REACH - further work on impact assessment

A case study approach

Executive Summary

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KPMG Business Advisory Services
REACE1/JvdK/mh

Contents

Note to the reader

This is the executive summary of the REACH extended impact assessment carried out by KPMG Business Advisory Services B.V. The final report is expected to be finished at a later stage. In Chapter 1, the background of the project is explained. In Chapter 2, the approach of the study is explained, describing the different industrial sectors that contributed to the study and the agreed-upon assumptions on testing costs and the methodology to be used in the study. In Chapter 3, the working process is described stepwise as it has been applied in the study. In Chapter 4, the results of the study are given as common findings across the sectors studied. In Chapter 5, the results for the four participating sector supply chains are presented. At the end of the report, you will find a glossary and a list of abbreviations.

1 Background and issue

1.1 Memorandum of Understanding

The REACH proposal was adopted by the Commission in October 2003. Since then, 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 of 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).

1.2 Objective of the study

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

- 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.

2 Approach

2.1 Contributing sectors

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

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

The electronics case is expected to finish at a later stage and the results are therefore not covered in this summary.

2.2 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 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.

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

Table 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 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. In this note, the downstream user (DU) is equivalent to the (in)organic producer unless stated otherwise. 'Chemical supplier (CS)' is equivalent to the material provider in the (in)organics sector, unless stated otherwise.

Automotive, electronics and flexible packaging sector	**(In)organic sector**
Chemical supplier	Material provider: Provider of raw materials to the (in)organic producer.
Formulator	not applicable
Downstream user / converter	(In)organic producer: producer of (in)organic materials by using raw materials

Table 2: Differences in terminology per sector

In total 10 case studies were carried out (see Table 1), one DU involved in each case study (Table 2). [The electronics case has not been finished yet; see annex B]

Level	**Automotive**	**(In)organics**	**Flexible Packaging**	**Electronics**
Chemical suppliers / mat. providers	3	5	4 (+ 5 for extra check)	1 + ?
Formulators	4	n.a.	4	2
Downstream. users/ (in)org producers	2	4	2	2

Table 3: Number of participating companies per sector and supply chain level

In table 4, the division of the participating companies in large 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.

Level	**Larger companies**	**SMEs**	**Of which importer**
Chemical suppliers/ material providers	11	2	3
Formulators	6	4	-
Downstream users / (in)organic producers	10	-	2
Total	27	6	5

Table 4: Distribution of large, SME and importing companies participating per supply chain level

2.3 Issues agreed upon in advance

2.3.1 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.

Individual registration costs (minimum QSAR)

		Total test cost	registration costs	**total**
V	1- 10 tonne	8.702	5.900	**14.602**
VI	10-100 tonne	151.573	11.150	**162.723**
VII	100-1000 tonn	243.467	38.630	**282.097**
VIII	> 1000 tonne	278.213	44.950	**323.163**

Consortia registration costs (minimum QSAR)

		Total test cost	Total registration cos	pre-reg and fees (per firm)	**total per firm - 2 firms**
V	1- 10 tonne	8.702	24.000	633	**16.984**
VI	10-100 tonne	151.573	29.250	633	**91.045**
VII	100-1000 tonn	243.467	59.130	3.167	**154.465**
VIII	> 1000 tonne	278.213	86.450	3.167	**185.498**
Number of firms					2

Considerations

1. Testing cost:
   - o scenarios of the ECB studies
   - o scenario with minimum use of QSAR's
2. Registration costs: use RPA study as basis and make following adjustments:
   - o annex V no longer require a CSA and CSR. Only overhead administrative costs will be needed
   - o registration and evaluation fees are added.
3. Distinguish between individual registration and consortium registration (two firms).

Table 4: Standardised testing and registration costs applied in this study

2.3.2 Methodology

From the suggested and agreed-upon (not by EEB/WWF) production processes (Table 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 (see paragraph 3 on Working process for more detailed description).

[1] ECB study: Pedersen F, De Bruijn J, Munn S, and Van Leeuwen K (2003).
Assessment of additional testing needs under REACH. Effects of (Q)SARS, risk based testing and voluntary industry initiatives, European Commission, Joint Research Centre, September 2003.
RPA, *Revised business impact assessment for the consultation document. Working paper 4*.
Assessment of the business impacts of new regulations in the chemical sector. Phase 2.
Prepared for European Commission Enterprise Directorate-General. London, 2003.

