Final Report

Framework Service Contract for the Procurement of Studies and other Supporting Services on Commission Impact Assessments and Evaluations

Interim, final and ex-post evaluations of policies, programmes and other activities

Interim Evaluation: Impact of the REACH Regulation on the innovativeness of the EU chemical industry.

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## Glossary

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<th>Term</th>
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<tr>
<td><strong>Article</strong></td>
<td>An object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition. (Article 3.3)</td>
</tr>
<tr>
<td><strong>Authorisation</strong></td>
<td>The system whereby restrictions are made on the placing on the market of substances of very high concern as identified by Annex XIV of REACH. (Title VII)</td>
</tr>
<tr>
<td><strong>C&amp;L</strong></td>
<td>Classification and Labelling</td>
</tr>
<tr>
<td><strong>CA</strong></td>
<td>Competent Authority</td>
</tr>
<tr>
<td><strong>Candidate list</strong></td>
<td>The identification of a substance as a Substance of Very High Concern (SVHC) and its inclusion in the Candidate List of substances for Authorisation creates certain legal obligations for the importers, producers and suppliers of an article that contains such a substance.</td>
</tr>
<tr>
<td><strong>CBI</strong></td>
<td>Confidential Business Information</td>
</tr>
<tr>
<td><strong>CMR</strong></td>
<td>Carcinogen, Mutagen, Reproductive toxin</td>
</tr>
<tr>
<td><strong>CSA</strong></td>
<td>Chemical Safety Assessment</td>
</tr>
<tr>
<td><strong>CSR</strong></td>
<td>Chemical Safety Report</td>
</tr>
<tr>
<td><strong>Distributor</strong></td>
<td>Any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties. (Article 3.14)</td>
</tr>
<tr>
<td><strong>Downstream User (DU)</strong></td>
<td>Any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user.</td>
</tr>
<tr>
<td><strong>ECHA</strong></td>
<td>European Chemicals Agency</td>
</tr>
<tr>
<td><strong>EIA</strong></td>
<td>Economic Impact Assessment</td>
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<tr>
<td><strong>EINECS</strong></td>
<td>European Inventory of Existing Chemical Substances</td>
</tr>
<tr>
<td><strong>ELINCS</strong></td>
<td>European List of Notified Chemical Substances</td>
</tr>
<tr>
<td><strong>ES</strong></td>
<td>Exposure Scenario</td>
</tr>
<tr>
<td><strong>eSDS</strong></td>
<td>Extended Safety Data Sheet (with Exposure Annex)</td>
</tr>
<tr>
<td><strong>Evaluation</strong></td>
<td>Evaluation is used in relation to several key processes in the registration process, including evaluation of testing proposals for further testing of a substance; examination of technical dossiers submitted for substance registration; valuation of a substance by a Member State; evaluation of an intermediate by a Member State.</td>
</tr>
<tr>
<td><strong>Exposure Scenario</strong></td>
<td>The set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. (Article 3.27)</td>
</tr>
<tr>
<td><strong>GLP</strong></td>
<td>Good Laboratory Practice</td>
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<tr>
<td><strong>Importer</strong></td>
<td>Any natural or legal person established within the Community who is responsible for import. (Article 3.11)</td>
</tr>
<tr>
<td><strong>Intermediate</strong></td>
<td>A substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance. (Article 3.15)</td>
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<tr>
<td><strong>IP</strong></td>
<td>Intellectual Property</td>
</tr>
<tr>
<td><strong>IPP</strong></td>
<td>Intellectual Property Protection</td>
</tr>
<tr>
<td><strong>IUCLID</strong></td>
<td>International Uniform Chemical Information Database</td>
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<tr>
<td><strong>Manufacturer</strong></td>
<td>Any natural or legal person established within the Community who manufactures a substance within the Community. (Article 3.9)</td>
</tr>
<tr>
<td><strong>Manufacturer Importer M/I</strong></td>
<td>Production or extraction of substances in the natural state. (Article 3.8)</td>
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<tr>
<td><strong>MS</strong></td>
<td>Member State</td>
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<table>
<thead>
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<th>Term</th>
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<td><strong>Notification</strong></td>
<td>The submission of specific information to the Agency in accordance with a legislative requirement, including notification of a substance in an article; notification of classification and labelling; notification of substances for the purposes of product and process orientated research and development; notification of restart of use by downstream user.</td>
</tr>
<tr>
<td><strong>Only Representative (OR)</strong></td>
<td>A natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an articles imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on importers regarding the registration of substances. The representative shall also comply with all other obligations of importers under the Regulation. (Article 8)</td>
</tr>
<tr>
<td><strong>PBT</strong></td>
<td>Persistent, Bioaccumulative, Toxic</td>
</tr>
<tr>
<td><strong>Phase-in substance</strong></td>
<td>A substance which meets at least one of the criteria in Article 3.20. Companies pre-registering their Phase-in Substances will be able to take advantage of the transitional provisions in Article 23</td>
</tr>
<tr>
<td><strong>PNEC</strong></td>
<td>Predicted No-Effect Concentration</td>
</tr>
<tr>
<td><strong>Pre-registration</strong></td>
<td>Pre-registration allows companies registering products already on the market (phase-in-substances) to take advantage of transitional arrangements for several years until the appropriate registration deadline is reached</td>
</tr>
<tr>
<td><strong>PPORD</strong></td>
<td>Product and process orientated research and development: scientific development related to product development or the further development of a substance, on its own, in preparations or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance. (Article 3.22)</td>
</tr>
<tr>
<td><strong>QSAR</strong></td>
<td>Quantitative Structure Activity Relationship model</td>
</tr>
<tr>
<td><strong>Registration</strong></td>
<td>The submission to the Agency of a technical dossier and, if required, a chemical safety report for a substance being manufactured in or imported into the European Economic Area (EEA)</td>
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<tr>
<td><strong>Restriction</strong></td>
<td>Any condition for or prohibition of the manufacture, use or placing on the market. (Article 3.31)</td>
</tr>
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<td><strong>RMM</strong></td>
<td>Risk Management Measures</td>
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<td><strong>RSS</strong></td>
<td>Robust Study Summary</td>
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<tr>
<td><strong>SCC</strong></td>
<td>Strictly Controlled Conditions</td>
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<td><strong>SDS</strong></td>
<td>Safety Data Sheet</td>
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<tr>
<td><strong>SIEF</strong></td>
<td>Substance Information Exchange Forum</td>
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<tr>
<td><strong>SIN list</strong></td>
<td>“Substitute it Now” list of undesirable substances of Chem Sec</td>
</tr>
<tr>
<td><strong>SME</strong></td>
<td>Small or Medium sized Enterprise (&lt;250 employees)</td>
</tr>
<tr>
<td><strong>Substance</strong></td>
<td>A chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition. (Article 3.1)</td>
</tr>
<tr>
<td><strong>SVHC</strong></td>
<td>Substance of Very High Concern</td>
</tr>
<tr>
<td><strong>TPR</strong></td>
<td>Third Party Representative</td>
</tr>
<tr>
<td><strong>Use</strong></td>
<td>Any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation. (Article 3.24)</td>
</tr>
<tr>
<td><strong>vPvB</strong></td>
<td>Very Persistent, very Bioaccumulative</td>
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Source: [http://the-nceec.com/reach-glossary/](http://the-nceec.com/reach-glossary/)
Executive summary

1 Objectives of the evaluation

The objective of this study is to provide an interim evaluation of the impact of the REACH Regulation on the innovativeness of the European chemical industry. The study aims to:

- Identify, test and apply methodologies for evaluating the relevance, coherence, efficiency, effectiveness, sustainability and impact of the REACH regulation in relation to the ability to innovate by the EU chemical industry.
- Provide recommendations to improve the mechanisms introduced by the REACH Regulation with a view to stimulating innovation (e.g. by encouraging private investment, increasing patenting or trade marking, speeding time-to-market, increasing communication in the supply chain, securing finance for innovation, etc.)

The role of REACH is considered from the point of view of: creating “new” knowledge, guiding the direction of the search process, supplying resources (e.g. capital – human as well as financial), facilitating the creation of positive external economies (e.g. in terms of information exchange, knowledge and visions); and, facilitating the formation of markets.

2 Methodology and research tools

The methodology was based on an analysis of the intervention logic of the Regulation as regards the effects on innovation. The data and information gathering exercise consisted of:

- Desk research – a review of relevant literature in the area of chemical regulation and innovation, in particular that pertaining to the REACH Regulation.
- Eight case studies on specific areas of the Regulation and its impact on innovativeness
- An interview programme - 93 interviews were completed with European and national industry associations, consumer and environmental groups, innovation-related organisations and companies, the Commission and ECHA.
- An online business survey of firms which attracted 577 responses. Responses in terms of key roles is statistically quite robust, with 192 (33.3%) being manufacturers of chemical substances and 121 (21%) formulators (mixers) of chemical substances or mixtures. Respondents from 22% of firms employed less than 50 people, 20% between 50 and 249, and 58% 250 or more.
- The results of the evaluation are assessed in the Innovation Union Scoreboard (IUS) framework.

The definition of innovation used in this project is that of the Oslo Manual¹: “an innovation is the implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organisational method in business practices, workplace organisation or external relations.” This is considered to be the outcome of the firm’s planned, day-to-day R&D and innovation activities and strategies.

¹ OECD/ European Commission (2005); Oslo Manual. Guidelines for collecting and interpreting innovation data, p.46
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3 Main findings

3.1 Relevance

Article 1 of the Regulation states “The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free movement of substances on the internal market while enhancing competitiveness and innovation”\(^2\). In addition, “Special account should be taken of the potential impact of this Regulation on small- and medium-sized enterprises (SMEs) and the need to avoid any discrimination against them.”\(^3\)

The study has found that the REACH regulation’s objectives regarding the innovativeness of the EU chemical industry as identified in the White Paper\(^4\) and current industrial policy needs as expressed in more recent EU strategic documents (e.g. EU2020 and Innovation Union) are as relevant as ever.

A major factor influencing the economic climate in which this evaluation has been conducted is that the industry has been through the most severe decline in economic activity since the Second World War.

3.2 Effectiveness

The effectiveness of the regulation in achieving its objectives was assessed in terms of a three-stage approach to the innovation process: conception (idea generation and evaluation), implementation (development/prototype, pilot application, testing) and marketing (production and market launch).

Conception stage (idea generation and evaluation)

The Regulation is informed by the view that innovation occurs at intersections between industries, and that the presence of and access to data provides support for conception of innovative ideas. REACH introduced industrial information transfer mechanisms aimed at capturing and disseminating data across industries and throughout the supply chain to support and stimulate the development of safe chemicals and practices.

The main mechanisms for data capture and dissemination have been the compilation of registration dossiers, the Substance Information Exchange Fora (SEIFs) or Consortia, the Safety Data Sheets (SDS) or extended SDS (eSDS), the Chemical Safety Report, the ECHA dissemination portal, and the transmission of information through the supply chain communicating identified uses.

The survey asked respondents whether the development of, or access to, information from the industrial information transfer mechanisms had acted as a stimulus to product conception or innovation in their organisations. 26% of respondents (including a disproportionately large share of SMEs) indicated that they had found the SDS of value in this respect, 17% the Registration dossier

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with Technical dossier and CSR and 9% the SIEFS. So although the overwhelming answer in each case is “no” (71% for SDS and eSDS, 78% for Registration dossier with Technical dossier and 83% for SIEFs), there have been positive results, and the SDS has been the most useful.

