppliers. Currently new food contact legislation is proposed by the European Commission (the “super regulation”). In this “super regulation” criteria are more stringent and the scope is expanded from raw materials (only plastics) to finished product (multi-layer
packaging material including non-plastics). As a result converters would have to perform more tests (such as migration studies) in order to be compliant. The flexible packaging industry is therefore concerned that due to the “super regulation” suppliers will reduce their portfolio of food contact grade materials for economical reasons.

Before a new packaging material is approved, an iterative process of testing is required. Through several test (figure 9.2) at formulator level, converter level and packer-filler level both the toxicological and technical properties need to be tested. In case of changes in the composition of the packing material re-testing is required at all levels.

Inks, varnish and adhesives formulators

The flexible packaging converters are supplied with inks varnish and adhesives by formulators.

Inks, varnishes and adhesives that are used in flexible packaging materials are mostly specialty products due to the required functional properties (e.g. sterilisable, pasteurisable), process requirements (e.g. antistatic) or legislation (food contact legislation). To meet these criteria inks, varnishes and adhesives contain many different additives (in small quantities). Typically, an ink formulator has 20,000 living formulations for inks used in flexible packaging printing. The diversity in adhesives is much smaller.

In the past five years the ink, varnish and adhesives formulators have consolidated. Some examples of large ink formulators are: Flint-Schmidt, BASF, Siegwerk and Sun Chemicals. Examples of large adhesives formulators are Henkel, Morchem and Rohm&Haas.

Flexible packaging inks can be grouped into 3 ink systems: solvent based inks, water based inks, and UV curing inks. Solvent based inks are still widely used in Europe but due to increasing environmental constraints (solvent emissions during printing) the converters gradually change to water based and UV curing inks where technically possible. The market for UV curing inks is young and developing it the next three to four years is critical for broad market acceptance. All three inks systems are included in the case study.
**Chemical suppliers**

The ink, varnish and adhesives formulators are supplied with pigments, solvents, resins and additives by large multinational chemical companies. Sometimes the formulators are supplied through agents or distributors.

Some examples of large suppliers of pigments are: BASF, Ciba Specialty Chemicals, Clariant and Dainippon Ink and Chemicals. A limited list of examples of large additives suppliers are: Air Products, BASF, Bayer, ExxonMobil Chemicals company, Degussa, Dow Chemicals, Johnson Matthey, Rohdia and Shell Chemicals.

As is illustrated (figure 9.3) the formulators and flexible packaging converters are relatively small compared with the chemical suppliers and the packer/ fillers.

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**Figure 9.3: the relative size of the companies in the flexible packaging supply chain**

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**9.2 Case study Background**

**9.2.1 Bottom-up process**

In cooperation with the sector organisations and discussed in the Working Group, the case study was focused on additives and pigments as used in inks, varnish and adhesives for flexible packaging.

In order to limit the scope of the study to manageable proportions film, foil paper and board were excluded. In addition solvents, resins and binders used in inks, varnishes and adhesives were excluded because they were considered unlikely to be withdrawn from the market due to REACH. In the table below the scope is summarized.
Table 9.1: scope of the case study flexible packaging

In the flexible packaging sector a large amount of different inks, varnish and adhesives exist, for these an even larger amount of additives and pigments exist. In order to structure and focus the case study in line with the methodology the additives and pigments were grouped into categories in close cooperation with the sector organisations and participating companies. These categories where used in order to circumvent confidentiality issues in the bottom-up process and where also used in for the simulation.

Categorisation of additives in inks and varnish

For the additives, 17 different functional categories were identified. Of these, 11 were considered not to contain substances of critical importance; either they were high-volume chemicals or substitutes were thought to be readily available, these were:

- Anti oxidant
- Catalyst
- Stabilizer
- Surfactant
- Tackifier
- Slip agent
- Acid Catalyst
- Plasticizers
- Thickeners
- Suspension agent
- Amine solubilizer

The remaining six categories of additives were considered to be of critical importance. Withdrawal of additives in these categories was expected to have a great impact due to their technical importance in the final product and their difficulty to substitute.
Therefore the case study for additives in inks was focussed on the following six categories of critical importance:

- Adhesion promoters.
- Anti-foam agents.
- Dispersing/ wetting/flow agents.
- Optical brighteners.
- Photo-initiators.
- UV stabilisers.

**Categorisation of additives in adhesives**

A similar procedure was followed for additives in adhesives where 7 categories of additives where identified. For 5 of these categories withdrawal was expected to have a great impact. The case study for additives in adhesives was focussed on these 5 categories of critical importance:

- Adhesion promoters.
- Anti-foam agents.
- Catalyst.
- Stabilizer.
- Surfactant.

**Categorisation of pigments**

For pigments a less detailed classification was defined. The pigments in inks where divided into the following groups:

- Process colours (see figure 9.4): being cyan, magenta, yellow and black which are used to realise the majority of colour shades during the printing process.
- Base colours: 10 to 12 colours used in large quantities in order to mix required colours at the converter before printing. Different converters use different sets of base colours.

- Spot colours: special colours used by the converter in relatively large quantities which are mixed by the formulator to match the exact requirements of the converters.

In addition to these three groups for pigments it is important to know that pigments are grouped into colour indices (for example PR 57:1). These colour indices indicate the chemical structure of the pigment. In the same colour index pigment suppliers offer different products (see Table 9.2). These products are all based on the same colour giving substance but get specific properties through different additives. For the purpose of this study this kind of products is called ‘packages’.

<table>
<thead>
<tr>
<th>Color index</th>
<th>Chemical Type</th>
<th>Random examples of pigment products (different suppliers)</th>
</tr>
</thead>
</table>
| PY 110 (Yellow) | Isoindolinone       | Cromophthal Yellow 3RT  
Irgazin Yellow 2RLT  
Irgazin Yellow 3RLTN                                                        |
| PY 13 (Yellow) | Disazo              | Symuler Fast Yellow 4306  
Symuler Fast Yellow 4306V  
Symuler Fast Yellow 4317  
Symuler Fast Yellow 4319  
Symuler Fast Yellow GRF                                                   |
| PR 57:1 (Red)  | Azo 4B toner (Ca)   | Irgalite Rubine L4BD  
Irgalite Rubine L4BE  
Irgalite Rubine L4BH  
Irgalite Rubine L4BN  
Irgalite Rubine LPBC  
Irgalite Magenta SMA  
Irgalite Magenta SMB                                                  |
| PB 15:2 (Blue)  | Cu-Phthalocyanin    | Heliogen Blue L 6875 F  
Heliogen Blue L 6870  
Heliogen Blau L 6990 F  
Heliogen Blau L 6989 F  
Heliogen Blau L 6975 F  
Heliogen Blau L 6901 F/L 6905 F                                      |

*Table 9.2: random examples of products in a certain colour index*

*Participating companies and number of selected substances*

During the bottom up process we identified the supply chain in close cooperation with the sector organisations and participating companies. A simplified representation of the supply chain is shown below (see figure 9.5).
30 pigments and 55 additives were selected from the critical categories. In addition five non-participating chemical suppliers were asked to indicate the likelihood of withdrawal for another 11 such additives.