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 table 6, a summary is given of the spread sheet. Where relevant, timing aspects were studied for the various issues.

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

Table 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 (Table 7).

7. Impact on Innovation													
Level						Question	Parameter	Answer			Comments	Evidence
MP	IP	CS	F	DU				Present	Baseline	REACH		
						3.1 R&D expenses						
		1			1	What are the companies total R&D expenses per year	EUR per year	3	5			6
					2	What are the companies total R&D activities per year	# of FTE's					
					3	What are the companies total R&D expenses per product group	EUR per year					
						a …….						
						b …….						
						c …….						
						d …….						
						NEW …….						
					4	What are the companies total R&D expenses per cost categorie	EUR per year					
						- manpower						
						- material						
						- external service providers						
						- …….						
					5	What are the companies total R&D expenses per market segment?	EUR per year					
						a …….						
						b …….						
						c …….						
		o	o	o	6	**What are the companies total R&D expenses per year related to total turnover revenu, considering REACH impact on the selected substance?**	%					
		o	o	o	6	**What are the companies total R&D expenses per year related to total turnover revenu, considering REACH impact on all substances?**	%					

Sample

4

1 Level (CS, F, DU) to which the question applies
2 Question
3 To be expressed as (units)
4 Timeframe to which the question applies
5 Answers, either quantitative or indicating trends
6 Reference to evidence supporting the answer

Table 7: Sample of the methodology spreadsheet

Limitations

This case study also has some limitations:

- the amount of substances/materials studied is limited; cumulative effect 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 (in)organics cases studied (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, no random sampling;
- multiple data collection methods are used;
- qualitative and quantitative data are combined;
- there is overlap of data collection and analysis;
- search for 'why' behind relationships;
- within case analysis and cross-case pattern search;
- the researchers will operate with an 'open mind' without preconceived ideas.

* Eisenhardt, K.M. (1989). Building theories from case study research. Academy of Management Review, 14 (4), 532-550.

3 Working process

As represented in Table 7, the companies at each supply chain level (CS, F, DU) are typically visited twice. The first visit took place in the order DU, F and 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.

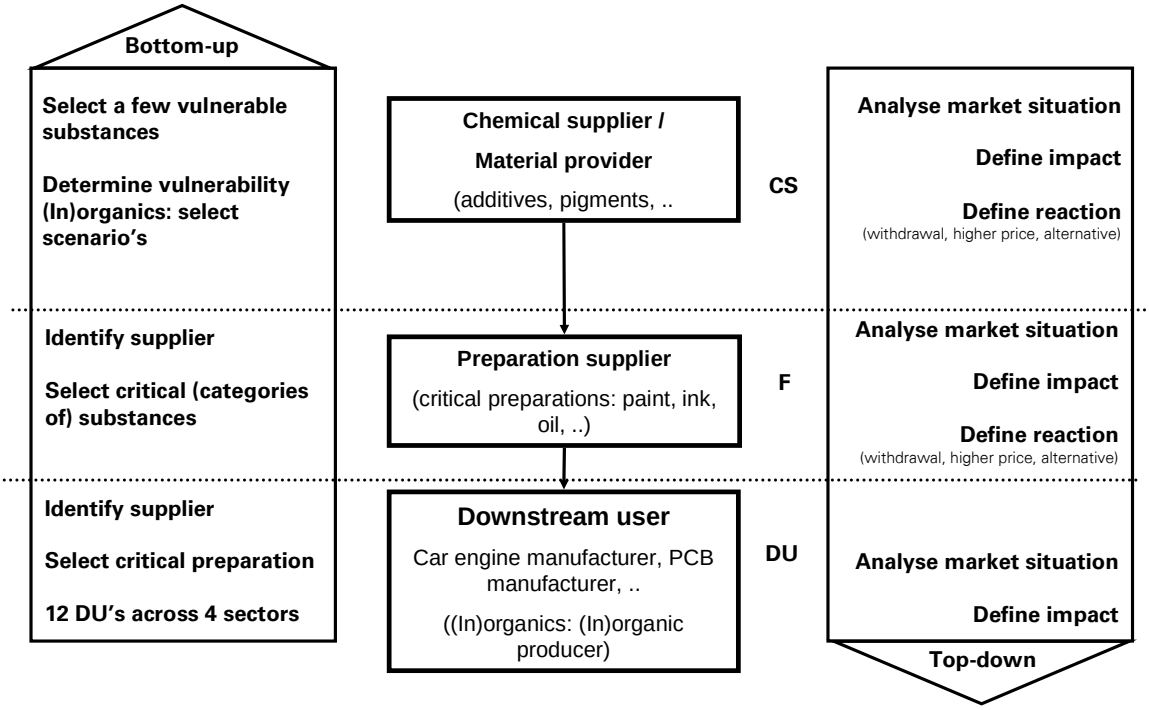


Table 7: Working process of this study: materials and suppliers are selected bottom-up and the reaction and impact are determined top-down the supply chain.