The survey also asked if respondents thought that REACH had led to increased access to and scrutiny of information about chemical substances. Over 72% considered that there had been an increase, and 18% thought it had increased a lot. Without doubt a great deal of data has been created, captured and is being disseminated as a result of the first phase of registration. More will be created as a result of ECHA’s evaluation of testing proposals. The data is held with the SIEF or consortia secretariats and the member companies. Data can be accessed by SIEF or consortia members through the IUCLID files, registration dossier and CSRs. Some of the information is made more publicly available through the ECHA website. Interviews indicated that the data creation, capture and sharing processes did not take place without friction.

Although 72% of survey respondent thought that there had been an increase in openness and scrutiny as a result of REACH, 69% of respondents said they had not been able to benefit from the increased openness and scrutiny, while 22% said they had been able to benefit “moderately” and 2% “a lot” (7% did not know). Interviews suggest that data generation as such does not necessarily lead to conception of new ideas and innovative activity. The responses from the interviews and the survey suggest that, overall, data generation has been more important than idea conception, and the former may have been at the expense of the latter, at least at this stage of the Regulation’s implementation and in the prevailing economic climate.

Industry Associations and companies interviewed tended to be of the view that this first registration period has dealt with large volume substances many of which have been in use for a long period of time, and their properties have on the whole been well known, so there was not much gap-filling involved. Firms have seen this process largely as a case of incurring additional costs and/ or opportunity costs for little benefit. Gap-filling might be more of a factor with the next cut-off dates when substances produced in smaller volumes about which less is known are registered.

The Commission’s Impact Assessment had identified a concern that the requirements of the REACH regulation could divert resources from other ‘truly’ innovative research (that is, the firm’s planned, day-to-day R&D and innovation) activities. In the survey, 63% of respondents indicated that this had been the case. Interviews with firms and associations confirm this view. However, while a shift of R&D and innovation resources to REACH compliance related activities was reported, 46% of the respondents indicated that there was an overall increase in expenditure on R&D and other innovative activities. Interviews with companies indicated that this was due to two factors: some R&D and innovation programmes could not be stopped due to their strategic importance to the firms in question, and some new opportunities had been opened up due to the coming into force of the Regulation.

Innovation is driven by many factors outside REACH that have a greater impact than the Regulation itself, in particular the state of markets and technology. As regards the effects of the mechanisms within REACH on the willingness and determination to innovate it can be said that despite having to
bear the additional costs of REACH, firms have continued to innovate and are keen to continue to do so.

**Implementation stage**

By requiring both new and phase-in substances to register and undergo testing under (largely) equal conditions REACH aimed to equalise the costs of developing new and phase-in substances. Formerly “old” substances did not require such rigorous testing, which disadvantaged work on new substances. There is support for R&D through various measures (volume exemption, product and process oriented research and development, polymers and intermediates). In addition, scope was created by allowing read-across and alternative ways to test results that would reduce costs and increase speed of testing in general and reduce the need to undertake animal resting in particular.

**Old and new substance testing**

47% of the survey respondents indicated that the higher testing costs for new substances had in the past been a disincentive for innovation (29% “moderately”, 18% “a lot”), and 39% that this was not the case. Of those that thought that higher testing costs for new substances was a disincentive for innovation, 29% considered that the Regulation had “partly” removed this disincentive to innovation and 4% completely, while 65% did not think so and 2% did not know.

Interviews suggest that barriers for research activity on new substances under REACH still exist. For example, the difference between "existing" and "new" substances under REACH is that for "new" substances between 1-10 t/a, one has to provide the standard test data of Annex VII. For "old" substances this is not necessary, according to Annex VII (a) (b) and (c), unless according to Annex III they are likely to cause a risk. Also, firms express some concerns about time and costs involved in registration procedures for new substances.

Most organisations spoken to suggest that it is still quite early in the day to say where the balance of research interest between new uses for existing substances is now – it is probably still not stable – and the current economic climate probably is also playing an important role in research funding programs. However, some of the large firms do report a shift of interest to new substances, and they are major spenders in the field of R&D and innovation.

**Support for R&D**

Survey findings suggest that:

- As regards the volume exemption (this exemption is not designed as a driver of innovation) (substances used in scientific experimentation, analysis or chemical research in a volume less than 1 ton per year are exempted from REACH registration, authorisation or restriction): 6% of respondents said that the volume exemption has led to increased R&D activity, 90% that it has not, and 4% don’t know.
- While 78% of survey respondents had not applied for the Product and Process Oriented Research and Development (PPORD) exemption (substances manufactured or imported for this purpose are exempted from registration requirements for a period of five years, or more on application),
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48% thought that PPORD was sufficiently long to enable the additional R&D necessary. Only 15% of respondents had applied for PPORD. The number of PPORDs appears to be declining or levelling off. Some 45% of PPORDs so far have been for German firms.

- The exemption on isolated intermediates (isolated intermediates on site or transported are exempted from REACH in quantities up to 1 ton per year and beyond that data to be provided by the manufacturer is still less than in the common procedure): this is seen as contributing to increased innovation by 11% of respondents (83% said “no”).

- As regards the exemptions for polymers, 28% was of the view that the exemptions did contribute to sustaining and increasing innovation, and 39% thought that it was sufficiently large for additional R&D the firm wished to undertake.

Read across and animal testing

49% of survey respondents indicated that provisions within REACH for the use of read-across as regards research/testing results led to a reduction in the need/costs for testing, 26% that it had not changed and 11% that it has increased (the rest do not know). However, 22% of respondents indicated that there had been a reduced need for animal testing (7% a good deal, 15% somewhat), 34% that it has not changed and 32% that it has increased (the rest do not know). Firms interviewed and survey responses take the view that ECHA has used a very strict/precautionary interpretation of their testing results and proposals. 60% of survey respondent said that provisions within REACH as regards animal testing have not had an influence on their firms’ capacities to introduce new substances (23% said there was a negative effect, 17% don’t know).

Some further findings related to implementation

89% (88% for large firms and 93% SMEs) of respondents (38% of which are SMEs) use external laboratories, of which 52% “sometimes”, and 37% “always”. 48% of firms using external laboratories indicate that they had experienced delays in access to laboratories due to capacity constraints at such laboratories due to REACH-related testing, and several commented that prices were beginning to rise.

37% of respondents said that the Regulation had reduced the expected rate of return on investment. This is not surprising, given the increased costs related to REACH on the one hand and uncertainty as to whether costs would be recovered through higher prices or greater sales on the other. 49% of respondents indicated that risks and uncertainty related to innovation had increased as a result of the REACH Regulation (13% substantially, 36% increased), and SMEs were particularly affected in this respect, making up 40% of the “substantially” group. Risks relate to potential liabilities under REACH, and uncertainty due to, for example, the level and timing of cash expenditures or production planning being dependent on ECHA processes.

Marketing stage (production and market launch)

This end-stage of the innovation process involves incurring costs for manufacture, launch and/or possibly setting up new firms.

REACH costs affect companies that fall within the ambit of the Regulation, to a greater or a lesser extent, throughout their value chain activities, whether research, manufacture or distributing, and
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through their links with other firms’ value chains. In some cases, such as, say a manufacturer of chemical products, the impact can be very deep and wide ranging, while in others, such as in a retailer of articles that contain chemicals, it could be quite minor. Costs are of various kinds: direct and indirect, (e.g. registration costs, SIEF participation, letters of access, etc.), opportunity costs (redirecting R&D personnel to compliance), and uncertain and intangible costs related to quantities and timing (e.g. testing proposals). The research suggests that costs in all these categories have had an effect on innovation. One very important general conclusion is that now innovation projects are more highly scrutinised in terms of costs, risks and returns before it is decided to go ahead with launch and marketing – also further up the pipeline - than was the case before the implementation of REACH.

As regards production and launch is concerned, 41% of survey respondents considered that time to market had increased, while 32% saw no change and 12% a reduction. It seems that some of the larger firms that would have submitted multiple enquiries across several countries in the past have been able to benefit by not having to deal with cases on a country-by-country basis. 31% of respondents to the survey indicated that the requirements for toll manufacturing under the Regulation had had a negative impact in their innovation activities (38% no impact, 2.5% positive, the rest “don’t know”). This impacts both this and the previous stage in the innovation process).

24% of respondents indicated that compliance has contributed to a better acceptance of their new products and technologies.

The impacts of REACH on costs of setting up new companies (start-ups/ spin-offs) depend on the nature of the start-up or spin-off in question. In general, for the majority of cases, unless firms stay small (under the relevant tonnage limits), it is probable that the costs of doing business will increase, and market entry costs will be higher. Some dynamic and highly innovative research companies are expressly following a strategy of staying small and passing on their innovations to larger multinationals with whom they have relationships that will do piloting and marketing, so that they can stay under the relevant tonnage bands.

We have been able to identify few initiatives at national level to support companies in their adjustment to REACH and encourage innovation - the REACH-FIT programme in Italy, and within the CNR programme in France. In addition, the Commission has launched the Subsport initiative, and some cluster organisations such as Axelera have started REACH-related programmes among member firms. Also, some national industry associations such as Federchimica provide fora for exchange of knowledge on substituting substances. These developments are possibly signs of an emerging trend to provide more support for adjusting to REACH and lead to innovation.

3.3 Efficiency

As regards outputs, certainly, a great deal of data has been generated, captured and disseminated systematically in the REACH process. Data generation is an on-going process and will continue as dossiers are evaluated and requests for further information and/ or tests are made, and new
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substances are brought into the ambit of REACH. However, it has not been possible to identify specific metrics (such as new patents, or registrations of new substances at ECHA) that can be isolated or unambiguously related to the effects of the Regulation.

As to the effect of REACH on innovation at their firms, as compared to the pre-REACH situation, 13% of respondents consider it as somewhat positive. 44% saw it as negative (including 14% as strongly negative) and 29% indicated that it had no effect (14% did not know).

In addition, firms were asked if REACH has signaled a direction for R&D or other innovative practices related to health, safety and environmental protection that would not otherwise have taken place in their firm. 42% of those that responded indicated that this was the case, including 5% that a fundamental reappraisal or research orientation had occurred. This suggests that in the long run more could be expected in terms of outputs.

The costs of implementing REACH are the subject of other studies that are part of the overall review of REACH that is under way and to which this report contributes.

3.4 Utility

Utility is assessed in terms of the key substitution mechanisms in REACH: registration, the candidate list, authorisation and restriction.

Registration of phase-in substances has an impact on substitution as some substances (e.g. SVHCs) might disappear from the market if not registered and may thus trigger innovation. In the case of downstream users the consequences of non-registration can be problematic as the inputs may be critical for development of formulations or substances, or in R&D work, sometimes in very small quantities. The whole issue has taken up a great deal of time at firm level, and is continuing to do so, and creates a good deal of concern among highly innovative companies based in the EU. Firms may also reduce the volume they are producing or importing to avoid the 1000 tons registration band. It remains to be seen what the effect of the 2013 registration will be. Potential SVHC substances are often registered by EU suppliers only as intermediates. Procurement of such substances which are indispensable for daily work in the lab (analyses, solvents) has become more difficult as a result. Some firms have also reformulated their preparations in such a way that they can avoid having to invest in registration.

Firms have expended substantial resources mapping out their supply chains and trying to obtain commitments from their suppliers that they will continue to supply in the future – these have become parts of the REACH costs associated with production and new product development.

Registration of new substances and uses under REACH can still be problematic as companies report, in addition to direct costs involved, delays in time (and consequent loss of orders), and issues about loss of intellectual property and confidential business information.