Of the companies that were approached with the request to participate in the case study finally four chemical suppliers, four formulators and 2 converters agreed to cooperate (also see table 9.3).

In the table below (table 9.3), the amount and size of the participating companies in the case study are indicated.

<table>
<thead>
<tr>
<th>Level</th>
<th>Large companies</th>
<th>SMEs</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical suppliers (pigments/ additives)</td>
<td>3</td>
<td>1 (additives)</td>
<td>4</td>
</tr>
<tr>
<td>Formulators</td>
<td>2 (ink &amp; varnish) 1 (adhesive)</td>
<td>1 (ink &amp; varnish)</td>
<td>4</td>
</tr>
<tr>
<td>Downstream users (converters)</td>
<td>2</td>
<td></td>
<td>2</td>
</tr>
</tbody>
</table>

Table 9.3: Size of the participating companies
9.2.2 Top-down process

In order to determine the impact of market withdrawal of substances at the level of formulators (ink and adhesive manufacturers) and end user (converters), a simulation was foreseen. The percentage of market withdrawal found in each of the different categories of pigments and additives was to be randomly applied to the actual raw materials used by the participating companies. The simulation approach was designed to circumvent expected issues concerning confidentiality.

When the case study revealed limited withdrawal of critical additives, the simulation was adapted in order to still be able to study the potential impact of market withdrawal at the level of formulators and converters. For the simulation the following assumptions were made concerning the withdrawal of additives:

- 5% withdrawal for economical reasons (for 6 critical categories, only low volume additives, but including critical additives).

- A withdrawal rate of 2.5% (based on an external study\(^{16}\)) for toxicological reasons (all 17 categories of additives).

The simulation was performed at 3 ink formulators of which one SME ink formulator. At two formulators the simulation was performed for UV curing inks. At the third formulator the simulation was performed for the whole portfolio of inks (solvent based, water based inks and UV curing inks). For these three formulators the assumed withdrawal rates corresponds to the withdrawal of 5-8 additives. For these the formulators determined:

- The number of inks that needs reformulation and percentage of total product portfolio.

- Reformulation difficult or simple (proven substitutes available).

- The number of reformulations for which production test at the converters are required.

- Indication of the reformulation effort (in man hour) and consequences for the R&D department.

- Indication of the percentage of de-selection in their product portfolio because substitutes are not available or reformulation costs are too high.

As result of discussions during the sector workshop, the sector agreed to perform a second simulation (re-run) based on withdrawal of non-critical low-volume substances only, since this first simulation included the market withdrawal of critical substances which were found unlikely to be withdrawn. The re-runs of the simulations were not part of the work of KPMG and could, for time reasons, not be verified by independent experts (employed by the European Commission) nor be discussed in the sector workshop and the Working Group.

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\(^{16}\) “Assessment of the business impact of new regulations in the chemical sector” by RPA and Statistics Sweden (June 2002) prepared for the European Commission
The results of the re-run are described in text box 1: ‘Re-runs of the simulation by the sector’ (paragraph 9.3.2).

9.3 Findings in flexible packaging case study

When discussing the findings of the case study, we distinguish between findings for the following areas: vulnerability, availability, competitiveness, innovation and benefits. In each section we will discuss the findings for chemical suppliers, formulators and converters. To conclude in a separate paragraph the findings based on reflections and remarks by cooperating companies and the participants in the sector workshop are mentioned.

9.3.1 Vulnerability

At two chemical suppliers, 24 critical pigments and additives were tested for vulnerability. Of the tested pigments and additives, some 75% were manufactured in quantities larger than 100 tonnes per year. Most of the tested products are important products in the product portfolio of the chemical supplier and are also used in other sectors. One substance was found to be vulnerable. This substance is imported by an SME chemical supplier and marketed in a quantity less than 100 tonnes.

Two other chemical suppliers could not provide the necessary data to test vulnerability with the NPV methodology on time. However, these two companies indicated that the majority of the 46 selected critical additives and pigments in question were important products in their product portfolio, and indicated that the likelihood of withdrawal due to REACH of these substances was limited.

In addition, five more companies were approached to test the representativeness of the findings. These companies indicated that for the 11 selected additives (in the following categories: adhesion promoter, anti-foam agent dispersants, surfactant and stabiliser) the likelihood of withdrawal due to REACH is low.

One of the chemical companies indicated that the standard costs for Registration used in this study by decision of the Working Group are significantly (20%) to low.

In conclusion, it can be stated that among the critical substances, little or no vulnerability was found. This means that the probability of market withdrawal of substances of strategic importance for reasons of registration costs is very low.
9.3.2 Availability

Chemical suppliers

The Chemical suppliers clearly indicated that they aim to keep their product portfolio intact. They were well aware of the importance to their customers of the selected critical substances. However, they also argued that, when considering the whole of their product portfolio, withdrawal of some products for economical reasons due to REACH is likely to occur. One large chemical supplier showed that the one-off registration costs for its whole portfolio corresponds to a third of its annual profit. For the SME supplier, it was calculated that the direct registration costs for only a limited number of products would correspond to a significant part of the profit. This supplier indicated that, due to REACH, most non-polymeric products will be withdrawn from its product portfolio (polymers are exempt from REACH).

For two chemical suppliers the product portfolio already consists for the majority of polymers. For these suppliers the overall costs of registration are lower and the chance of withdrawal for economic reasons is limited. One of these (a large supplier) indicated that costs of registration for single substances could be spread over the whole portfolio.

Chemical suppliers indicated that if substances are to be withdrawn the following criteria will be taken into account:

• importance to customers;
• strategic importance within the portfolio;
• probability of reformulation success (in the case of ‘packages’);
• indication of potential toxicological properties;
• availability and price of raw materials.

As a result, REACH will lead to an accelerated rationalisation of products of limited strategic importance or that are at the end of their economic lifecycle.

Concerning pigment inks, one large pigment supplier emphasised that although some individual pigments might be withdrawn it is very unlikely that due to REACH a whole colour index would be withdrawn. Furthermore the pigment supplier indicated that the likelihood of withdrawal of pigments in base colours is low and that withdrawal of pigments in process colours is unlikely. Due to possible market withdrawal of non-critical substances, however, the composition of the ‘packages’ may need to be changed.
Formulators

Formulators of inks, varnish and adhesives indicate that they also aim to keep their portfolio intact. In particular for adhesives the impact of REACH is expected to be limited. Inks and varnish however contain more additives than adhesives and inks also contain pigments. Market withdrawal of substances would therefore have a bigger impact on inks.

As mentioned the main reason for the difference in impact of REACH on adhesives and pigments & varnishes is that the number of additives in adhesives is lower. In addition these additives have a less crucial role since the product properties of adhesives are mainly defined by other substances (binders, resins). Finally the formulator indicated that for cost control reasons for all additives alternatives are ready available.