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.

'Bottom-up' in the supply chain

1. **At downstream user level, determine suppliers.** The selected end-use materials (Table 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 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, cement and old tyres). **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.

'Top-down' in the supply chain

5. **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.

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.

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;
        - 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 is to do this across all of the sectors studied. The members of the Working Group participated in the Validation workshop.

4 Findings

This chapter contains the findings about the sectors studied:

	Code		Sector
1.	AM	:	automotive
2.	IO	:	(in)organics
3.	FP	:	flexible packaging
4.	EL	:	electronics (to be included)

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
4. Business benefits
5. Recycling and recovery

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

4.1.1 Level of vulnerability at chemical supplier level

A total of 152 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 per sector:

- the amount of substances to which the NPV method was applied;
- the amount of selected critical substances of the NPV assessed substances;
- the amount of vulnerable substances of the amount of critical respectively non-critical substances.

	NPV assessed substances	Critical substances NPV assessed	Vulnerable and critical substances	Vulnerable and not critical
Automotive	50	24	1*	8
Flexpack	24	22	1	0

*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 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%. Almost all the vulnerable substances found are in the 10-100 and 1-10 tonnage band.

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.

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;
- FP: 23 tested, none vulnerable;
- AM: 20 tested 1 vulnerable.

4.1.2 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 CS, 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 DU 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).
- Changing a formulation leads to significant DU approval costs (AM&FP) 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 in the automotive and flexible packaging 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 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).
- Continuity of supply, trust, quality and customer communication are important prerequisites for suppliers (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 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.

IO: Impact on raw materials
- withdrawal of primary raw materials unlikely.
- a shift from secondary raw materials back to primary raw materials / fuels could occur.

4.1.3 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. In one case, it amounted up to 20% of annual turnover.

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 and less critical downstream (with some reduction in profit). They indicated that they will do this only after discussion with the customer.

In absolute terms, the amount of money required for registration can be significant for the registrant.
Measures planned by companies to reduce costs are:
- Consortia forming (AM & FP).
- 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).

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 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 be difficult for SMEs to fund the direct costs (AM&FP).

4.1.4 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. On the one hand, the formulations they produce are technically highly

* (In)organic producers and material providers will absorb the direct costs of REACH, notably those who are active in a global market and cannot influence world product prices.

dependent on the substances the 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.

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

This uncertainty is also triggered by the awareness at formulator level that *if* withdrawal of critical substances takes place (see paragraph 4.1.3 for reasons), 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).

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).
- 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).

4.2 Competitiveness

4.2.1 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.

Increase in product cost of pigments & additives as a result of testing and registration up to 20% (one-off) at CS level
FP: 6% (on whole portfolio) with consortia and available information; 20% without consortia (for selected products).
AM: 6% without consortia; SMEs, 17% with consortia.

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) to 30% (engine oil) in the value of a preparation; for pigments in ink, it can be more. It should be noted, however, that cumulative effects can occur from other (not studied) substances. Although for the end-user products studied (Table 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).

The direct costs get diluted down the value chain if passed on

…as additives make up 10% (paint) to 30% (engine oil) in the value of a preparation (for pigments in ink, it can be more).

Cumulative effects might occur from other (not studied) substances; however, major other components exempt (resins) or less vulnerable (solvents).

4.2.2 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.

CS and F expect to absorb or in some situations pass on the direct costs

- Formulators expect to pass on costs (also at least partially those of existing products) on new products, in combination with offering improved functionality (AM).
- Passing on costs may be more difficult for SME companies (FP) and where global competition and international sourcing is particularly strong.

For downstream users

The direct REACH cost of the end-use materials studied (Table 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 4.2.1) 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)
- From F to DU level, these cost get further diluted (AM & FP)

Context:

- Even a low impact on profitability could be a serious issue given the overall pressure on profitability in global operating industries (AM).
- Profit margin in 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).