As regards the effects of placing a substance on the candidate list on innovation, the study suggests that this is having an effect through substitution, reformulation and withdrawal. At this stage it appears that reformulation has been the most common response (60%), followed by withdrawal from
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portfolios (52%) and a request for substitution of such substances from suppliers (51%), and then launching of initiatives to develop new substances to substitute them with (27%). Industry is concerned by the uncertainty created by the candidate list. Firms are not sure if the substances they are working with to substitute substances in the candidate list with are not going to be on the candidate list themselves in due course. Premature deselect ion of substances (“blacklisting”) is also a major issue.

At present restriction is not attracting as much discussion as the candidate list and authorisation. Most restriction dossiers have been taken over from previous legislation. We have not been able to find evidence of restriction driving innovation.

The authorisation process has been accompanied by intense lobbying by the stakeholders involved. Survey responses on what the effect of the placing of substances on the authorisation list has been for their firms are that 43% launched initiatives to reformulate, 44% withdrew those products from their portfolio and 41% requested suppliers to substitute those substances. 25% launched initiatives to develop new substances to replace them.

Benefits for consumers, the market and society.

There has been a very wide range of innovative responses to the Regulation. These range from renaming “innocent” substances so that they are not associated with SVHCs with similar–sounding names, withdrawal of eco-friendly substances due to high registration costs, or changing the nature of products (oligomerisation) to avoid registration costs; through to substitution of SVHCs by safer ones, development of new uses and substances, new organisational developments and even relocation of firms or activities outside of the EU. In some of these cases there have been benefits, in others benefits are less apparent, if not absent. At this stage it is too early to say what and where the net benefits to consumers, markets and society are. Companies have to the present been preoccupied with meeting regulatory needs and adapting accordingly. Clear benefits are expected to emerge in the longer term.

3.5 Consistency

From the point of view of consistency, the focus is on the relationship between processes within the REACH Regulation and the requirements of the protection of intellectual property, specifically through patenting, and also related matters of confidential business information.

The main areas of concern identified with regard to the protection of intellectual property were: information requirements to downstream users (potentially leading to the disclosure of critical know-how related to the formulation technology used); where procedures cannot be/ were not patented, loss of key intellectual property; concerns in relation to the required data and information sharing among SIEF members; in relation to patenting there were questions as to whether the significant pre-publication requirements under REACH may make it harder to protect new developments under patent law; and, finally, certain non-EU manufacturers were worried over the capacity to protect their intellectual property in cases that an EU-based importer but not developer that acts as a representative may be allowed to shift to another manufacturer.
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74% of the survey respondents did not think that there were conflicts as regards protecting intellectual property and making information available at registration and throughout the supply chain. Among the 24% that did, 60% were manufacturers of chemical products and 63% were large firms. Conflicts tended to arise mostly in the context of SIEFs, and creation of the SDS and CSR. When asked if REACH provided sufficient intellectual property protection to promote innovation, some 18% of respondents said “yes”, 42% said “no”, and 40% said they “do not know. The survey findings that 26% think there is a conflict between registration requirements and IP protection (74% do not) while 42% think there is insufficient protection of intellectual property to promote innovation, appear contradictory. This may be the due to the view that registration is seen as pertaining to phase-in substances, while innovation relates to new substances and uses. In the former case, especially for the first registration period, the view is that substances are better known and intellectual property may not be such an issue, whereas in the second case, by definition, creation of new intellectual property is a different matter. However, the survey results are not definite on this point.

The situation as regards REACH and patenting, in practice, does not appear to be fully clarified and resolved. In principle, in order for a patent to be registered, no-one other than the patentee may know about the specific patent knowledge before application for the patent. This has resulted in a potential conflict with the REACH provisions, as, to be able to put a substance on the market – even for trials or testing – the substance must be registered (have a CLP number), and to register, information about the product or use in question must be made public which suggests there is a conflict with patent law. Companies can claim confidentiality under REACH on payment of a fee, but it appears this request is rarely granted (and the fee is not returned when not granted) If work on a new molecule or use (non-phase in substance) is being undertaken, there is generally a need to inform ECHA. Feedback from the survey on volume exemptions suggests that the volume exemption may often be too low for the testing and piloting required. This means that issues about CLP labelling and public knowledge of the substances re-emerge.

Firms were asked if the provisions as regards Confidential Business Information have been supportive of innovation. 35% of survey respondents thought that they don’t, and 19% that they do. However, 46% indicated that they do not know. This is quite a significant share and could be a cause for concern, if for example those people either are not familiar with the relevant REACH provisions, or are not aware of the nature of confidential business information. Some companies interviewed expressed the view that those involved in REACH may be more technically oriented, and may not always be aware that they may be divulging sensitive competitive company information or IP.

3.6 Distribution of benefits and costs

This study focuses on the effect of the Regulation on SMEs. Innovation in SMEs depends on several factors. The population of SMEs comprises a highly diverse group of firms, ranging from micro-firms to mini-multinationals which can fill one or several of the REACH roles. They can play an important role in the chemical industry innovation “ecosystem” due to their links with large firms, the various networks they belong to and close relationships with customers. SMEs also have a different role in the economic structure depending on the economies involved. The survey results have suggested that, in addition to the “normal” problems that SMEs have to deal with (e.g. access to finance, recruitment of skilled and specialised resources, etc.), some REACH specific issues affect their
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innovative behaviour, and particularly in the case of small firms (less than 50 employees), disproportionately: the effect of uncertainty created and increases in time-to-market; the effect of costs of registration and dealing with the administrative matters surrounding the implementation of the Regulation among downstream users has had a disincentivising effect on innovativeness. There has been some unanimity among interviewees that SMEs tend to be disadvantaged by the Regulation vis à vis larger firms. This study looked at the effect of REACH on access to markets, innovation and protection for IP in SMEs.

Access to markets.

As far as access to input markets is concerned, there is a requirement for more highly skilled staff (in-firm or outsourced) to deal with REACH requirements. SMEs tend to have fewer resources to recruit specialised staff required, especially smaller companies. If activity is outsourced, there is still an opportunity cost.

As regards access to material supplies, the key driver of accessibility is the effect of Registration costs on acquisition of inputs – whether as a manufacturer, a formulator or a distribution intermediary. We have obtained evidence of SME formulators having problems in financing letters of access, innovative importers closing their businesses as they could not afford registration costs, or having to review business relationships with long-standing suppliers pending appointment of an Only Representative. Concerns have also been expressed about supply of “exotic” small volume imported substances to research laboratories. There are also instances where reductions of suppliers have occurred (both from within the EU and outside) which has an impact on access to and price of material inputs.

We have been able to identify very few new funding sources that have emerged as a result of REACH to finance innovative activities – whether for SMEs or larger firms. The increases in business risk and uncertainty for innovation as a result of the Regulation may make it harder to obtain funding for innovation projects – both from internal and external sources, public and private.

Output markets have been affected to the extent that it is possible to recover the costs of implementing the Regulation or not. In reality, few SMEs are exporters.

Innovation

In the survey, small firms (less than 50 employees) indicated that they benefited (proportionately) more than larger firms in terms of conception of products resulting from increased openness, particularly from the SDS (33% of those that indicated they were stimulated to have new ideas were small, 34% medium sized; compared to a 22% and 20% representation respectively in the overall survey population). Small firms were also relatively highly represented (32%) among those who had experienced a “substantial” transfer of resources from “true” (day-to-day, planned) innovative activities and strategies to compliance related work as a result of REACH. They also registered a high share of responses in terms of seeing this shift as permanent.

Of the 15% (45 in number) of survey respondents that indicated that they had applied for PPORD, 2 were small firms (0.5%) and 10 medium-sized firms (22%), the remaining 75% being large firms.
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Intellectual property protection

28% of responses of those that thought that protection for IP to promote innovation within REACH was “highly insufficient” were from small firms. 26% of responses to the survey question as to whether the provisions within REACH as regards confidential business information that registered “highly insufficient” were from small firms.

The research suggests that SMEs have tended, in general, not just as regards protection of intellectual property or confidential business information, to have been more negatively affected than larger firms, but that within the SME category it has been particularly small firms that have been negatively impacted.

4 Conclusions

Conclusions and recommendations are presented in the Innovation Union Scoreboard framework.

Impacts on inputs/ enablers

(a) Human resources

There has been a redirection of skilled, sometimes highly skilled, personnel and resources in firms from R&D and innovation-related activities to compliance work (63% of survey respondents). Most survey respondents think this is permanent. We agree with this assessment. However, there has also been an increase in expenditure on R&D and related innovative activities at some 46% of respondents’ which has offset this transfer of resources, while 31% indicate no change in expenditures and 14% a reduction.

However, it is expected that the demand for highly skilled R&D and other personnel will increase, also as a result of substances produced or imported in lower volumes coming within the ambit of the regulation. As less may be known about these substances, there may be an increased need for research and testing. From the supply side, several universities provide courses on REACH, and a constellation of service providers has also developed. In the medium to long term this could increase the supply of appropriately skilled human resources.

(b) Open research systems

There has been an increase in the information base of the industry. Even if this is not the fully open system of universities, there has been an increased level of openness and scrutiny as a result and some benefits have been evident. The SDS seems to have made the strongest contribution to stimulating new product conception.

As far as the creation of new knowledge is concerned, our research suggests that the extent to which much of the information codified at the time of the 2010 deadline is really new knowledge is questionable. But additional testing and bringing new substances into the net of the Regulation should lead to new knowledge creation, and probably more so for the next cut-off dates of 2013 and 2018.
New links with universities and networks developed by companies as a result of REACH have tended to focus on the compliance/ regulatory elements (consultants) of the Regulation, rather than as drivers of innovation.

(c) Finance and support

There have not, as far as we could identify, been any funds launched or targeted specifically to support innovation initiatives under REACH. REACH compliance costs also appear to have had a negative impact on rates of return on investment, while uncertainties about actual costs and their timing in the case of new substances/ uses have not helped financing decision-making in general. The Regulation has also increased business risks due to various potential liabilities created by REACH obligations – that offsets some benefits of safer substances and also increased uncertainty.

As regards support, few examples such as the REACH-FIT programme in Italy that deals specifically with support for innovation under REACH, or the CNR’s research programme, have been identified. The Commission’s Subsport initiative, and some clusters like Axelera have started REACH-related development programmes. Also, some national industry associations such as Federchimica provide fora for exchange of knowledge on substituting substances, These developments are possibly signs of an emerging trend to provide more support for adjusting to REACH and encouraging innovation.

Impact on firm activities

(a) Firm investments/ activities

The survey findings suggest that some long term shift in the orientation of R&D towards more health-safety-environment (HSE) related goals is occurring, at least partly related to the stimulus provided by REACH. There has also been widening in the scope of innovative activities to include more work on new substances as a result of the changed testing regime of the Regulation, in particular at larger firms, but barriers to research in new substances and uses remain.

Substitution mechanisms within REACH have also had an impact. Registration costs, possible delays in the process of registration and potential issues surrounding protection of intellectual property can influence the decision to register a new substance or use. This can in turn also influence the availability of substances for future usage. It seems that the return on investments in new registrations needs to be more certain and possibly higher to compensate for increases in costs and uncertainties, whether there are SVHCs involved or not. There are also unintended consequences as when firms avoid registration by reformulation.

The candidate list is a, if not the, major driver for change at present. But attention to unintended consequences tends to distract firms from their planned innovative activities, as for example when retailers or DUs request greater levels of SVHC absence than required within the Regulation, it generates excessive paper/administrative work, and there is uncertainty about which substances may in future appear on the candidate list.

Authorisation has had a similar effect to the candidate list, although for a smaller group of firms which have been affected, and the costs and consequences involved for the firms and DUs concerned
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tend to be greater. As a result, while on the one hand such companies may be highly motivated to
develop alternative solutions to the substances involved, the costs of going through the authorisation
process, being substantial, imply an opportunity cost in terms of funds that could have been spent on
innovation as well.