During the case study limited indications were found for withdrawal of strategic additives and pigments at large chemical suppliers. However at formulator level we observed uncertainty and concern about the availability of (crucial) additives and pigments and the rate and timing of withdrawal. This concern of formulators is mainly caused by the relatively big impact (in terms of reformulation effort) that withdrawal of a small amount of substances would have. During the case study this mechanism was explored with a simulation at ink formulators.

The simulation showed that a limited withdrawal of additives (five to eight additives, including critical additives) would lead to reformulation of 50-75% of the inks. For UV curing inks, a relatively new technology, the withdrawal of substances would have a big impact because these inks contain many crucial inks for which alternatives are not readily available. Formulators indicated that substitution of additives in UV curing inks cost 60-500 thousand euro. However on the basis of the case study results the likelihood of the withdrawal of these critical substances is limited (for non-critical substances see text box 9.1: ‘Re-runs of the simulation by the sector’).

Converters

For converters the withdrawal of process colours, base colours or whole ink systems would lead to severe problems. Chemical suppliers and formulators however indicate that the likelihood of such withdrawal is very low. Converters also indicated their intention to keep their product portfolio intact. In case of a limited withdrawal of inks, varnishes or adhesives, converters expect to have alternatives available. The amount of testing related to a limited amount of reformulation (say twice today’s rate) is expected to be manageable.

Input from the sector workshop

During the sector workshop these findings were mostly recognised by the participants. However the participants emphasised that proper availability of raw materials is crucial. Based on the finding that among non-critical substances a certain amount of market withdrawal is likely to occur, the workshop concluded that technically this withdrawal of non-critical substances should not present great problems to formulators; they cope with occasional market withdrawal today. A small percentage of market withdrawal however affects a much larger percentage of the preparations in the formulators’ portfolio (see box ‘Re-run simulations by the sector’).
The timing of the withdrawal therefore determines to a large extent the downstream effect. If the withdrawal is evenly spread across time, the effect is manageable. If however, the withdrawal is postponed till the last possible moment that will lead to a number of undesirable effects such as the stop of all innovation during the reformulation period, a loss of profitability to both formulators and converters by not being able to supply, and a forced delocalisation outside the EU of the manufacture of flexible packaging materials. Good relationships between chemicals suppliers and downstream users and contracts demanding continued supply for a number of years may reduce the unexpected withdrawal of non-critical substances, but the supply chain is very complex. In addition an ‘early warning system’ for non-registration and authorisation is considered necessary to prevent disruption in the flexible packaging market.

9.3.3 Competitiveness

Chemical Suppliers

The impact of REACH on the competitiveness of large chemical suppliers is expected to be limited.

The cost increase for raw materials used by chemical supplier to produce additives and pigments are expected to be lower than the current cost increases that range from 15% to more than 100%. The direct one-off costs for registration are calculated to be 20% of the product costs of pigments and additives for individual products based on the standard costs and no consortia forming. When consortia forming and information already available is taken into account the direct on-off costs for registration for the whole product portfolio at one supplier were calculated to be 6%. This supplier sees consortia forming as a good possibility to reduce its overall costs of registration.

For the SME chemical supplier, the direct one-off cost was calculated to represent a significant part of its profit. The SME chemical supplier indicated that due to limited capacity and complexity of REACH consortia forming was not considered as an option to reduce cost. Since the possibility to pass on the cost is limited, the supplier expects that his portfolio will be reduced to polymeric products.

The costs of registration will have a temporary negative effect on the profitability of the chemical suppliers. This profitability is currently below 5% and therefore the chemical suppliers will pass on part of the costs as is currently done with cost increases. Although the chemical supplier cannot clearly indicate whether REACH will have an impact on their market share they do not see REACH as a driver for delocalisation.

Chemical suppliers will need additional qualified staff for testing and reformulations of ‘packages’. In addition chemical suppliers indicated that due to reformulations the customer service would increase. Although one chemical supplier is concerned that through REACH the product recipe will become public, others chemical suppliers do not foresee problems with confidentiality or communication. Nonetheless all suppliers indicated that more guidance is required concerning the identified use and the exchange of information in the supply chain.
Formulators

Based on the cost of chemicals, the impact on the competitiveness of the large formulators is limited. For inks, adhesives and varnishes the cost increases for additives due to REACH have a limited impact on the product cost. Cost increases for pigments could have a bigger impact on the product costs of inks, but formulators will pass on part of the costs. When considering a limited amount of reformulation the formulators do not perceive REACH as a direct driver for delocalisation.

For SMEs the impact on competitiveness is bigger compared to large formulators because reformulation costs are comparable; a limited amount of reformulation can have a significant impact on profitability. Some examples

- 5 reformulations with existing alternative additives impacts the profitability with >10%
- One formulation of a crucial additive with no existing alternative would impact profitability with >10%

Considering the results of the simulation, the impact on profitability could be significant due to reformulation costs (EUR 60,000 to EUR 500,000 per reformulation) of a large part of the portfolio. Since the likelihood of withdrawal of critical substances is limited, the impact was not quantified.

Communication in the sector about the toxicological properties of products is normal, due to requirements of food contact legislation. Therefore confidentiality with regard to toxicological information is generally not seen as a risk. Nevertheless the present REACH proposal can be considered to contain the obligation for formulators to mention not only the hazardous, but also the non-hazardous substances in the Safety Data Sheet of the preparation. For the ink makers this equals the complete disclosure of the formulation of the ink.

Converters

For the converters the impact of REACH on product cost is limited, because of a limited cost increase of inks, varnishes and adhesives (some 5%). Although the negotiation power of converters is limited, if cost increases are sector wide the converter will also pass on part of the costs. The ability of converters to absorb cost is limited because currently the profitability of the converters is moderate or slightly negative.

Delocalisation could have an impact in the case of the import of articles (finished flexible packaging) however converters indicate that the local presence of converters is still important for the packer. Currently the import of flexible packaging is limited and confined to low converted commodities. The converters expect that REACH will not change this as long as the price increases are limited and timely delivery remains possible.

In conclusion, it can be stated that the price rises of chemicals resulting from the direct cost of REACH are expected to have little effect on the competitiveness in the flexible packaging supply chain. IF a large number of reformulations will be necessary, however (see text box 9.1: ‘Re-runs of the simulation by the sector’), this would have a substantial effect. The effect
includes the reformulation effort itself both at formulator level and at the level of chemical suppliers that sell ‘packages’. It also includes the effort to introduce these new formulations into the production process of the converters and to test the packaging materials produced with these new preparations for meeting customer requirements and compliance with food contact legislation.