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.

4.2.3 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 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.

4.2.4 Impact on portfolio

As already indicated in paragraph 4.1.2, 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 (IO, AM & FP).

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).
- Ability of SMEs to form consortia and fund direct costs (AM & FP).

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

- For CS, 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.

4.2.5 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).

4.2.6 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.

DU and F 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'

- 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).

Preliminary finding from electronics sector (to be reviewed at finalization of the study)
In the electronic sector cooperation in the value chain has turned out to be problematic, indicating that confidential business information (CBI) is a major issue in this sector. Information on the composition of preparations is highly sensitive and disclosure would result in competitive disadvantages or loss of market shares (protection of CBI is important with regard to the pay back for R&D investments).

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 companies see intellectual property / confidential business information at risk (CS/F), because of communication/disclosure requirements under REACH.

- 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).
- 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 (4.1.4), critical substance loss requires long adaptation times and many resources, as has been more specifically indicated in the box below.

Worries about the extent and timing of possible future legal substances limitations under REACH (AM, FP, IO).

- Importance: cars have long lead-time; re-engineering of 'running series' (models under production) expensive (AM).
- Restricted access to certain raw material sources limiting competitiveness (IO).

If occurring at a high rate, impact may be high (AM&FP).

- Longer term testing is needed to ensure reliability.
- Limited amount of time available to companies to find alternatives and earn back investments; capacity problems expected.
- Reformulation will take away resources from innovation and customer-oriented R&D, which may have negative implications further down the chain (e.g. developing new products and processes).

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

4.3 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 4.1.2), 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.

No increase in R&D expenses expected (AM, FP & IO).

Limited diversion of R&D resources due to REACH implementation.

- …because of limited economical withdrawal of critical substances.
- Some indicate delay in time-to-market (CS: from 2 to 2.5 yrs 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).

4.4 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, FP & IO).
Risk management easier (AM).
Rationalisation (1x at FP).

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

* 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.

(In)organics sector expects little benefits
'as the current environmental and workforce legislation deals adequately with their materials'.

4.5 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 the 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.

A Annex (in)organic sector

A.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 recyclers (including recovery)***. 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 sector, paper sector, cement sector and the steel sector.

A.2 Case study background

A.2.1 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.

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 and described in the Memorandum of Understanding (MoU). 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

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

Compared to the number of raw materials used by the (in)organic producers, a limited number of raw materials/fuels has been investigated in the study of KPMG. 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.

A.2.2 Scenario approach

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 the (in)organic sector study has selected the way to register the substance for further study regarding the impact on REACH. 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 a likely interpretation in practice?
- Vulnerability: Are there high direct costs for the registrant in this scenario?

The variables for the scenarios are:

- Possible interpretations of REACH.
- Single 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.

Definition in REACH	**REACH requirement**
Natural mineral, not chemically modified, and does not meet the criteria for dangerous substance/preparation	Exempt from REACH
Waste and/or secondary material (raw material or fuel)	Totally or partly included or exempt from REACH
Preparation (single or consortium registration)	Registration of the substances (≥ 1 ton/year) in the preparation
One substance (single or consortium registration)	Registration as one substance

In this annex, only the selected scenarios are described and the findings based on those scenarios are reflected.

A.3 Findings

A.3.1 General

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.

A.3.2 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.

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

Likely and vulnerable[2] scenarios for zinc concentrate inside the EU:

Definition in REACH	Interpretation for zinc concentrate	Scenario
Preparation (single or consortium registration)	i) The mine blends (mixes) its output (raw materials) in order to deliver a consistent product (zinc concentrate) and thus may in fact meet the current EU criteria for a 'preparation'. ii) Currently, (zinc) concentrates are traded by industry as preparations.	Single registration of zinc concentrate as a preparation of 5 common substances

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

Likely and vulnerable[3] scenarios for zinc concentrate from outside the EU:

Definition in REACH	Interpretation for zinc concentrate	Scenario
One substance (single or consortium registration)	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	Single registration as a substance per quality (50 different qualities of concentrate imported form outside the EU

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 registration of each different composition of the zinc concentrate per material provider could be a likely and vulnerable scenario.

The results are based on the selected scenarios as described above.

Availability

Zinc concentrate is a mineral derived from nature and, therefore, REACH-related direct costs will not influence the availability of zinc concentrate for the *material provider in the EU*. Thus withdrawal, substitution, reformulation or redesign of zinc concentrate is not likely.