The issue of restriction does not appear to have been very active to date.

To support research and development, the volume exemption has been sufficient for 28% of survey
respondents, and 6% have increased R&D as a result, but it is considered too low by many. Not many
firms use the PPORD and it appears that the number registered each year may be declining. The
position with isolated intermediates is considered increasingly complex and concerns are expressed
about registration requirements. The situation as regards polymers, while highly valued and
considered useful by some is having some unintended consequences.

(b) Linkages and entrepreneurship

The industrial information transfer mechanisms created by the Regulation have increased supply
chain collaboration and linkages with DUs, also in other industries than chemicals. Some positive
innovative results have been identified as a result, but at this stage the majority of respondents to the
survey indicated no benefits and there are major concerns expressed about a possible deluge of 50-
100 page long SDSs, especially by SMEs for whom this could lead to major problems.

(c) Intellectual assets

A significant number (42%) of survey respondents think that REACH has not provided enough
protection of intellectual property to promote innovation. Companies think that the additional costs
placed on requesting IPP/ CBI at ECHA are too high, especially when the requests may not be granted
or prove ineffective.

Impact on outputs.

(a) Innovations

A great deal of activity in terms of product and process as well as organisational and marketing
innovation is occurring as a result of the Regulation. However, while this can be considered
innovation as defined in the Oslo approach, it does not necessarily result in new substances, uses or
properties, or even “safer” products.

In order to come to some overall conclusion about the impact of the Regulation on innovation, firms
were asked what the effect on innovation has been compared to the pre-REACH situation. 43%
responded that it is negative while 13% responded positive, and more thought it would worsen in the
future than improve. Importantly, for innovative SMEs these responses were similar but more
accentuated, with well over 50% seeing the position as negative and 38% expecting it to worsen. We
have not found evidence of the creation of new firms to exploit opportunities created by the
Regulation as yet.

(b) Economic effects
A general point is that the issues around compliance and related costs and constraints make some non-EU locations more attractive for undertaking innovative activities. It appears that some delocalisation of innovation has occurred, but REACH has not always been the only or main driver.

As an overall conclusion it can be said that the situation reflects what was foreseen in the Commission’s Economic Impact Assessment. In the short term, which is where the implementation of the Regulation is at the moment, it was considered possible that negative effects could dominate due to the effects of having to meet compliance requirements being stronger than innovation incentives. Significant positive impacts on innovation were only expected in the longer term.

4 Recommendations

The following recommendations are put forward.

4.1 Enablers

**Human resources:** There is a need for a cadre of people who have good chemical knowledge but who actually want to be REACH managers/administrators, rather than chemists. There is also a need for highly skilled researchers and toxicologists – but who have a good knowledge of REACH. The aim of this recommendation would be to put measures in place to ensure that very highly skilled resources are not drawn from their normal R&D activities to deal with REACH administration, while increasing the supply of those who can deal with REACH process work. To put such a plan into action would involve a survey of what is being done at present in these areas and then finding organisations and/or networks that could help to fill the gap.

To increase **awareness** of REACH-related innovation, launch an annual competition for “REACH-innovator of the year”. A programme such as this could be managed by for example CEFIC and sponsored by the chemical industry, Member State governments and the Commission. It would draw attention to positive aspects and highlight success that is possible, and share knowledge among companies.

To support REACH-related innovation carry out a review to see if there are similar initiatives to that of the CNR in France as regards funding research into substitution of substances on the authorisation list (as was found in the Axelera cluster), in other Member States, and if not, to highlight the possibilities of undertaking and supporting such programmes. As a first step, this would require a survey of MS research support programmes, followed up by a conference and development of an action plan. Where such initiatives are identified and already in place, **knowledge sharing networks** could be supported through for example the ECRN (European Chemical Regions Network).

To encouraging **private funding** for REACH-related innovation, it would probably be best to work through an organisation such as CEFIC that could engage with suppliers of funding through venture or seed funds such as the European Venture Capital Association, or the European Business Angels Network, so that more awareness about the possibilities within REACH for innovation is raised. Initiatives towards the regulated banking sector should also be evaluated. The possibilities in **public sector funding** could be increased by making key national level funding organisations such as Oséo or
the various Scottish funds aware of possibilities within REACH. There may be scope for design and launch of specific programmes such as FIT-REACH in Italy.

At EU level the profile of REACH could be increased in programmes such as FP7, and those organisations funding or supporting those programmes (such as DG Research) could be encouraged to increase their outreach activities to identify more REACH-related projects.

4.2 Firm activities

The research suggests that there are uncertainties surrounding the candidate list that could be addressed which will help firms in their REACH-related innovation activities. These revolve around what it is that places substances in the candidate list, if there is any prioritisation involved, and if there is a target number of substances for the list, how that number is arrived at, so that when firms start to work with new, or different substances they can do so with some certainty that those substances will not themselves appear on the candidate list at some later stage. It is understood that ECHA considers the situation to be quite clear, but the widespread lack of clarity among firms suggests that at least there is a communication and explanation exercise required, if not more than that. This could be developed through for example establishing an industry-ECHA forum, or using one of the organisations already in existence such as CARACAL to fully scope out the issue and develop a detailed action plan.

Continued and increased encouragement of the development of QSARS and similar alternative testing methods. A survey should be undertaken to see what the state of development of such tools is, what other such projects are under way, how effective they are, where delivery schedules are from the point of view of the 2013 registration deadline, and if they are effectively operated and appropriately funded.

The Commission, in consultation with industry and ECHA, should consider if it is possible, and useful, to develop a version of the PPORD that would make it more attractive for smaller firms, and also generally promote the use of the PPORD. This could be through, for example reducing disclosure requirements, and possibly extending its duration so that very long-running research programmes (e.g. 20 years) could be included. PPORD should be automatic as long as the necessary data set is complete, and not discretionary.

The Commission, in consultation with industry and ECHA should give consideration to raising the volume exemption to a level that would provide for higher volume testing and piloting.

ECHA should consider lengthening the consultation times for animal testing (with the proviso that this does not interfere with speedy registration).

A pan EU-survey of availability of GLP labs should be undertaken to identify bottlenecks in supply that can affect both the next registration and testing of routine innovations, and make recommendations if appropriate. This survey could be managed by the Commission through an open tender procedure.
Firms have indicated that there would be some benefit if ECHA were to clarify guidance as regards toll manufacturing (there are different interpretations in different Member States).

Further guidance from ECHA for firms on how to deal with patenting and IP issues in general – and how that relates to CLP in particular would be valued.

A project should be undertaken to identify ways to make it easier and cheaper for firms to protect IP and CBI within REACH, especially small firms. Such a project could have as starting point bringing together all the data ECHA currently holds on firms and their substances through the REACH systems such as REACH IT, EUCLID, and CLP inventory) and how it is collected, and submitting this to a critical review to identify what is mandatory in terms of the regulation and what not, what is really critical in terms of HSE, and where, if possible data needs can be reduced or where and how additional protection to IP and CBI can be provided.

4.3 Outputs
Improved predictability about timing and costs and reduced expected times for processing of new substance/use inquiries and registration by ECHA. This would reduce some uncertainties in the innovation process and encourage innovation. It is understood that ECHA has reservations about the completeness and quality of submissions, but ways to work through this should be developed and resources provided to ECHA as it seems there is currently a bottleneck at this stage of the process.

ECHA should work towards a way to provide increased predictability about timing and costs and reduced expected times for registration for phase-in substances which could also encourage innovation using those substances.

A research project should be carried out into the feasibility of developing a new category in REACH, that of a "small chemical company", in line with EU definitions of firm sizes, and with a chemical function/volume dimension, such as, for example, usage volumes of substances. Such firms could, for example, be subject to reduced REACH registration obligations, or be able to claim reduced costs for Letters of Access.

From the point of view of improving the overall understanding between the regulator and industry, it is suggested that all ECHA staff above a certain level spend one week a year in a chemical industry SME.
This is the draft Final Report submitted by the Centre for Strategy & Evaluation Services (CSES) LLP for the assignment: “Interim evaluation: Impact of the REACH regulation on the innovativeness of the EU chemical industry”. In this section we set out the aims and context of the project, the scope of the evaluation, the key evaluation questions and the report’s overall structure.

1.1 Aims and context of the project

The REACH regulation entered into force on 1 June 2007. A specific provision in the regulation imposes the obligation that every five years the Commission publishes a general report on: (a) the experience acquired with the operation of this Regulation, and; (b) the amount and distribution of funding made available by the Commission for the development and evaluation of alternative test methods.

To this end the Commission is conducting a broad interim review of the regulation with regard to the REACH objectives of: human health, environmental protection, single market, competitiveness and innovation, from the point of view of relevance, effectiveness, efficiency, consistency, acceptability, coherence and economy. In view of the complexity and the number of key players involved, the overall review exercise has been split into thematic studies that evaluate each topic in detail. This project relates specifically to the REACH objectives targeted at enhancing the innovativeness of the EU chemical industry. The study is closely related to the broader concept of competitiveness which has been subject of a separate study. The findings of this report may be used in development of the report from the Commission due by June 2012.

The report identifies key lessons learned from the early phase of the implementation of the regulation, enumerates weaknesses as well as strengths, and recommends possible solutions and improvements.

1.2 Scope of the evaluation

The study covers the period from the introduction of the REACH regulation on 1 June 2007 until the end of 2011. It covers all Member States and touches on effects of market players from non-EU countries involved in business activities in the European chemicals market. According to the specification for this project the role of REACH is considered primarily in terms of: creating “new” knowledge; guiding the direction of the search process; supplying resources (e.g. capital – human as well as financial); facilitating the creation of positive external economies (e.g. in terms of information exchange, knowledge and visions); and, facilitating the formation of markets.

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6 http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/review2012/
7 This refers to the search processes of suppliers of technology and customers, see: http://www.iset.uni-kassel.de/extool/3johnson%5EJacobsson.pdf p.4
8 By identifying development needs and opportunities, attracting or drawing resources.
1.3 Evaluation questions

The terms of reference specify that the following evaluation questions should be addressed.

Relevance
- How are the REACH regulation’s objectives regarding the innovativeness of EU chemical industry standing up versus the initial needs identified in the White Paper, and current needs as expressed in more recent EU strategic documents (EU2020 /Innovation Union)?

Effectiveness in achieving objectives

Conception stage (idea generation and evaluation)
- The ability of an industry to generate new ideas is a function of multiple variables. It is believed that the innovative ideas come at the interceptions between industries, and therefore the more the industry is interlinked with other branches of the economy, the more likely it is to find innovative solutions. REACH introduced a number of internal mechanisms to foster industrial information transfers in the supply chain (such as Downstream Users information requirements or SIEFs). What was the effect of these mechanisms on the information base of the chemical industry and how did it contribute to the time-to-market or ability to find new innovative solutions?
- The REACH regulation introduced an unprecedented scale of openness and scrutiny over the chemicals industry. What (if any) effects have this open access (e.g. to safety assessments) had on the industry’s willingness and determination to innovate?
- The phasing in of the REACH regulation involved a comprehensive exercise of the testing and assessing significant number of existing substances and chemical products. It was feared that this requirements could divert the resources from other ‘truly’ innovative research activities. On the other hand, it was also believed that the information gathered from this phasing-in stage and data sharing could fill gaps in the knowledge about the properties of existing substances/uses and therefore could lead to unleashing of hidden potential from these currently available technologies. What is therefore the balance between these two expected effects?