Input from the sector workshop

According to an industry expert at the sector workshop the problems would be surmountable provided that market withdrawal would indeed be limited to non-critical substances and would be evenly spread out over time. The participants (formulators) emphasised that in the case of withdrawal of additives and pigments over a short time period, the capacity to reformulate inks and varnishes would be insufficient and products could become temporarily unavailable. The participants expected that this would have severe negative effects on the industry, not in the least because it could stimulate import of readymade packaging materials from outside the European Union.

Re-runs of the simulation by the sector

At the sector workshop it was agreed to re-run the simulation, but only based on the possible withdrawal of non-critical low-volume substances; the Working Group was informed about this in the validation workshop. Besides, the additive and pigment producers ran a similar simulation on the possible withdrawal of their raw materials. In both cases a 5% withdrawal rate was applied to non-critical, low-volume substances actually in use. In the case of ink makers this was limited to additives and pigments. The re-runs of the simulations were performed in the same way as the earlier run which was validated in the sector workshop.

The simulations at a pigment manufacturer and an additives manufacturer, using a 5% withdrawal rate among non-critical, low volume substances, showed a need for reformulating an average of some 3% and 17% of their portfolios of 160 and 300 products respectively. Pigments and additives are raw materials to the ink makers. A reformulated pigment or additive is per definition not the same as the ‘old’ product and can generally not be used as a substitute without further changes to the formulation of the ink or varnish.

The simulation at one ink maker showed that a 5% withdrawal of non-critical pigments and additives results in a need for reformulation of some 30% to 35% of all the 17,000 different flexible packaging inks in its portfolio. The simulation at a second ink maker, who investigated modern UV curing inks and varnishes, showed a need for reformulating some 75 % of all the 900 different base materials for these products in its portfolio.

These simulations illustrate how a small percentage of market withdrawal, even for non-critical substances, will give rise to a percentage-wise much larger need for reformulation.

The re-runs of the simulations were not part of the work of KPMG and could, for time reasons, not be verified by independent experts hired by the European Commission nor be discussed in the sector workshop and the Working Group.

Textbox 9.1: Re-run of the simulation by the sector

At the sector workshop it was agreed to re-run the simulation, but only based on the possible withdrawal of non-critical low-volume substances; the Working Group was informed about this in the validation workshop. Besides, the additive and pigment producers ran a similar simulation on the possible withdrawal of their raw materials. In both cases a 5% withdrawal rate was applied to non-critical, low-volume substances actually in use. In the case of ink makers this was limited to additives and pigments. The re-runs of the simulations were performed in the same way as the earlier run which was validated in the sector workshop.

The simulations at a pigment manufacturer and an additives manufacturer, using a 5% withdrawal rate among non-critical, low volume substances, showed a need for reformulating an average of some 3% and 17% of their portfolios of 160 and 300 products respectively. Pigments and additives are raw materials to the ink makers. A reformulated pigment or additive is per definition not the same as the ‘old’ product and can generally not be used as a substitute without further changes to the formulation of the ink or varnish.

The simulation at one ink maker showed that a 5% withdrawal of non-critical pigments and additives results in a need for reformulation of some 30% to 35% of all the 17,000 different flexible packaging inks in its portfolio. The simulation at a second ink maker, who investigated modern UV curing inks and varnishes, showed a need for reformulating some 75 % of all the 900 different base materials for these products in its portfolio.

These simulations illustrate how a small percentage of market withdrawal, even for non-critical substances, will give rise to a percentage-wise much larger need for reformulation.

The re-runs of the simulations were not part of the work of KPMG and could, for time reasons, not be verified by independent experts hired by the European Commission nor be discussed in the sector workshop and the Working Group.
9.3.4 Innovation

Chemical suppliers

In general the R&D budgets of chemical suppliers will be maintained. As a result the chemical suppliers expect that during the phase-in period the R&D focus will temporarily shift from developing new products to REACH related activities such as:

- Testing in order to complete the information for the registration dossier.
- Reformulating of products (packages) due to potential withdrawal of substances.
- Customer service in order to introduce reformulated products (packages).

Concerning the time to market chemical suppliers could not quantify the impact of REACH; both positive and negative impact is expected. One supplier is concerned that a reduced availability of raw materials (due to withdrawal of non-critical substances) would limit his flexibility to develop new products and thereby potentially increase the time to market. A second chemical supplier indicated that for low volume products (< 1 tonne) the time to market will be shorter because the threshold in the current legislation is 10 kg, whereas the threshold in REACH is 1 tonne a year.

To conclude one chemical supplier regrets that REACH does not contain rewarding mechanisms which encourage the innovation of new products.

Formulators

Based on the main finding of the case study (limited withdrawal of critical substances), a possible negative impact of REACH on innovation is limited for the formulators. Furthermore, formulators are used to respond to reformulation of chemical suppliers due to rationalisation and indicated that a slight increase in this rationalisation is manageable. The formulators will not increase their R&D budget, meaning that an increase in reformulation efforts will result in a temporary decrease of the development of new products. The expectations of companies about the time-to-market for substances differ from being approximately the same to an increase with several months.

However, the impact of rationalisation of the chemical supplier portfolio (withdrawal of non-critical substances) depends on the timing and the extent of the rationalisation (see box ‘Re-runs of the simulation by the sector’). The formulators are concerned that withdrawal of substances by chemical suppliers will be concentrated over a short time period since keeping substances earmarked for withdrawal on the market for as long as legally possible makes economic sense. As a consequence the resulting reformulation work would also need to be concentrated over a short period of time.

Considering the outcome of the simulations, reformulation of a large part of the product portfolio at the level of formulators would be necessary. If indeed this work needs to be concentrated over a short period of time, this would also lead to capacity problems and shortages of qualified staff and, in addition, the development of new products would significantly decrease.
Converters

As for the formulators the impact of REACH on innovation for the converters depends on the amount of reformations and the timing. Based on the results of case study the impact of REACH on innovation is limited.

Converters indicate that a temporary doubling in the amount of reformulation is manageable. But because the converters will not increase their R&D budget an increase in reformulation efforts will result in a temporary decrease of the development of new products.

For every reformulation of an ink, varnish or adhesive the converter need to perform qualification test. These tests include:

- Test at the converter to establish that the reformulated preparation can be used in the production of the packaging material
- Test at the converter to guarantee that the packaging material with the reformulated preparation still meets the requirements of the packer/ filler (for example sterilizable)
- Tests at the packer-fillers to guarantee that the packaging material with the reformulated preparation can be used on the packaging line at the required conditions (for example run speed)

The costs for manpower and material of these tests can amount to between 30 and 60 thousand euro per reformulation. These costs are based on the current food contact legislation. Under the future ‘super regulation’ for food contact materials the costs of qualification tests will increase due to additional migration studies.

Input from the sector workshop

During the sector workshop these findings were mostly recognised by the participants. However the participants (formulators) emphasised that the withdrawal or change in composition of pigments and additives over a short time period would lead to a shortage of qualified staff and result in delivery problems and a significant reduction in new product development.