Direct REACH costs are not likely to cause an increase in the cost of zinc concentrate for both the importer and the material provider in the EU. 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.

[2] See paragraph 2 for explanation of 'likely' and 'vulnerable'.
[3] See paragraph 2 for explanation of 'likely' and 'vulnerable'.

Regarding the direct costs of REACH for the scenario of single 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 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 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.

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. And 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 requirements are applicable. 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. REACH could potentially have a positive influence on reference numbers and guidelines. This transparency of classification enforced by REACH for all parties in this sector may also benefit the creation of a level playing field in the EU.

A.3.3 Paper case

Two materials are 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.

Likely and vulnerable scenario for chemical pulp:

Definition in REACH	Interpretation for chemical pulp
Natural mineral, not chemically modified, and does not meet the criteria for dangerous substance/preparation	Chemical pulp is a *natural material* derived from wood. Even though chemicals are used in the production process of chemical pulp, the polymeric cellulose fibres are not chemically modified.

Likely and vulnerable scenario for recovered paper:

Definition in REACH	Interpretation for recovered paper
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

The two selected materials are both assumed to be exempt from REACH 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 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[4], 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 productio*n.

Availability

Both selected raw materials (chemical pulp and recovered paper) are assumed to be exempt from REACH (see earlier for an explanation) and therefore REACH has a low impact on the availability of the raw materials chemical pulp and recovered paper.

Competitiveness

For the selected scenario, 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

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

[4] 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.

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 concentration is very much below the dangerous one[5]. 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, more information about the composition of raw materials would become available to the producer.

Recycling of recovered paper

Recovered paper is assumed to be exempt from REACH 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.

A.3.4 Cement case

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

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

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

In the table below, the selected scenarios for each material is given.

Likely and vulnerable scenario for *fly ash*:

Definition in REACH	Interpretation for fly ash	Scenario
One substance (single or consortium registration)	Fly ash is a by-product and could be seen as one substance.	Registration as one substance

Unfortunately, the material provider of fly ash was not yet ready to participate in this study due to internal discussions regarding the interpretation and definition of fly ash according to REACH.

[5] Always 100 to 1000 fold below the limit of dangerous concentration.

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

Likely and vulnerable scenarios of *blast-furnace slag*:

Definition in REACH	**Interpretation for blast furnace slag**	**Scenario**
Preparation (single or consortium registration)	Blast-furnace slag is a by-product of the production of iron and could therefore be seen as a preparation of two or more substances.	Consortium registration of 6 substances in the preparation

Likely and vulnerable scenario for *old tyres*:

Definition in REACH	**Interpretation for old tyres**	**Scenario**
Waste and/or secondary material (raw material or fuel)	Old tyres are part of disposed of cars, trucks, etc.	Old tyres are exempt from REACH

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.

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).

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 environmental situation 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 CO_2, energy use and the substitution by primary raw materials.

Due the substitution of secondary fuel (old tyres) by fossil fuels, the CO_2 emission (0.1 ton CO_2/ton clinker) will increase. Furthermore, disposal of old tyres instead of recovery (1,000 ton) causes a 0.2% increase in the total land-filled waste disposal.

A.3.5 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.

Likely and vulnerable scenarios of *iron ore*:

Definition in REACH	**Interpretation for iron ore**	**Scenario**
One substance (single or consortium registration)	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.	Consortium registration per current supplier. Assumed: 6 suppliers/material providers

The yearly volume of iron ore exceeds the highest threshold for registration (> 1000 t/yr).

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 on the EU market under current market conditions.

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 they will have to be absorbed

REACH-related direct costs are still substantial as elements of the current cost-saving programme implemented by steel producers are 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.

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.

A.4 Findings sector workshop

This paragraph reflects the conclusions and recommendations of the REACH Alliance[6] 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.

[6] 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.

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 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[7] 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.

[7] 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.