Implementation stage (development/prototype, pilot application, testing)
- On the one hand the REACH regulation dramatically shifted the centre of gravity in terms of the safety assessment of the existing chemicals towards manufacturers/industry; on the other hand it has upheld certain barriers for research activities on new substances. These changes must (may?) have impacted the balance of interests for research activities. What is therefore the current centre of interest (new substances vs new uses for old substances) and how did it translate into better products?
- The REACH regulation proposed certain measures intended to limit the number of animals used in testing stages. How did the requirements related to the reduction of animal tests impact the industry capacity to introduce new substances or to develop new uses for existing substances?

Marketing stage (production and market launch)
- All economic operators intending to put chemical substances on the market in volume higher than 1 tonne per year are requested to register them with the ECHA. This process involves certain human and financial resources. To what extent does the cost associated with this requirement impact the landscape of innovative companies? Especially, what is the impact of these requirements on the costs of setting up new companies (start-ups / spin-offs)?

Introduction

Efficiency of the introduced processes

- The data generation mechanisms presented in the above mechanisms came with a significant price tag to the industry. How efficient these were in increasing the innovativeness of the industry? What was the ratio of costs of the system to the number of new products/patents/solutions [We will develop a proposal for an innovation efficiency indicator and gather related data]?

Utility of the outputs of the processes

- What was the effect of substitution mechanisms (registration, restrictions, authorizations and candidate list) on innovation in the market? To what extent can these 'forced' innovations be assessed as beneficial for the society, the market and consumers?

Consistency of the introduced mechanisms with legal framework

- What is the relationship between REACH registration requirements and patenting procedures and how it does impacts on innovation?
- How was the intellectual property issue resolved by industry players? What consequences for the innovation were observed?

Distribution of the benefits and costs

- How did the regulation affect SMEs in terms of access to market, innovation and intellectual properties protection? Are there any segments of the market which gained/lost disproportionally as compared to others in relation to their ability to innovate?

1.4 Structure of the report

The report is structured as follows:
- The next section sets out key aspects of the industry background to the project
- Section 3 presents the methodological framework and evaluation tools.
- In section 4 the evaluation questions are considered.
- Section 5 presents the conclusions and recommendations.
- The annexes contain additional background information, the case studies and interview lists.
In this section we identify some key features of the European environment for innovation in chemicals

2.1 The European chemicals industry in a global perspective

The chemical industry is increasingly global, where companies with globally integrated value chains compete in well-defined segments and niches. World trade in chemicals more than tripled between 1995 and 2008 and accounts for over 11% of world trade\textsuperscript{10}. Global chemical industry sales grew from €1166 billion in 1999 to €1871 billion in 2009 (more than 60%), of which the EU accounted for €449 billion, 24% of the total. The bar chart below puts the development of the chemical sector of the EU27 in a global perspective over the period 1999-2009. In 2009 the EU27 accounted for 45% of chemicals exports and 37% of imports.


Table 2.1 demonstrates that growth in production in the Asia Pacific region, including China, India and Japan (despite the decline in Japan), has outstripped that in other parts of the world. According to CEFIC\textsuperscript{11}, in the 10-year period from 1999 to 2009, the EU chemical industry experienced an average growth rate of 0.4%, slightly higher than the 0.3% average growth rate for total EU manufacturing. There has been a decrease in the total employment of the sector from 1.48million in 1999 to 1.2million in 2009 reflecting to an extent the productivity gains but also the general cost-saving and restructuring step taken over the last decade.


Interim evaluation: Impact of the REACH regulation on the innovativeness of the EU chemical industry. Final Report.

Background - The European chemical industry

Table 2.1  Growth in production in the chemical Industry

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Asia-Pacific</td>
<td>8,6</td>
<td>10,8</td>
</tr>
<tr>
<td>Latin America</td>
<td>5,5</td>
<td>1,7</td>
</tr>
<tr>
<td>NAFTA</td>
<td>1,4</td>
<td>-0,8</td>
</tr>
<tr>
<td>EU27</td>
<td>1,7</td>
<td>-1,5</td>
</tr>
<tr>
<td>World</td>
<td>4,4</td>
<td>3,6</td>
</tr>
</tbody>
</table>

Source: ACC and CEFIC

After pharmaceuticals, the chemical industry is the second most productive manufacturing sector (in terms of value-added per employee) in Europe. Productivity rates in the EU chemical industry during the period 1999 to 2009 increased at 2.2% (higher than the average in the manufacturing sector in the EU) while labour cost per employee increased at 3.3%. However, when excluding 2009 (when production declined by 11.4% as a result of economic crisis) from the calculation, labour productivity and labour cost per employee have been increasing at a relatively similar rate of 3.3%.

2.2 Some structural aspects of the chemical industry in Europe

Within the EU, the chemical sector it is one of the largest industrial sectors and an important source of direct and indirect employment in many regions. In 2009 the EU chemical industry included some 29 000 enterprises employing approximately 1.2 million people, representing 4% of total employment in the manufacturing sector. Table 1.2 summarises the structure of the EU industry in terms of size of firm.

Table 2.2  The EU chemical Industry – firm sizes

<table>
<thead>
<tr>
<th>Firm size</th>
<th>Number of firms as a % of total</th>
<th>Sales as a % of total</th>
<th>Number employed as a % of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micro (1-9 employees)</td>
<td>61</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Small (10-49)</td>
<td>23</td>
<td>6</td>
<td>9</td>
</tr>
<tr>
<td>Medium (50-246)</td>
<td>12</td>
<td>20</td>
<td>23</td>
</tr>
<tr>
<td>Large (250+)</td>
<td>4</td>
<td>72</td>
<td>65</td>
</tr>
</tbody>
</table>

Source: Eurostat 2005

With a total production value of €1871 billion in 2009\textsuperscript{12}, the chemical industry's contributed some 1.1% to the EU’s gross domestic product, representing about 10% of the total of the manufacturing sector. However the chemicals sector contributes to all branches of the economy. Some 30% of the combined output of the chemical and pharmaceutical industry is sold to end users, while the rest is sold to other industries, services and agriculture. The EU chemicals industry supplies almost all sectors of the economy and it has a key position in the value chain: raw materials and feedstock are transformed into tailor made solutions for customers from the chemicals industry as well as other industries, downstream in the value chain.

The output of the EU chemicals industry covers five product ranges: Petrochemicals, Basic Inorganics, Polymers, Specialities and Consumer Chemicals.

Background - The European chemical industry

- Petrochemicals, basic inorganics and polymers are produced in large volumes, and are sold within the chemical industry itself or to other industries. In 2009, petrochemicals represented 25% of the total EU chemicals sales, polymers 23% while basic inorganics 12%.
- Specialty chemicals cover the auxiliaries for industry, paints & inks, crop protection, and dyes and pigments. Specialty chemicals are produced in small volumes but, nevertheless, in total represented 26% of total EU chemicals sales in 2009.
- Consumer chemicals are mainly sold to final consumers and include soaps and detergents, perfumes and cosmetics. They represented 14% of total EU chemicals sales in 2009.

As regards the distribution of chemical sales among the EU 27, Germany (25%) leads Europe, followed by France (15%), Italy and the United Kingdom (10% each). Together, these four countries generated 60% of EU chemicals sales in 2009, valued at €269 billion. The share rises to 88% when including the Netherlands (8%), Spain (8%), Belgium (7%) and Ireland (5%). Poland (2%) has the largest share from “new” Member States.

Within the EU 27 the 8 leading chemicals clusters are located at: Rheinessen-Pfalz (Mainz) DE, Düsseldorf DE, Vlaams-Gewest (Antwerpen) NL, Rhone-Alpes (Lyon) FR, Darmstadt (Frankfort) DE, Koln DE, Munster DE and Cheshire (UK).  This is an important factor in discussions on the impact of REACH on innovation as innovation tends to be concentrated in such highly innovative clusters (see case study 2 in annex 7).

2.3 The landscape of innovative firms in the chemical industry

The present institutional innovation set-up in chemicals can be summarised as follows: the large global companies have long term research plans that align with corporate strategy and visions stretching well into the future. They do fundamental research but also carry out extensive market research on trends and respond to markets and customers accordingly. These firms have some of their research done by specialist research laboratories, often in universities with which they have developed long term collaborative relationships. The researcher carrying out the work may be doing so under the supervision of a professor and earn a PhD for the results. These large firms are also increasingly moving towards complementing their capabilities by funding SMEs to carry out research for them, which if valuable, can either mean that they buy the firm (or its technologies) and it becomes part of the large company or they will help that SME develop through a symbiotic relationship. These large firms may have the equivalent of VC operations or new business start-up divisions within them to support innovation.

The above set-up is complemented by a body of SMEs and specialised engineering firms who can be highly innovative but do not necessarily have very structured innovation strategies. They tend to remain very close to customers and their innovation is driven by anticipating and meeting customer needs. In recent years, it seems that, as suggested above, these groups – the large firms, the labs, the SMEs and the customers are moving closer together into “open innovation” systems that can cross borders and even continents.

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13 EU Cluster Observatory and Ketels, C. (2007); The role of clusters in the chemical industry, p.30
2.4 Trends in innovation

A recent report on the future of the global chemical industry suggests that overall the expenditure on R&D as a percentage of revenue has been declining in specialty, commodity and integrated chemical companies. A report for Europe Innova on Sectoral Innovation Systems in Europe: Monitoring, Analysing Trends and Identifying Challenges in the Chemical Sector, summarises some of the key features of innovation in the chemicals industry in the EU. These are set out below.

The chemical sector ranks high in terms of resources devoted to R&D, accounting for some 20% of business R&D, close to the electronic equipment industry. From the point of view of overall R&D intensity, while the EU overall devotes less resources to R&D than Japan or the USA, some individual countries - Germany, the UK and France for example, do compare favourably with the USA and Japan. The EU and the USA account for a similar share of chemical patents at the European Patents Office (EPO), with Germany accounting for some 38% of European patents, followed by the UK and France, at about 15% each and Italy at 10%, so between them these four countries account for some 60% of chemical sales in the EU and 80% of patents. Since the 1990’s there has been a declining share in EU patents at the EPO, with largest increases in the shares of China, India and Israel.

It has been estimated that between 2010 and 2013 78% of new chemical capacity would be installed in China and the Middle East. Due to the multinational character of the large European chemical industry companies and the tendency to relocate development activities closer to customers along the value chain, the development part of R&D has gradually moved nearer to the large emerging markets.

The use of patents to protect innovations in chemicals compared to manufacturing industry overall varies by country in the EU. Even in countries with high levels of patent protection in manufacturing, it is higher in the chemicals industry, and is particularly prevalent in France and Germany, as well as Italy, The Netherlands and Finland. These countries also use trademarks to protect intellectual property (IP). Design registrations in chemicals are generally not as widely used in chemicals, with the exception of a few countries such as Estonia, Romania and Slovakia.

There is great variation in terms of R&D intensity (R&D/revenues) at the sub-sector level. Pharmaceuticals have a significantly higher R&D intensity in relation to the remaining parts of the chemicals sector. Still, even beyond the pharmaceuticals sector, R&D intensity is higher in speciality and consumer chemicals (around 3%) than in basic industrial chemicals (around 1%). Moreover, the R&D intensities have been diverging over time. While the R&D intensity for speciality chemicals remained in the range of 3.0-3.5% during 1998-2008, it has in general declined from over 2% to 0.5% for commodity

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15 Deloitte (2010); The decade ahead. Preparing for an unpredictable future in the global chemical industry, DTT, p.7.
16 Patel, P.(2008), SPRU, University of Sussex. The points in the text are from pp.12-25.
17 Deloitte (2010), p.9
Background - The European chemical industry

During the same period (Deloitte, 2010), the purpose of R&D spending also differs depending on the sector. Basic chemicals firms tend to spend more on process and organisational innovation in contrast to the agrochemicals, paints and varnishes companies (specialty and fine chemicals) and the consumer chemicals that are much more focused on product and marketing innovation.