9.3.5 Benefits

Chemical Suppliers

In general chemical suppliers do not recognise benefits of REACH. Nevertheless some issues were identified that are seen as minor benefits or could become benefits if certain requirements are met.

The chemical suppliers indicated for example that if systems for information flow work properly after the phase-in period of REACH more information on substances properties will be available. As a consequence the requirements and needs in the supply chain are clearer and the design of safer product becomes easier.
Furthermore the chemical suppliers expect that under REACH differences in enforcement between EU countries will still exist and therefore they do not expect a level playing field to emerge.

To conclude, one chemical supplier indicated that an increased rate of rationalisation could be seen as a benefit.

**Formulators**

In general formulators do not recognise benefits of REACH. They indicate that due to the current requirements of food contact legislation, a considerable amount of knowledge about toxicological properties is already available. Furthermore the formulators indicated that a lot of effort is put in the development of safe products.

The formulators expect that under REACH differences in enforcement between EU countries will still exist and therefore they do not expect a level playing field to emerge.

**Converters**

In general converters do not recognise benefits of REACH. Nevertheless some issues were identified that are seen as minor benefits or could become benefits if certain requirements are met.

One converter expects that REACH could lead to better information about toxicological properties and the intended uses. Due to this increase in knowledge the required tests for food contact could become easier.

Converters expect that under REACH differences in enforcement between EU countries will exist and therefore they do not expect a level playing field to emerge.

To conclude the converters do not see rationalisation as a benefit.

**Input from the sector workshop**

During the sector workshop these findings were mostly recognised by the participants. The participants emphasised that the new ‘super regulation’ (food contact legislation) would probably have a bigger effect on the availability of information and more important benefits than REACH.
10 The Electronics case study

10.1 Sector background

Given the complexity of the Electronics sector as a whole means it is difficult to pick a single representative case study. Printed Circuit Boards (PCBs) have been chosen because the core aspects of REACH registration can be studied and they are commonly used as they are present in thousands of products. Results of this case study, however, are only representative for the electronic assembly supply chain itself.

PCBs are platforms that are made of laminated materials and provide interconnection for integrated circuits and other electronic components. Semiconductor designs are increasingly complex and require PCB’s with many layers of narrow densely spaced wiring.

The global market for PCBs is constantly growing due to the increased use of electronic equipment and increasing demand from the growth markets. The competition in the PCB assembly market is fierce. In the past years the migration of the OEMs (Original Equipment Manufacturers) and assemblers to Asia has seen a structural evolution in the electronics sector.

Below, the printed circuit board assembly is placed in the supply chain and process flow diagram. The PCB assembly process is complex and uses expensive base materials.

![Printed Circuit Board (PCB) Assembly: Supply Chain and Process Flow Diagram](image)

Table 10.1: Flow diagram of Printed Circuit Board Assembly (PCB)
10.2 Case study background

In cooperation with the sector organisations and discussed in the Working Group, two cases have been defined around an important product in the electronic industry: the Printed Circuit Board (PCB). The preparations that are used for the production of PCBs are called PCB assembly preparations or, shortened, preparations. According to the basic methodology of this study, two of those preparations were selected at downstream level and followed upstream. For reasons of confidentiality, the names and type of the preparations will not be given. The substances the formulator needs for the production of those preparations are supplied by either a chemical supplier or a distributor (primarily for lower-volume substances). The case study focused on two supply chains covering the selected preparations. A simplification of the supply chains is shown below.

Table 10.2: Simplified representation of the supply chains studied in the Electronics case study. The selected preparations the downstream users use, are not supplied by the participating formulators and therefore the relationship between the formulator and downstream user is called a ‘non direct relationship’

Participation of companies

It proved to be difficult to find companies willing to participate in this electronics case study. One of the arguments for not participating was that companies in the supply chain were not willing to provide information for confidentiality reasons. Eventually two downstream users were willing to participate, from an invited sample of seven downstream users contacted. At chemical supplier level, of the 13 selected suppliers, 2 chemical suppliers were prepared to have an in-depth interview.
Reasons for the other 11 not to participate are mentioned below:

- 6 did not recognise the use of the substance in electronics;
- 2 chemical suppliers deliver 2 substances that are exempt from REACH (volume being lower than the 1 tpa threshold and the substance being a polymer respectively);
- 2 chemical suppliers appeared to be based outside the EU;
- 1 chemical supplier was identified only at a late stage in the study and could not meet the deadline.

In the whole supply chain, a total of 6 in-depth interviews were carried out using the questionnaire (methodology spreadsheet) as described in earlier in this report under ‘Methodology’. From the 11 non-participating chemical suppliers, the researchers obtained general information such as: type of substance, strategic importance, volume range and the likelihood of withdrawal.

The number of the chemical suppliers, formulators and downstream users that participated in the study is shown below.

<table>
<thead>
<tr>
<th>Level</th>
<th>Number of companies</th>
<th>In-depth interviews</th>
<th>General information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical supplier (incl. distributor)</td>
<td>13</td>
<td>2</td>
<td>11</td>
</tr>
<tr>
<td>Formulator</td>
<td>2</td>
<td>2</td>
<td>n.a.</td>
</tr>
<tr>
<td>Downstream user</td>
<td>2</td>
<td>2</td>
<td>n.a.</td>
</tr>
<tr>
<td>Total</td>
<td>17</td>
<td>6</td>
<td>11</td>
</tr>
</tbody>
</table>

*Table 10.3: Participants in the electronics case study*

In the table below, the amount and size of the participating companies in the electronics case study are indicated.

<table>
<thead>
<tr>
<th>Level</th>
<th>Large companies</th>
<th>SMEs</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical supplier (incl. distributor)</td>
<td>1</td>
<td>1 (distributor)</td>
<td>2</td>
</tr>
<tr>
<td>Formulators</td>
<td>1</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Downstream users</td>
<td>2(1)</td>
<td></td>
<td>2</td>
</tr>
</tbody>
</table>

*Table 10.4: Size of the companies that provided detailed information during in-depth interviews*

Note 1: One of the companies was an R&D and small-scale manufacturing facility and not a high-volume production facility.

**Selecting critical substances for the case study**

In line with the methodology, critical substances in the two selected preparations (PREP 1 and 2) were identified. In total 12 of these critical substances were selected, supplied by 13 different chemical suppliers or distributors. Two chemical suppliers supplied the same substance.
Of the 12 critical substances selected, vulnerability under REACH was assessed for 4 substances (using the NPV method). These 4 substances were supplied by two chemical suppliers.

<table>
<thead>
<tr>
<th>Substances</th>
<th>PREP 1</th>
<th>PREP 2</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of critical substances</td>
<td>6</td>
<td>6</td>
<td>12</td>
</tr>
<tr>
<td>Exempt from study for various reasons</td>
<td>5</td>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>Vulnerability assessed</td>
<td>1(2)</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

Table 10.5: The number of critical substances, the number of exempt substances and the substances for which the NPV method was used for the two selected preparations

Note 2: Although the substance is produced in the EU, the NPV methodology was used at the level of an SME distributor in order to see effect of registration of imported substances for SME distributors

The findings of the case study are described below. External verification could not be organised within the timeframe of the study, nor has a full sectoral validation taken place in a workshop setting. Instead a meeting with representatives of the downstream users was arranged on 19-5-2005. During this meeting the findings were presented and discussed. The main outcomes of this discussion are mentioned in the paragraphs “comments from the sector”.