B Annex electronics sector

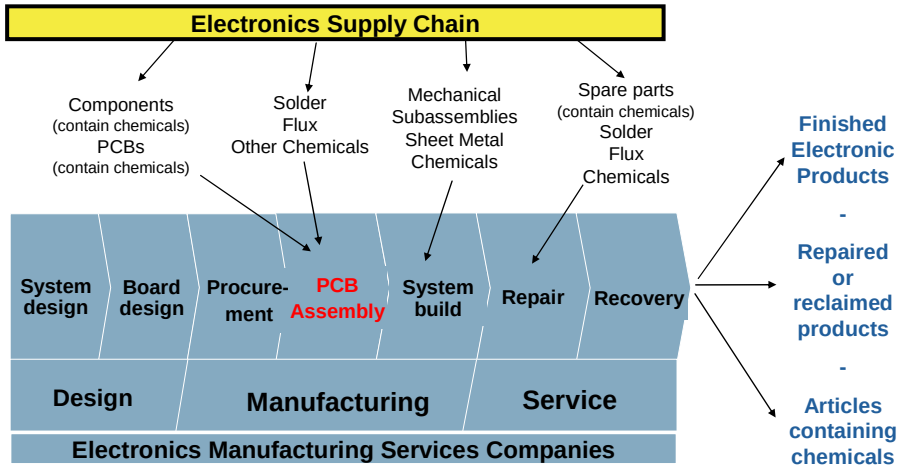
From the very beginning of the Further impact assessment studies under the Memorandum of Understanding between the European Commission and Industry, the electronics sector has participated in this study. Due to unforeseen circumstances, the electronics sector case study has been somewhat delayed but will be finalised within several weeks.

Insert: some information about the electronics sector in Europe

The electronics sector case study is of particular interest, because it represents an important and modern industry sector in Europe, for which chemical preparations and substances are of key importance. It is an industry with manifold and highly complex production processes. In these processes, a large variety of chemical preparations and substances are used, with high performance and quality characteristics, essential to many parts of the production process.

As discussed in the Working Goup, printed circuit board assembly is the part of the sector studied. This is a new area of study, not covered by previous studies and not in the range of possible worst cases in relation to REACH. Printed circuit boards are used in thousands of products and thus represent an important and representative area for the sector as a whole. Below, the printed circuit board assembly is placed in the supply chain and process flow diagram.

Printed Circuit Board (PCB) Assembly: Supply Chain and Process Flow Diagram



Issues that are studied at the level of downstream users, formulators and chemical suppliers are:

- Vulnerability of substances according to the REACH registration cost versus net present value of future profits.
- Availability of substances.
- Possible impacts of REACH on competitiveness.
- Innovation.
- Benefits of REACH.

The findings on these issues will be put in the context of the sector background (turnover, profitability, market developments, competition, etc.).

Two printed circuit board manufacturers (downstream users) have been selected to participate in the study. The critical preparations/substances that have been selected are two assembly preparations. For each of the preparations, a formulator has been identified, as well as three chemical suppliers for the critical substances in those preparations.
The spreadsheet of the methodology (see 2.3.2) had been completely finalised by one chemical supplier and partially by one downstream user and both formulators.

Some results of the study will be available before the High-level meeting of 27 April and will be submitted.

By now it is clear that the study will deliver interesting results for the electronics sector, as well as for the further impact study as a whole.

C Annex automotive sector

C.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. The market is characterised by strong competition, both in Europe (import competition) and on the world market.

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.

C.2 Case study Background

The focus of the case study is on additives that are used in paints, engine oils and metal working fluids. Other materials that are used in these products, but excluded from the case study, are solvents, resins and mineral oil. These materials are either exempt from REACH or produced in large volumes, making them less vulnerable to economical withdrawal.

At downstream user level, preparations of critical importance have been identified: two types of paints (a base coat and a clear coat), two 'soluble' engine oils and one 'soluble' metal working fluid. Six additives of critical importance have been identified in these products and followed upstream. During this 'bottom-up process', two downstream users, four formulators and three chemical suppliers were selected.

C.3 Summary of Automotive Case Study Findings

Note to the reader.
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.

Vulnerability

The selected six substances that are 'critical' at formulator level appeared to be 'not vulnerable'*. To get an impression of the overall vulnerability of the portfolio, a larger part of the portfolio was also assessed; this was done for three companies in total: one smaller and two larger companies.

At one SME manufacturer/importer (> 50% of the portfolio assessed), the percentage of vulnerable substances (related to the total portfolio) was found to be 17%. Almost all vulnerable substances found were in the lower than 100 and lower than 10 tonnage band.

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 chemical supplier did not provide the required figures 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.

* This was done using the NPV (net present value) method which identifies vulnerable substances. A substance is regarded vulnerable if the REACH testing and registration costs exceed its net present value of expected future profits.