Business R&D tends to concentrate in the large companies that are active in more than one segment of the above markets. Revenues from base chemicals and commodities can be reinvested in research and innovation for new products and technologies. Thus, large companies have generally maintained R&D levels while, in comparison, R&D expenditure in smaller companies is in general lagging. Importantly, compared to many other industries, the chemicals industry is characterized by long development times and long pay back periods. Thus, the increasing pressure from global capital markets to deliver quick returns poses a special challenge for start-ups and early stage companies.

Public sector R&D activity plays an important role in the chemical sector. Links between internal R&D capabilities and external sources of scientific knowledge are particularly important for successful innovation. Universities and small firms are critical to carrying out basic research and developing product innovations and it is particularly important even today, especially in new fields. However, while the EU public sector (universities and research centres) is a leader in terms of number of scientific publications, it is performing less well compared with the US in terms of citations of publications in chemistry, while being almost equal to the US in chemical engineering.

As a knowledge-based sector, the chemical industry relies on the high skills of its workforce. Employees with medium and high education account for around 80% of the workforce with the share of the high education segment increasing. Close to one-third (32%) of its employees have attained tertiary education, compared with an average of 26% for all sectors. However, according to CEFIC, there has been a rapidly dwindling number of students graduating in chemical-related disciplines in Europe during the past 10 years. It appears that in the context of the global restructuring of the industry, the talent required for modern firms appears to be a combination of broad technical skills and marketing skills, together with some highly specialised knowledge of a certain customer segment or application or technology. There is less demand for very highly qualified pure technical people. Also, the increased capital intensity of the industry may reduce the attractiveness of the industry for potential new entrants.

In relation to the supporting parameters for the development of innovation, while internal access to finance is, according to the findings of the 4th Community Innovation Survey, generally available to large and small companies, external sources of financing are less so in general for all sectors.
firms, external private sources of finance – particularly important for SMEs and start-ups - appear rather restricted. It is lower than for other technology-intensive sectors but it is counterbalanced by high levels of public sector support. The market dominance of a few large firms in certain segments of the chemical sector is also considered by some as a particularly important obstacle to innovation for small size firms, but this is very much dependent on which subsectors of the industry are being described. Small start-up firms in biotechnology, nanotechnology, or solid-state materials may be very important, but are thought to be less so in large volume chemical production. In addition, there may be a symbiotic relationship between such small firms and large ones. By contrast, market demand and feedback from suppliers appears to play a positive role in the development of innovation but only a few EU Member States provide a lead market advantage for the sector. The impact of EU and member states’ policies and regulations tends to vary among countries but the general position is that it played - at the time of the study – a limited role.

There is also a view that the nature of innovation in the chemical industry is changing. Thus, for example Frost & Sullivan\textsuperscript{24} suggest that in the past, the chemical industry focused on technical innovation as the key to growth and differentiation, but that recently companies have depended more on customer knowledge, application skills and other areas, than on technical innovations. Innovation can be in new strategies, new business processes, and new applications, basically anything which has been started or introduced for the first time. With the adoption of 6 Sigma in many firms, innovation comes from production, distribution, quality, etc. An example is the case of Air Liquide, which focuses on gases, and when margins from gases were declining, rather than innovating in gases, constructed plants at the customer sites and became involved in gas management and hazardous chemical management services to improve their margins. BASF’s COLOR CARE system, is an innovative software-based tool that saves money for automotive manufacturers by ensuring precise colour match between new vehicle bodies and add-on parts.\textsuperscript{25}

In addition, some chemical companies are following large pharmaceutical companies that have outsourced much of their drug innovation abilities to contract research organisations or other firms, and now focus on branding and marketing. Venture capital units have been set up by some large chemical companies to tap any good technologies and products. The trend seems to be that smaller firms have established liaisons with the universities and are able to speed up their innovation, which is then sold to large chemical companies.

The European Competitiveness Report\textsuperscript{26} also makes the wider point that non-technological innovation, particularly organisational innovation, plays an important part in maintaining and improving competitiveness and growth, both as an enabler and facilitator of technical innovation and in its own right. The view is that in the future firms need to exploit knowledge networks beyond their organisational boundaries, and due to the increasing complexity and interdisciplinary nature of knowledge, need to adopt open and user-centred innovation.

\textsuperscript{24} Innovation in the chemical industry - How is it changing? Is innovation really on the decline?, 30 Apr 2004 by Krithika Tyagarajan Frost & Sullivan
\textsuperscript{25} A recent case study by McKinsey & Co of Dow Corning further elaborates these views – how “traditional” chemicals businesses can be transformed by application of marketing technologies.
\textsuperscript{26} 2007, pp.164-5
Background - The European chemical industry

Globalisation in the chemical industry has meant that as companies evolve, the drivers of innovation change as they downsize, restructure, or pursue various cost cutting strategies. At one end, an elite group of global players has emerged, with specialized firms and other smaller localized family owned operations searching for application niches and differentiated strategies. In the less research intensive parts of the chemical industry, for example some parts of the paint industry, innovation has moved from technical innovation to innovation based on marketing and supply chain excellence. M&A and other low cost initiatives, like shifting production to China, have taken priority and investment in basic research seems to have declined. Parts of the chemical industry may go the way of glass, steel or other basic materials.
In this section we set out the evaluation framework of the study. We provide an analysis of the expected impact of the Regulation on innovativeness and present the research tools used to answer the evaluation questions.

3.1 Methodological considerations: the intervention logic

Based on the description of the key mechanisms of the Regulation and the available support structure, an intervention logic diagram for the regulation has been developed (see chart 3.1). It connects the needs, problems and issues identified in the White Paper ‘Strategy for a future Chemicals Policy’ with the generic goals stated in that document and, subsequently, with the more specific goals of the Regulation. One level further down we refer to the operational elements defined in the provisions of the Regulation relating to registration, authorisation and other procedures. The actions on the ground concern the structures and mechanisms established at a European and national level by the Commission, the Agency, Member States and the industry. Certain human and financial resources (costs) need to be incurred by the relevant stakeholders for the operation of the various structures, the compliance with the Regulation requirements and its enforcement. The stated objectives are linked with respective anticipated outcomes, including the direct outputs (e.g. substances registered/authorized, SIEFs), results (e.g. hazardous substances substituted, improvement of information exchange across the supply chain) and longer-term impacts such as increased innovation, of the Regulation.
Evaluation framework and research tools

Using the research tools set out below, we evaluate the REACH regulation in relation to its impact on the innovativeness of the EU chemical industry from the perspective of relevance, effectiveness, efficiency, utility, consistency and distribution of benefits and costs.

3.2 The expected (potential) impact of the REACH Regulation on innovation - Earlier studies

Many studies were carried out before the entry of the REACH Regulation into force to determine the costs and benefits of REACH for businesses, the European economy and society. An overview of 35 such studies on the impact on REACH for the period up to October 2004 was compiled on behalf of the Dutch Presidency. The impact of REACH on the innovative capacity of the European Chemical industry was examined in a number of them pointing to both positive and negative potential impact from the implementation of the Regulation. The summary of the conclusions as regards innovation is provided in annex 3. While not a complete review of all studies undertaken (for example, it does not include the Royal Commission on Environmental Pollution, 24th Report, Chemical in Products, 2003), it does illustrate the very wide ranging views expressed on the relationship between REACH and innovation.

A review of the studies suggests that in the short term negative effects could dominate. One important negative effect foreseen concerns the administrative burden of REACH for firms. The resources (human and financial) to be dedicated to administrative tasks could detract from other more productive and innovation oriented activities. In that respect, SMEs would be expected to face a greater burden and might face survival problems. In addition, time delays or restrictions in the availability of certain substances as a result of the registration, authorisation and restriction process were also seen in those studies as potentially impeding the capacity of firms to develop new products. On the positive side, the fact that due to the non-application of the registration requirements to substances used at volumes below 1 ton there could be a reduction of costs for some companies. Similarly, the extension of the exemption period provided for authorisation and restriction of hazardous substances should also contribute in this direction. In addition, the fact that REACH poses an equal burden for the registration of old and new substances is expected to eliminate the disincentive for the development of new substances that existed in the past.

In the long term REACH was expected to lead to an increase in R&D activity and innovation for a number of reasons. A key expected impact was that REACH restrictions and requirements will create opportunities and demand for the development of new substances. REACH was expected to foster competition in the field of product safety and R&D for the development of alternative safer products which should be rewarded on the market. In that respect, according to some studies, SMEs or start-ups could benefit from such changes because they were considered more flexible and able to find niches in the market. In addition, the information exchange promoted by the Regulation through the operation of the SIEFs and the exchange of information on the uses and characteristics of substances across the supply chain would make information available on existing market opportunities and lead to new ideas for the uses of existing substances or for the development of new products. From a different perspective, some research suggested that the impact of REACH may not be on the innovation rate.

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29 EU 2004 REACH. The impact of REACH. Overview of 35 studies on the impact of the new EU chemicals policy (REACH) on society and business, (Ecorys, Opdenkamp Adviesgroep), pp.48-50
Evaluation framework and research tools

(quantitative) but on the innovation direction (qualitative), namely to change the direction of research activity towards more environmentally friendly and less toxic substances and products.\(^{30}\)

Additional concerns to the potential negative short term effects outlined above were raised in the consultation for the initial version of the Regulation organised by the Commission in 2003. One key issue related to the protection of intellectual property and the possible disincentives for innovation related to it\(^{31}\). In the case of procedures that cannot be patented, issues of disclosure and resultant loss of critical intellectual property were raised. Similarly, there were concerns in relation to the required data and information sharing among SIEF members and how intellectual property may be lost. A regards patenting there were also questions as to whether the significant pre-publication requirements under REACH may make it no longer possible to protect new developments under patent law. Finally, certain non-EU manufacturers were worried over the capacity to protect their intellectual property in cases where an EU-based importer but not developer that acts as a representative may be allowed to shift to another manufacturer.

The Commission addressed these concerns by tightening up the protection of confidential business information. The most sensitive information (relating to exact production tonnages, customers, etc.) would always be treated as confidential and companies could apply for more extensive confidentiality.\(^{32}\)

In sum, there was a range of potentially positive and negative effects on the innovation activity of the chemical industry and of downstream users. They concern the general philosophy of the Regulation or are closely linked to specific provisions, procedures and the actual implementation. The evaluation examines how these mechanisms work in practice to create, promote or hinder R&D and innovation.

3.3 The Innovation Union Scoreboard framework

In this project the overall impact of the REACH Regulation is considered with reference to the Innovation Union Scoreboard (IUS) framework\(^{33}\). The IUS has been developed to provide a structured, quantifiable approach to how Member States are developing as regards key indicators of innovation. The view is that by influencing the key factors underlying the innovation process, as identified in the IUS, it should be possible to influence innovative activity at Member State and, as a consequence, at EU level. The IUS indicators are set out in the table 3.1. REACH may have an influence on some of these variables (as grouped into enablers, firm activities and outputs), and by understanding the influence that REACH has on them, we should, where possible, be able to come to some overall statements on the impact on innovativeness in the context of the chemicals industry.