10.3 Findings of the Electronics case study

10.3.1 Vulnerability of substances

Four critical substances were assessed using the NPV methodology. Two of them were imported by a formulator and 2 others were supplied by a chemical supplier. Using a relatively short, but in this sector realistic, pay-back period of three years, 2 were found to be vulnerable. One of the two vulnerable substances was calculated to be very close to the break-even point (i.e. slightly vulnerable); the two non-vulnerable substances were far from the break-even point (i.e. quite profitable).

All four substances tested are imported in quantities less than 25 tonnes a year.

10.3.2 Impact on Availability

Chemical suppliers

The impact of direct registration17 cost of REACH on the availability of substances is limited. Many substances used in electronics appeared also to be used in other sectors and consequently are produced in high volumes (>100 tpa).

About half of the 12 selected critical substances were found to be high volume substances; therefore the product cost increases due to REACH are expected to be limited.

17 Including test costs and administrative costs
Even for the substances that were found vulnerable, the chemical suppliers indicated that they will not withdraw these from the market. For one low-volume (2 tpa) vulnerable substance, the chemical supplier indicated that the substance will be maintained, but under the precondition that the costs (estimated to be equivalent to a 30% price increase prolonged for 3 years) can be passed on.

For the SME distributor it is difficult to carry the registration costs. It imports (and probably has to register) 10% of its total portfolio in volume. For the majority of the imported substances, the one-off registration cost is 100% or more of the profit margin of that substance.

Therefore, the SME distributor will only register if either the formulator or the supplier is willing to share the costs. The distributor doubts whether suppliers from outside the EU will share in the cost of registration. For most imported substances, formulators will not find alternatives within the EU, which increases the possibility for the SME distributor to pass on the costs. If the costs for particular substances can not be passed on, their distribution for the EU might stop.

The formulators aim to maintain their portfolio. One of the arguments is that reformulation of preparations that have proven to be successful might lead to liabilities for product recalls. Also reformulation is expensive. To be able to maintain the portfolio, the formulators are prepared to pay a higher price for the critical substances and indicated they would even consider registering substances themselves if necessary, depending on the amount of available toxicity data, required tests and exposure information. Therefore the impact of REACH on the availability of the selected critical preparations is limited so long as formulators are able to absorb or pass on the costs.

Both formulators indicated that substitutes for the selected critical substances are not available. So if these substances are withdrawn, the formulator needs to reformulate the preparation. The capacity to deal with substitutes depends on the life cycle of the preparation. For both selected critical preparations the average lifecycle is short (on average 2-3 years). This means that investments or costs due to REACH (for reformulation) need to be absorbed in a short time frame. However if formulators could wait with reformulation of their products until a natural moment (end of life cycle) withdrawal of substances would have a limited impact.

Formulators also use substances which are used in the electronics sector only and that are supplied to them in very low (< 10 tpa) quantities. Of the 12 selected critical substances, 5 substances were supplied to the formulator in a volume lower than the 1 tonne per year threshold. For these 5 substances, formulators fear withdrawal. However, it appeared from the case study that substances delivered in small quantities to formulators are not always small quantity substances at chemical supplier level. For 1 substance used in a quantity less than 1 tonne by the formulator, the case study revealed it was a large volume chemical (HPV) at the level of the CS.
Downstream users

As the formulators aim to maintain the portfolio, in general, the impact on the availability of the preparations for the downstream user will be limited. The two selected critical preparations are also not likely to disappear or be reformulated.

One downstream user indicated that even if formulators decide to reformulate their products, no redesign of PCBs is needed, assuming that the reformulated preparations have comparable features (for instance being thermo-resistant).

It is difficult for formulators to pass on the costs to downstream users. Downstream users tend to keep the price of PCBs to a minimum. Product costs are very important and sometimes a product is even redesigned in order to save costs. For the two selected critical preparations, both downstream users have alternative suppliers. This gives them the opportunity to look for suppliers offering the lowest price, making it more even more difficult for the formulators to pass on the costs. Unless the cost increases due to REACH are equal for all downstream users, the formulators are likely to be forced to absorb the costs of REACH. However, if a downstream user is not successful in finding a supplier that is prepared to absorb the costs, the downstream user has to take (part of) these costs or accept that the availability of the substances/preparations in the EU is put at risk.

Comments from the sector

The findings regarding the impact on availability are acknowledged by the sector representatives.

The sector stresses that the researchers picked the two critical preparations from two different formulators to study. Critical preparations were not therefore chosen by the downstream users in the study. The sector thinks that findings from this case study are therefore more relevant to the formulator level rather than the downstream user (PCB assembler/manufacturer).

The companies repeated their fear for withdrawal of critical substances supplied to the formulator in a volume lower than the 1 tonne per year. They stressed that often exotic chemicals are purchased for critical uses in very low volumes in the semi-conductor sector. Withdrawal of these substances would have extremely serious negative consequences for semi-conductor manufacturing in Europe.

The sector representatives indicated that substance availability could also be influenced by other elements in REACH, such as authorisation, due to the uncertainty in this process.

The sector indicated that the ability of downstream users to change to other formulators due to cost increases may not always be possible because if one formulator needs to register the substance so may all others and therefore, the cost of registration will apply to all formulators who supply the DU.

The sector representatives recognised that withdrawal due to registration costs of REACH could lead to reformulation but they added that reformulation of preparations could also occur due to authorisation and/or substance reclassification.
Downstream users are worried about the possible withdrawal of substances of very high concern, as itself or included in preparations, as some of them are critical in their manufacturing processes. These substances/preparations of critical importance were not assessed in this study, but other impact studies revealed some of them may disappear from the EU market, due to the REACH Authorization process.

Sector representatives indicated that in addition to the reformulation costs due to qualification tests by formulators and downstream users, there may also be indirect costs arising from the need to register the alternative substance.

10.3.3 Impact on Competitiveness

Chemical suppliers

Based on the case study results, we conclude that, in general, the impact of direct registration cost of REACH on the competitiveness of the chemical supplier will be limited.

However, the impact on competitiveness is substantial for the SME distributor. For this company (mostly distributing in volumes lower than 100 tonnes per year) registration costs are high relative to the annual profit.

For 3 of the 4 substances tested for vulnerability, the one-off direct costs of REACH have a limited impact on the product costs. For the other substance tested, the one-off cost for registration are significant (>50% of cost price) because its yearly volume is just above the lower volume threshold (of 1 tpa).