Availability

In many instances, chemical suppliers in the automotive sector do not market the substances they manufacture as 'single substances', but combine them into 'packages' with a particular functionality. Typically, one particular substance is used in many packages. Chemical suppliers therefore prefer registering such a substance to using an alternative because of the associated costly reformulations and re-testing.

Chemical suppliers will not automatically withdraw substances that appear 'vulnerable'. Market considerations are very important. The likelihood that substances are withdrawn that are critical for customers (formulators) is low. 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.

Furthermore, any reformulation of an existing product causes disruption and additional cost to the business. 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 often gives competitors new opportunities to compete.

In the cases studied, the impact of economic deselection on the downstream users is expected to be low. 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.

A change in formulation requires retesting the product, not just on formulator level but also at downstream level. Indeed, if this change affects the manufacturing process or final product itself, the required resources are significant.

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.

Competitiveness

Direct costs & profit

The impact of REACH on the competitiveness of large chemical suppliers is expected to be limited. REACH increases the total product price of substances by on average 10% (one-off costs) on the total portfolio. This ranges from 6-17%, depending on the portion of non-polymeric substances in the portfolio. The chemical suppliers in the study expect to pass on the costs downstream as they have done 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).

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

For the formulator, the cost price increase of preparations 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 (causing indirect costs), the impact on the preparation product price is larger. The cost to redevelop major products can be up to EUR 0.5 million (paint) to EUR 2 million (oil) per product. For engine oil, this could increase the cost price of products by 10% (one-off).

Direct REACH costs of selected materials will have a low impact on the profitability of the end products (cars). 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: total costs of paint < 1% for a typical car); this can, however, be different for other materials and costs add up on.

It should be noted, however, 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).

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 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 thee chain and adapting 'safety data sheets'.

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.

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.

Innovation

The companies in the sector generally do not expect to increase their R&D budget. The expectations of companies about the impact on the time-to-market differ from unchanged to an increase of several months.

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. One company indicated that they expect some delay in time-to-market as their R&D department is also involved in registration activities. One company that manufactures part of its substances as polymers indicated that they might shift innovation towards polymers to circumvent registration (polymers are exempt from REACH).

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.

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.

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.

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.

D Annex flexible packaging sector

D.1 Sector background

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 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 and the import and export ratios are low at 1.3% and 6.2% respectively. The average flexible packaging converter has 135 employees and profitability of 4.5% (EBIT). The customers (packer-fillers) of the flexible packaging converter are large multinational companies, such as Unilever and Kraft-foods.

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.

Before a flexible packaging material is approved by the packer-filler, an iterative testing process is required at the level of ink formulator, the flexible packaging converter and the packer-filler. In case of changes in the composition of the packing material re-testing is required at all levels.

D.2 Case study Background

The case study was focused on additives and pigments as used in inks, varnish and adhesives for flexible packaging. Film, foil paper and board were excluded in order to limit the scope of the study to manageable proportions. 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.

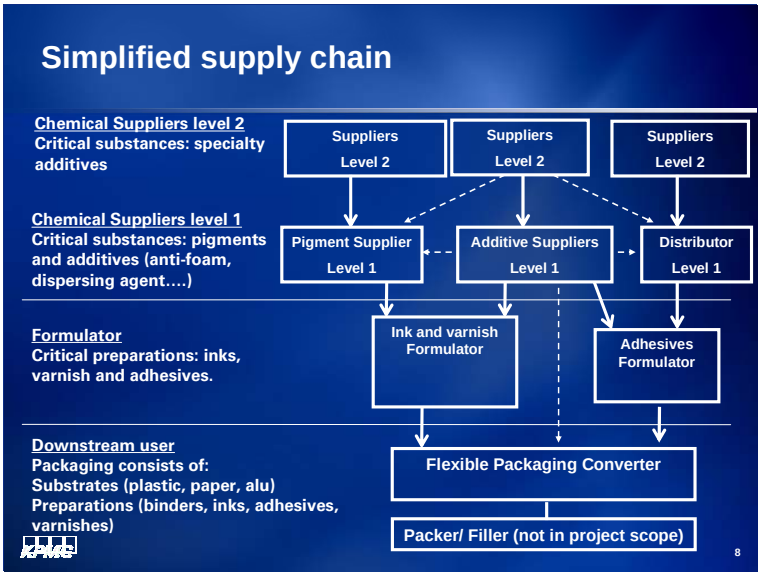
For the additives, 17 different functional categories were identified. Of these, 11 were considered not to contain substances of critical importance; either they were high-volume chemicals or substitutes were thought to be readily available. The remaining six categories of additives were considered to be of critical importance: adhesion promoters, anti-foam agents, dispersing/ wetting/flow agents, optical brighteners, photo-initiators and UV stabilisers. 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. The case study for additives was limited to these six categories. A similar procedure was followed for additives in adhesives and for pigments in inks.