**Evaluation framework and research tools**

### Table 3.1 European Innovation Scoreboard Indicators

<table>
<thead>
<tr>
<th>Main type/ innovation dimension/ indicators</th>
<th>Enablers</th>
<th>Firm activities</th>
<th>Linkages &amp; entrepreneurship</th>
<th>Intellectual assets</th>
<th>Outputs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Human resources</td>
<td>Firm investments</td>
<td>SMEs innovating in-house as a % of SMEs</td>
<td>PCT patents applications per billion GDP (in PPS€)</td>
<td>Innovators</td>
</tr>
<tr>
<td></td>
<td>New doctoral graduates (ISCED 6) per 1000 population aged 25-34</td>
<td>Business R&amp;D expenditures as a % of GDP</td>
<td>Innovative SMEs collaborating with others as a % of SMEs</td>
<td>PCT patents applications in societal challenges per billion GDP (in PPS€) (climate change mitigation; health)</td>
<td>SMEs introducing product or process innovation as % of SMEs</td>
</tr>
<tr>
<td></td>
<td>Percentage population aged 25-34 having completed tertiary education</td>
<td>Non-R&amp;D innovation expenditure as % of turnover</td>
<td>Public-private co-publications per million population</td>
<td>Community trade marks per billion GDP (in PPS€)</td>
<td>SMEs introducing marketing or organisational innovations as % of SMEs</td>
</tr>
<tr>
<td></td>
<td>Percentage population aged 20-24 having attended at least upper secondary education</td>
<td></td>
<td></td>
<td>Community designs per billion GDP (in PPS€)</td>
<td>High-growth innovative firms</td>
</tr>
<tr>
<td></td>
<td>Open, excellent and attractive research systems</td>
<td></td>
<td></td>
<td></td>
<td>Economic effects</td>
</tr>
<tr>
<td></td>
<td>International scientific co-publication per million population</td>
<td></td>
<td></td>
<td></td>
<td>Employment in knowledge-intensive activities (manufacturing and services) as % of total employment</td>
</tr>
<tr>
<td></td>
<td>Scientific publications among the top 10% most cited publications worldwide as % total scientific publications of the country</td>
<td></td>
<td></td>
<td></td>
<td>Medium and high-tech product exports as % total product exports</td>
</tr>
<tr>
<td></td>
<td>Non-EU doctoral students as a % of all doctorate students</td>
<td></td>
<td></td>
<td></td>
<td>Knowledge-intensive services exports as a % of total service exports</td>
</tr>
<tr>
<td></td>
<td>Finance and support</td>
<td></td>
<td></td>
<td></td>
<td>Sales of new to market and new to firm innovations as % of turnover</td>
</tr>
<tr>
<td></td>
<td>Public R&amp;D expenditure as a % of GDP</td>
<td></td>
<td></td>
<td></td>
<td>License and patent revenues from abroad as % of GDP</td>
</tr>
<tr>
<td></td>
<td>Venture capital (early stage, expansion and replacement) as a % of GDP</td>
<td></td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>
Evaluation framework and research tools

3.4 Expected (potential) impacts of REACH on innovativeness in the European chemicals industry: summary

Using the IUS as a framework, areas where REACH can have an impact on innovation are:

(a) Impacts on inputs/ enablers

Human resources

• Compliance with REACH consumes, and will continue to consume, skilled and highly skilled technical resources involved in data preparation, SIEFs, testing and evaluating activities. They are also an involved in developing SDSs, eSDSs, CSRs, exposure scenarios and updating and monitoring them. This cannot be seen as directly innovative activity. In as much as this absorbs existing and new degree, post graduate and doctoral graduates, questions can be asked as to what the impact will be on innovativeness of firms at present and over the term of operation of the Regulation. It is also an opportunity cost. It is expected that the demand for such labour will increase, or at least not decrease, as substances produced or imported in lower volumes come within the ambit of the regulation because less may be known about them. There is also a requirement for learning how to manage REACH and keep up to date with developments in the Regulation.

• However, at the same time, in the medium to longer term, new career opportunities will open up for people in areas such as toxicology, biochemical research, and other new areas which attracts new entrants to the labour market for testing, reformulating, substitution and development of new substances and uses which increases the overall high-level resource base in the chemicals industry and provide a stimulus to further innovation.

• Compliance with the regulation also absorbs skilled staff from the professional and business services sector to deal with legal, administrative, operational aspects associated with REACH. A whole new cadre of REACH-related service providers is being created. While there may be benefits from this, in the meantime the cost of these service providers has to be borne by the industry and society. The effect on innovativeness now and over the medium to longer term needs to be considered.

• Training and educational courses are developed for people involved in REACH, from technical compliance diplomas, to postgraduate university courses at master’s level in chemistry and REACH.

Data/ Knowledge/ IP (Research systems)

• SIEFs and the research involved in completing dossiers are contributing to the creation capture of data and knowledge about chemicals substances. This approach may contribute to innovation, but it may also have some inhibiting aspects related to IPP and CBI.

• The extent to which this links with knowledge networks and the tertiary education system contributing to an excellent research system is to be considered.

Finance

• The effect of the REACH regulation on the availability of internal funds to support innovation (retained profits) and external funds such as venture capital or loan finance for technology development (early stage, expansion and replacement) needs to be considered, as does possibly
Evaluation framework and research tools

more conventional sources of funding that large established MNEs have access to, as they seem currently still to be the main sources of innovation.

(b) Impact on firm activities

Investment, expenditure, scope

- Firms’ business strategies may have to change as a result of the impact of REACH. This could involve rationalisation of production for manufacturers and downstream users and the possible withdrawal, or restrictions placed on production or use, of chemical substances, for downstream users. This can be either a result of their entry on to the candidate list or the decision of their manufacturers that it is not justifiable to keep them on the market because of costs of registration or inability to source required raw material inputs either from within or outside the EU. It may also lead to expansion and addition of new product lines as new opportunities become apparent or other competitors withdraw, depending on circumstances. What has the effect been on the business environment in terms of risk, uncertainty, opportunity? All this may impact innovative activity.

- The regulation encompasses all substances, both old and new, unless they are specifically exempt. This is expected to address the imbalance between old and new substances that existed previously as regards testing – which is in theory an incentive for more research on new substances that could lead to increased innovation.

- Information search to complete the technical dossier and the chemical safety report may bring new knowledge to light that could be a spur to innovation. The actual processes involved, e.g. the role of the SIEFs, might also stimulate organisational innovations in the form of new collaborative ventures between those organisations who do and those who don’t have information.

- Information exchange throughout the supply chain is expected to increase knowledge and identification of market opportunities which should both generate new ideas (conception) and may contribute to finding ready ways of implementation and marketing. Development of such open and user-oriented innovation systems is considered a strong positive stimulus to innovation. This could also reduce time to market if registered substances are used.

- The REACH registration mechanism has implications for development of new products or uses, both with new and existing substances.

- The candidate list and authorisation are clear signals to the market as regards future use of SVHCs.

- Will REACH lead to an increase in expenditure on R&D and innovation, or to an increase in non-R&D related expenditure as a percentage of turnover?

- Have the exemptions for R&D been supportive of innovation?

Linkages and entrepreneurship

- The supply chain communication activities envisaged in the REACH regulation, as well as aspects of the development of the Technical Dossier and CSR all suggest the development of linkages external

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34 Estimates provided by studies before the entry of REACH into force of the expected proportion of substances that would be withdrawn varied greatly (from 1% to 30%) on the basis of different assumptions.
Evaluation framework and research tools

3.5 Defining and measuring innovation

Before detailing the research tools, we first consider some issues around the idea of innovation and its measurement.

3.5.1 Defining innovation

By the term “innovativeness” is understood “performance in innovation”, that could be linked to the Innovation Union Scoreboard index. The definition of innovation used in this project is that of the Oslo

Evaluation framework and research tools

Manual\(^{36}\): “an innovation is the implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organisational method in business practices, workplace organisation or external relations.” This includes:

- **Product innovation**: introduction of a good or service that is new or significantly improved with reference to its characteristics or intended uses. This includes significant improvements in technical specifications, components and materials, incorporated software, user friendliness or other functional characteristics.
- **Process innovation**: implementation of a new or significantly improved production or delivery method. This includes significant changes in techniques, equipment and/or software.
- **Marketing innovation**: implementation of a new marketing method involving significant changes in product designs or packaging, product placements, product promotion or pricing.
- **Organisational innovation**: implementation of a new organisational method in the firm’s business practices, workplace organisation or external relations.

This approach also underlies the Community Innovation Surveys.

Within the context of the chemical industry, and more particularly, REACH, this raises questions such as:

- Should reformulation of a mixture using known substances and/or recipes (e.g. to reduce SVHC content or avoid registration costs) be considered an innovation?
- Should a reformulation of a mixture that is functionally not equivalent to the original mixture be considered an innovation (less useful or lower performance)?
- If this new reformulation is less hazardous, but equally or more risky, should that qualify as “safer”?\(^{37}\)
- Should only development and marketing of new substances or new uses (for both old and new substances) be considered as innovations?
- Should a known substance that was not used in the past by a company because an alternative was considered better in terms of performance but cannot be used anymore as it is a SVHC, and is now used, be considered an innovation (e.g. due to the consequences of the REACH Regulation), if it becomes a new company product and is launched on the market as such?

Responses to these questions vary a good deal depending on whether one is talking to chemists in R&D laboratories, REACH managers and marketing managers in chemical companies, or even between different departments/ministries in Member State governments and the EU Commission. Practitioners often refer to developments such as some of those listed above as “substitutions”, rather than innovation, implying a difference in value between the two concepts. The term innovation is sometimes reserved for instances of new or improved properties or uses of chemicals.

While the intention within REACH is to drive the innovation of “safer” products, it is, similarly, not always unambiguously clear what a “safer” product is, due to issues surrounding hazard, risk, and knock-on effects on downstream or end users.

In this report we have not adopted a specific, exclusive approach but we have tried to work within the outlines of the Oslo approach set out above. This means we consider “true” innovation that which

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\(^{36}\) OECD/European Commission (2005); Oslo Manual. Guidelines for collecting and interpreting innovation data, p.46

\(^{37}\) For example: a substance with less intrinsic danger (hazard) that has a greater chance of coming into contact with a consumer (risk).
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occurs as a result of the normal business processes within the firm, whether ad hoc or part of a long term strategic planning process, as driven by markets and technology.

It may also be useful at this stage to distinguish between two main dimensions of innovation. One is “disruptive innovation” which might revolutionise or even create a whole industry. The other is less dramatic and more “incremental” and could occur at different stages of the product cycle and in different types of markets.

3.5.2 Measuring innovation

Measuring innovation is not an exact science, and generally expenditure on R&D is taken as a proxy for innovation. However, the various Community Innovation Surveys have made good progress in this area and moved away from a focus on R&D expenditure.

Various measures of innovation indicate that, overall, the chemical industry is among the most innovative industries. A study on innovation performance ranking of European industries put “chemicals and chemical products” in fourth place, after “electrical and optical equipment”, “ICT” and “Computer services and related activities”. The proportion of innovative firms is higher in chemicals than in manufacturing industry as a whole, both in terms of product and process innovation, and in organisational and marketing innovation. This is consistently observed across different countries in the survey mentioned.

3.6 Research tools

In this sub-section the key research tools and how they are developed is presented.

3.6.1 Desk research

An extensive body of literature has evolved in the area of chemical regulation and innovation, and in the past decade or so this was supplemented by that pertaining to the REACH Regulation. There is also an important body of academic literature related to the effects of intervention on innovation in the environmental, and health and safety field. Our research focused on work related to the REACH Regulation and the reviews that gave rise to the Regulation. Relevant parts of this literature have been incorporated into the body of this report and the annexes.

3.6.2 Interview programme

93 interviews were completed. It was more difficult than envisaged to identify innovation-related organisations in the chemical industry that can speak about REACH in an informed manner. This in itself is an interesting finding – the relationship between REACH and innovation is quite intricate and requires specialists or people involved on a day-to-day basis at firm level to give informed responses on the...
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matters in question. As a result we have spoken to fewer innovation-related organisations and more firms than initially foreseen. Annex 6 provides a list of organisations interviewed.