The large supplier expects that consortium forming is possible for most of the substances in the portfolio. Therefore, the impact due to REACH on the profit for the whole portfolio is expected to be limited. Also for the 5 additional substances from the ‘not in-depth interview’ category, chemical suppliers indicated that the cost increase due to REACH is limited because the substances are also used in other sectors and/or that consortia are likely to be formed for registration.

As indicated earlier, for the SME distributor (importing and probably registering 10% of the total portfolio in volume), the one-off registration cost is 100% or more of the profit margin per imported substance. IF the company decides to withdraw these substances, the impact on the company’s profitability would be significant (>10%). However, the company indicated, substances are only imported if they are not available in the EU and can provide added value to customers; so there is a good change that the SME distributor can pass on the costs.

Companies (CS) will probably rationalise their portfolio before the registration deadline to prevent unnecessary registrations. However, one chemical supplier indicated that rationalisation may not only have negative effects (less products) but could also have positive effects (lower costs) for the customer.
Chemical suppliers are not sure whether they will be able to cover the use of their substances in the electronics sector sufficiently in the ‘identified use’. They feel that the current REACH draft is not specific about the level of detail that is required of the relevant scenario. Furthermore, suppliers are not always aware of the application of their substances in the electronics sector, since some substances are provided in very small quantities. In addition, due to concerns around confidentiality, formulators and downstream users may not share details on the specific use of the substance with the supplier.

**Formulators**

In the present case study, both formulators indicated that cost increases due to REACH cannot be passed on to downstream users. Therefore, it can be concluded that the impact of the direct registration costs of REACH on the competitiveness of the two selected preparations is likely to be limited.

That is because the increases in product costs due to REACH for the 4 critical substances tested for vulnerability, would lead to a limited increase of the final product price of the selected preparation, because they make up only 1-10% of these preparations in volume. Even for the imported substances by the formulator, and the substance with the expected price increase of 30%, the impact on the total product cost is limited.

IF, however, critical substances are withdrawn by the chemical supplier, alternatives are not readily available and consequently the preparations would need to be reformulated. The reformulation costs are estimated to be a minimum of EUR 200,000 per reformulation for in-company development plus testing at the customer (this figure does not take into account any cost increases due to a need to register the alternative substance under REACH for example). These investments need to be paid back within 1 to 3 years, due to the high speed of product evolution in the sector.

Formulators themselves expect some withdrawal of low-volume substances (1 to 10 tonnes) that are supplied to the electronics sector only. They think this will lead to a temporary higher rate of portfolio changes during the phasing-in period.

One of the formulators mentioned that, due to the global market, the formulator cannot influence the price of preparations and, therefore, the direct costs due to REACH have to be absorbed by the formulator.

To conclude formulator highlighted two concerns potentially impacting the competitiveness of the companies: *identified uses* and *confidential business information*.

**Identified uses**

Concerns were expressed at formulator level, whether the chemical supplier is willing to register for the appropriate ‘identified use’, as the formulator generally uses substances only in small quantities (1-10 tpa). However, in general, good contact exists between the chemical supplier and the formulator.
Confidential business information (CBI)

Formulators indicated they are not able to share detailed information about specific applications with their suppliers. They consider this as confidential information, especially in the first years of the life-cycle of a preparation, when it has not yet become a commodity and gives a competitive advantage to the formulator and also to the downstream user. One of the formulators indicated that if this information will have to be disclosed, some new and strategic products will be at risk. This confidentiality issue could become a barrier in the communication between the formulator and the chemical supplier, thus making it more difficult for the formulator to achieve the proper registration of all substances and their uses. The impact of this issue depends heavily on how detailed the exposure scenarios have to be under REACH.

Downstream users

Both downstream users and formulators indicated that in the global electronics market, costs increases cannot be passed on by the formulators to the downstream users. Direct costs due to REACH would have to be absorbed by the formulator. Therefore, in general, the impact on competitiveness due to REACH is expected to be limited for the downstream user.

For the critical substances studied, direct REACH costs will have a low impact on the profitability of the end products (PCB). This is because the impact at formulator level is already found to be low and, in general, the volumes of the chemical materials studied are relatively low in PCBs. It must be noted, however, that it is difficult for the downstream user to pass on even a small cost increase to consumers given the global market.

One of the downstream users indicated that they do not foresee any problems with the registration of their product, the PCB Assembly, as an article according REACH. Due to procedures and systems adopted as part of product assurance measures to guarantee compliance with the RoHS directive\(^{18}\) and further internal regulations and targets, all components are subjected to analysis prior to approval and subject to reporting requirements as part of ongoing compliance checks. This system is a part of the environmental management system of the downstream users and they believe these systems can be adapted to comply with REACH.

Comments from the sector

The findings regarding the impact on competitiveness are acknowledged by the sector representatives.

The sector stresses that the researchers picked the two critical preparations from two different formulators to study. Critical preparations were not therefore chosen by the downstream users in the study. The sector thinks that findings from this case study are therefore more relevant to the formulator level rather than the downstream user (PCB assembler/manufacturer).

Regarding competitiveness, the sector representatives indicated that competitiveness could also be influenced by authorisation.

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\(^{18}\) The RoHS directive (2002/96/EC) stands for Restriction of Use of certain Hazardous Substances. RoHS bans the use of heavy metals (Pb, Hg, Cd, Cr(VI)) and flame retardants (PBBs, PBDEs) in electronic equipment.
They also emphasised that protection of confidential business information is very important when considering competitiveness. They raise the concern that the present proposal does not go far enough in protecting confidential business information. The concern is that PCB assemblers and formulators in Asia could get access to both non-confidential and confidential information without the need for any financial outlay and can therefore manufacture their product at lower costs. The sector strongly feels that unless confidentiality and protection of confidential business information is guaranteed, REACH could negatively impact the competitiveness of the sector.

Moreover, given that communication and transfer of information up and down the substance’s supply chain is a key determining factor in the workability of REACH, sector representatives felt that this aspect could also have wider implications in addition to negative impacts on competitiveness.

The sector sees the need to stress that a key finding on ‘workability’ on formulators is of crucial importance also to the downstream user sector in its own right, namely that detailed information about specific applications represents confidential information, especially in the first years of the life-cycle of a preparation, when it has not yet become a commodity. This gives a competitive advantage to the downstream user, as well as the formulator. Moreover, the issue of specific applications includes the point of identified/unidentified use of substances.

The sector is concerned that consortia forming could also potentially impact competitiveness of the supply chain through monopolisation of substance prices.

The sector feels that there may be an impact on competitiveness regarding the registration of substances in articles particularly as the current ‘substance in article’ provision in REACH is unclear and more guidance would be needed for effective implementation. Furthermore, requirements in relation to substances in articles may affect very differently EU manufacturers of articles and non-EU manufacturers of articles.

While the sector representatives recognise that systems in place for RoHS can contain information also suitable for REACH, the requirements for REACH for electronic products go beyond that for RoHS and additional work will be required from downstream users. Furthermore, in complying with RoHS, many problems have arisen that are likely also to arise under REACH. While this might be manageable for the limited number of substances under RoHS, it may be very difficult when dealing with the amount of substances under REACH.