During the bottom-up process two converters, four formulators and four chemical suppliers were asked to cooperate. For a simplified supply chain see the figure below. Out of the

substances actually used by the participating ink and adhesives producers, 30 pigments and 55 additives were selected from the critical categories. In addition five chemical suppliers were asked to indicate the likelihood of withdrawal for another 11 such additives.

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 unavoidable demands for confidentiality.

When the case study revealed limited withdrawal of additives, the methodology was extended with a simulation in order to be able to study the potential impact of REACH at the level of formulators and converters. Based on an external study[8], a withdrawal rate of 2.5% for toxicological reasons (all additives) and another 5% withdrawal for economical reasons (only for low volume additives, including the critical additives) was assumed. Based on these assumptions the formulators performed simulations and calculated the number of reformulations required.



D.3 Summary of 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. Wherever relevant in this discussion the origin of the findings is clearly indicated. A distinction

[8] 'Assessment of the business impact of new regulations in the chemical sector' by RPA and Statistics Sweden (June 2002) prepared for the European Commission

is made between the findings during company visits and resulting from the use of the NPV method and findings based on reflections and remarks by cooperating companies and the participants in the sector workshop.

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 on time provide the necessary data to test vulnerability with the NPV methodology. 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 (adhesion promoter, anti-foam agent dispersants, surfactant and stabiliser) the likelihood of withdrawal due to REACH is 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.

Availability

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).

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

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 and varnishes. The

simulation at ink formulators showed that a limited withdrawal of additives (five to eight additives, including critical additives) would lead to reformulation of 50-75% of the inks. On the basis of the case study results the likelihood of the withdrawal of critical substances is limited (for non-critical substances see box 'Re-runs of the simulation by the sector').

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.

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 down stream 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 delocation 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.

Competitiveness

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 at one supplier for the whole product portfolio, the direct on-off costs for registration were calculated to be 6%. These costs will have a temporary a negative effect on profitability, which is currently below 5%; therefore, chemical suppliers will pass on part of the costs.

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 are limited, the supplier expects that his portfolio will be reduced to polymeric products.

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. 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.

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.

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 pass on part of the costs.

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.

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. However, one chemical supplier is concerned that the product formulation will become publicly available due to REACH. 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. From an ink makers' point of view this almost equals the complete disclosure of the formulation of the ink in question.

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 box '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.

According to the industry experts at the sector workshop, however, 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.

Innovation

The companies in the sector (CS, F, Converter) generally do not expect to increase their R&D budget. During the phase-in period companies expect a shift from developing new products to reformulation, redesign and customer service due to the withdrawal of additives and pigments and reformulated inks, varnish and adhesives. Based on the case study results, the impact as a result of withdrawal of critical substances is expected to be limited. The impact of rationalisation of the chemical supplier portfolio depends on the timing and the extent of the rationalisation (see box 'Re-runs of the simulation by the sector').

The expectations of companies about the time-to-market for substances differ from being approximately the same to an increase of several months. One chemical supplier indicated that, for small volume substances, the time-to-market might be shorter because the requirements of REACH are reduced compared to the current legislation.

When considering the simulation, reformulation of a large part of the product portfolio at the level of formulators would lead to capacity problems and shortages of qualified staff. Based on the findings of the case study, the likelihood of this is limited.

During the sector workshop these findings were mostly recognised by the participants. However the participants (formulators) emphasised that the withdrawal of additives in 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.

Benefits

In general, companies (CS, F, Converter) did not recognise benefits of REACH. All companies indicated that, in their view, a level playing field would not emerge because to differences in enforcement between EU countries. Furthermore, companies indicated that due to requirements by food contact legislation, considerable knowledge about toxicological properties is already available.

Some issues that were recognised as minor benefits by some companies were: improvement of information flow, clearer understanding of requirements and increased rationalisation.

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.

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.

According to the sector, 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.

E Glossary and abbreviations

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.

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.