The sector representatives noted that both formulators and downstream users operate in a global market and therefore their costs are tightly controlled by the international marketplace. EU manufacturers, who have to deal with REACH and potentially have to absorb additional costs, are going to be put at a competitive disadvantage in this global market.
10.3.4 Impact on Innovation

Chemical suppliers

There are differences in opinion whether or not REACH is expected to benefit innovation. One chemical supplier thinks not; REACH may even have a negative impact on the research time available, due to the registration requirements. It was recognised however, that for SMEs, with volumes lower than 1 tonne, REACH might have a benefit19.

Formulators

The impact of REACH on innovation is expected to be limited because formulators prefer (the costs of) registration above reformulating. That is because reformulation is costly and was estimated to be a minimum of EUR 200,000 euro per preparation. This estimate includes part of the qualification test costs that are required at the downstream user, but does not take into account any cost increases due to a need to register the alternative substance under REACH.

IF reformulation is required, one formulator indicated that the R&D capacity would shift from developing new preparations to finding substitutes and testing reformulations. The other formulator indicated that the capacity for development of new products will be maintained and that in order to deal with reformulations, additional personnel will be hired.

The impact on the time-to-market is limited because, as a formulator said it, this is currently determined by the downstream users and will therefore be maintained.

Downstream users

For downstream users, the impact of direct registration costs of REACH on innovation is expected to be limited because the number of preparations that have to be reformulated by the formulator is expected to be limited. IF present selected preparations remain available, no diversion of resources from market-driven innovation is expected to take place.

If, however, preparations will be reformulated by the formulator, these need to be tested by the downstream user in qualification tests. One downstream user indeed is concerned that due to these tests innovation would be delayed especially if he has to deal with many reformulations in a short period of time. Another downstream user does not expect that reformulations would have an impact the innovation.

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19 The threshold in the current legislation is 10 kg, whereas the threshold in REACH it is 1 tonne a year.
Comments from the sector

The findings regarding the impact on innovation are acknowledged by the sector representatives.

The sector stresses that the researchers picked the two critical preparations from two different formulators to study. Critical preparations were not therefore chosen by the downstream users in the study. The sector thinks that findings from this case study are therefore more relevant to the formulator level rather than the downstream user (PCB assembler/manufacturer).

A sector representative noted that there may be impacts on innovation in other ways than those found in the study. For example, if the range and number of substances available under REACH is reduced due to portfolio rationalisation or deselection, then there will be a subsequent reduction in the number of substances available to innovate new products with.

A sector representative highlighted the potential risk at downstream user level (manufacture of parts, components and articles) of financial and human resources being diverted from innovation and R&D in order to deal with registration requirements.

A sector representative stated that innovation may also be negatively affected if the concept in REACH of ‘identified use’ is defined to narrow. When a new innovative use is found for an existing substance, this can not be readily implemented if a too narrowly defined ‘identified use’ prevent this. A sector representative raised the concern that the availability of qualified staff to manage REACH either within the Agency, the Member States, industry or test facilities could become a problem.

10.3.5 Benefits

Chemical suppliers

Chemical suppliers acknowledge that, REACH could have benefits for HSE. Because of more information sharing, the level of knowledge about the substances will increase. One REACH system with the same procedures could decrease the doubt about safety. Finally, this will have a positive influence on the reputation of the chemical industry as a whole.

Formulators

The commonest recognised benefit is the ability of REACH to facilitate the formulator in getting sufficient and reliable information from all suppliers. Better information also improves the protection of workers. At present, it takes a lot of effort for formulators to acquire the necessary HSE information themselves.

More information should improve the quality of the MSDSs, although better information does not automatically lead to safer products. One formulator indicated that the incremental REACH benefits will be limited due to existing regulations for the sector (such as RoHS).
**Downstream users**

Downstream users acknowledge that REACH could have benefits for the HSE performance at downstream user level. A crucial boundary condition is having enough time for deployment and informing of personnel in advance.

Another benefit due to REACH could be the availability of more and better information about the preparations from the formulators and the substances from their suppliers. Historically and currently, the information from suppliers is difficult to obtain for the downstream user. REACH forces the formulators to regularly update the information on the preparations.

**Comments from the sector**

The findings regarding the impact on HSE benefits are acknowledged by the sector representatives.

However, it is felt that more and better information about substances and preparations does not always automatically result in benefits for the HSE performance at downstream user level.
A  Glossary and abbreviations

Additive package: Formulated specialty chemicals; unique blends of additives packaged in a single formulation to achieve optimal performance characteristics.

Article: Manufactured product that has a final shape that is related to its use.

Authorisation: Use-specific permission to use substances of very high concern.

Commodity chemicals: Products that are generally highly price sensitive, produced by a number of companies throughout the world, and tend to meet accepted standard specifications.

Downstream user: Companies that use substances professionally or industrially (on their own, in preparations). Example: a manufacturer who mixes different chemicals to make ink, or uses the ink to print leaflets.

Existing chemicals: Chemicals that were reported to be on the market in 1981, when the requirement to notify new chemicals entered into force. There are about 100,000 existing chemicals. According to estimations, some 30,000 of them will be subject to registration under REACH.

Exposure: To come into contact with a substance. The amount of a substance someone comes into contact with is often modelled on a computer.

GHS: Globally Harmonised System for classification and labelling of chemicals.

HSE: Health, Safety & Environment

Identified use: Any use of a particular substance that the registrant has been made aware of. Downstream users have the right to demand from their suppliers that they register substances for all their uses.

New chemicals: Chemicals that have been placed on the market since 1981. These have to be notified to the Competent Authorities under the current EU chemical legislation. There are around 3,400 ‘new’ chemicals currently on the market.

Polymers: Large molecules consisting of repeated chemical units (monomers) joined together. Examples of polymers: plastic materials, two-component glue.

Preparation: Mixture or solution composed of two or more substances.

Product and process-orientated research and development (PPORD): Substances used in PPORD will have time limited exemptions from testing requirements.

R & D: Research and development.

Registrant: The manufacturer or the importer submitting a registration.

Registration: The first administrative step of REACH. The manufacturers and importers submit information in a standardised format, to demonstrate that they are managing their chemicals safely.

SMEs: Small and medium sized enterprises (headcount < 250; turnover < € 50 million)

Specialty chemicals: performance products (‘offered for what they do, not for what they are’)

Substances in articles: Hazardous substances that are released from articles as part of their function will generally have to be registered. If the release is not intentional, the substances may have to be notified.

Substitution: Avoiding use of a hazardous substance by replacing it with another substance (a substitute) or by changing production methods.

Tonnage threshold: Volume-based criteria for different requirements under REACH, formulated as ‘X tonnes/year per manufacturer/importer’. Will affect registration deadlines.

Tpa: tonnes per annum.
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