Table 3.2 Interview programme

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU level</td>
<td></td>
</tr>
<tr>
<td>Commission</td>
<td>3</td>
</tr>
<tr>
<td>ECHA</td>
<td>3</td>
</tr>
<tr>
<td>Industry/trade associations/ firms</td>
<td>22</td>
</tr>
<tr>
<td>Consumer and environmental groups</td>
<td>1</td>
</tr>
<tr>
<td>National level</td>
<td></td>
</tr>
<tr>
<td>Innovation – related organisations</td>
<td>7</td>
</tr>
<tr>
<td>National industry/trade associations</td>
<td>23</td>
</tr>
<tr>
<td>Innovative companies</td>
<td>34</td>
</tr>
<tr>
<td>Total</td>
<td>93</td>
</tr>
</tbody>
</table>

3.6.3 The survey of firms

The survey was launched in September 2011 and remained open for six weeks. Respondents were given the opportunity to answer in terms of a given role as defined by the REACH regulation:

1. Manufacturer of chemical substances or preparations
2. Importer of chemical substances or preparations
3. Producer of articles that contain chemical substances
4. Importers of articles that contain chemical substances
5. Formulator (mixer) of chemical substances or preparations
6. End users of chemical substances or preparations in professional activities or in industrial activities where substances or preparations are used as processing aid and do not form part of the final product
7. Distributor/ retailer of chemical substances, preparations or articles that contain chemical substances intended to be released
8. Other roles

An additional category of Research and Development Organisation (including Contract Research Organisations) was added to the list.

The survey questionnaire was translated into the 22 official EU languages, and respondents accessed the survey through a single web page. The link to the survey was distributed through various European, national and regional associations and organisations that CSES identified and who were asked to forward the link to their member associations and companies. The Commission services and ECHA also promoted the survey through their communication channels.

There were 577 responses (see table 3.3). The largest group of respondents was manufacturers of chemical substances (33.3%) followed by formulators (mixers) of chemical substances (21%). The remaining responses were relatively evenly spread between the other roles.
Evaluation framework and research tools

Table 3.3  Please indicate in what role you will be answering this questionnaire.

<table>
<thead>
<tr>
<th>Role</th>
<th>No</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and Development organisation (including Contract Research Organisations)</td>
<td>26</td>
<td>4.5</td>
</tr>
<tr>
<td>Manufacturer of chemical substances</td>
<td>192</td>
<td>33.3</td>
</tr>
<tr>
<td>Importer of chemical substances or mixtures</td>
<td>55</td>
<td>9.5</td>
</tr>
<tr>
<td>Producer of articles that contain chemical substances</td>
<td>52</td>
<td>9.0</td>
</tr>
<tr>
<td>Importer of articles that contain chemical substances</td>
<td>14</td>
<td>2.4</td>
</tr>
<tr>
<td>Formulator (mixer) of chemical substances or mixtures</td>
<td>121</td>
<td>21.0</td>
</tr>
<tr>
<td>End user of chemical substances or mixtures in professional activities or in industrial activities where substances or mixtures are used as a processing aid and do not form part of the final product</td>
<td>28</td>
<td>4.9</td>
</tr>
<tr>
<td>Distributor/ retailer of chemical substances, mixtures or articles that contain chemical substances intended to be released</td>
<td>24</td>
<td>4.2</td>
</tr>
<tr>
<td>Other</td>
<td>47</td>
<td>8.1</td>
</tr>
<tr>
<td>No response</td>
<td>18</td>
<td>3.1</td>
</tr>
<tr>
<td>Total</td>
<td>577</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Source: CSES Survey

In terms of sector of activity, more than half the respondents are from chemicals and chemical products, with the remainder very widely distributed, reflecting the wide scope of the chemicals industry (table 2.4). Within chemicals and chemical products, among those that indicated which sub-sector they are active in, most were from specialty chemicals, followed by consumer chemicals (table 3.5). This is a positive outcome as these are the roles and sectors that are the primary targets of the Regulation, and specialty chemicals is the area with the highest share of R&D expenditure as a percentage of turnover.

One caveat that has to be born in mind as regards responses is that REACH is a very complex Regulation. Where replies are not provided by specialists, as in the case of for example an owner manager of a micro firm, or a management generalist such as maybe a sales director for a large firm, there is the possibility that responses are to questions that have not been understood correctly, or the responses themselves are technically incorrect. The majority of job titles of those that completed the survey though suggest that most are REACH specialists.
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Table 3.4 In which sector of the economy is your firm mainly active?

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mining and quarrying</td>
<td>3</td>
<td>0.5</td>
<td>Fabricated metal products, except machinery and equipment</td>
<td>11</td>
<td>1.9</td>
</tr>
<tr>
<td>Food products</td>
<td>7</td>
<td>1.2</td>
<td>Computer, electronic and optical products</td>
<td>10</td>
<td>1.7</td>
</tr>
<tr>
<td>Beverages</td>
<td>2</td>
<td>0.3</td>
<td>Electrical equipment</td>
<td>10</td>
<td>1.7</td>
</tr>
<tr>
<td>Tobacco products</td>
<td>1</td>
<td>0.2</td>
<td>General and special purpose machinery and equipment</td>
<td>3</td>
<td>0.5</td>
</tr>
<tr>
<td>Textiles</td>
<td>18</td>
<td>3.1</td>
<td>Motor vehicles, trailers and semitrailers</td>
<td>4</td>
<td>0.7</td>
</tr>
<tr>
<td>Wearing apparel</td>
<td>3</td>
<td>0.5</td>
<td>Other transport equipment (motorcycles, ships, railway, air and spacecraft)</td>
<td>3</td>
<td>0.5</td>
</tr>
<tr>
<td>Leather and related products</td>
<td>3</td>
<td>0.5</td>
<td>Furniture</td>
<td>1</td>
<td>0.2</td>
</tr>
<tr>
<td>Wood and products of wood and cork, except furniture; manufacture of articles of straw and plaiting materials</td>
<td>1</td>
<td>0.2</td>
<td>Other (sport equipment, games and toys, medical and dental instruments, musical instruments, jewellery)</td>
<td>6</td>
<td>1.0</td>
</tr>
<tr>
<td>Paper and paper products</td>
<td>4</td>
<td>0.7</td>
<td>Repair and installation of machinery and equipment</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Printing and reproduction of recorded media</td>
<td>3</td>
<td>0.5</td>
<td>Electricity, gas, steam and air conditioning supply</td>
<td>2</td>
<td>0.3</td>
</tr>
<tr>
<td>Coke and refined petroleum products</td>
<td>9</td>
<td>1.6</td>
<td>Water supply; sewerage, waste management and remediation activities</td>
<td>1</td>
<td>0.2</td>
</tr>
<tr>
<td>Chemicals and chemical products</td>
<td>325</td>
<td>56.3</td>
<td>Construction</td>
<td>3</td>
<td>0.5</td>
</tr>
<tr>
<td>Basic pharmaceutical products and pharmaceutical preparations</td>
<td>17</td>
<td>2.9</td>
<td>Other</td>
<td>13</td>
<td>2.3</td>
</tr>
<tr>
<td>Rubber and plastics products</td>
<td>25</td>
<td>4.3</td>
<td>No response</td>
<td>66</td>
<td>11.4</td>
</tr>
<tr>
<td>Other non-metallic mineral products</td>
<td>5</td>
<td>0.9</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Basic metals</td>
<td>18</td>
<td>3.1</td>
<td>Total</td>
<td>577</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Source: CSES Survey

Table 3.5 Chemicals and chemical products (subdivisions)

<table>
<thead>
<tr>
<th></th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Petrochemicals and polymers</td>
<td>30</td>
<td>5.2</td>
</tr>
<tr>
<td>*Basic inorganic chemicals (fertilisers and nitrogen compounds, dyes and pigments, industrial gases)</td>
<td>17</td>
<td>2.9</td>
</tr>
<tr>
<td>*Pesticides and other agrochemical products</td>
<td>6</td>
<td>1.0</td>
</tr>
<tr>
<td>*Specialty chemicals (paints &amp; inks, crop protection, and dyes and pigments)</td>
<td>78</td>
<td>13.5</td>
</tr>
<tr>
<td>*Consumer chemicals (soap and detergents, cleaning and polishing preparations, perfumes and toilet preparations)</td>
<td>50</td>
<td>8.7</td>
</tr>
<tr>
<td>*Other chemicals products (e.g. glues, explosives, essential oils)</td>
<td>23</td>
<td>4.0</td>
</tr>
</tbody>
</table>

Source: CSES Survey

The majority of respondents were located in Germany, followed by Italy, then the UK, the
Netherlands, Spain, France and Belgium. Between them these countries represent more than 80% of EU chemical sales. The large share of German respondents is not surprising given the pre-eminence of Germany in the EU chemicals industry and the distribution of patenting activities between EU regions. Among non EU 27/EEA respondents, most were located in the USA.

Table 3.6 In which country is your business located?

<table>
<thead>
<tr>
<th>Country</th>
<th>Nº</th>
<th>%</th>
<th>Country</th>
<th>Nº</th>
<th>%</th>
<th>Country</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
<td>11</td>
<td>1.9</td>
<td>Liechtenstein</td>
<td>0</td>
<td>0.0</td>
<td>Chile</td>
<td>1</td>
<td>0.2</td>
</tr>
<tr>
<td>Belgium</td>
<td>26</td>
<td>4.5</td>
<td>Lithuania</td>
<td>0</td>
<td>0.0</td>
<td>Brazil</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>0</td>
<td>0.0</td>
<td>Luxembourg</td>
<td>1</td>
<td>0.2</td>
<td>Canada</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Cyprus</td>
<td>0</td>
<td>0.0</td>
<td>Malta</td>
<td>4</td>
<td>0.7</td>
<td>China</td>
<td>1</td>
<td>0.2</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>8</td>
<td>1.4</td>
<td>Netherlands</td>
<td>42</td>
<td>7.3</td>
<td>India</td>
<td>2</td>
<td>0.3</td>
</tr>
<tr>
<td>Denmark</td>
<td>14</td>
<td>2.4</td>
<td>Norway</td>
<td>1</td>
<td>0.2</td>
<td>Israel</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Estonia</td>
<td>2</td>
<td>0.3</td>
<td>Poland</td>
<td>15</td>
<td>2.6</td>
<td>Mexico</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Finland</td>
<td>11</td>
<td>1.9</td>
<td>Portugal</td>
<td>4</td>
<td>0.7</td>
<td>New Zealand</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>France</td>
<td>33</td>
<td>5.7</td>
<td>Romania</td>
<td>4</td>
<td>0.7</td>
<td>Russia</td>
<td>0</td>
<td>0.0</td>
</tr>
<tr>
<td>Germany</td>
<td>119</td>
<td>20.6</td>
<td></td>
<td></td>
<td></td>
<td>Saudi Arabia</td>
<td>1</td>
<td>0.2</td>
</tr>
<tr>
<td>Greece</td>
<td>2</td>
<td>0.3</td>
<td>Slovenia</td>
<td>1</td>
<td>0.2</td>
<td>Switzerland</td>
<td>6</td>
<td>1.0</td>
</tr>
<tr>
<td>Hungary</td>
<td>9</td>
<td>1.6</td>
<td>Spain</td>
<td>39</td>
<td>6.8</td>
<td>USA</td>
<td>20</td>
<td>3.5</td>
</tr>
<tr>
<td>Iceland</td>
<td>0</td>
<td>0.0</td>
<td>Sweden</td>
<td>9</td>
<td>1.6</td>
<td>Other</td>
<td>1</td>
<td>0.2</td>
</tr>
<tr>
<td>Ireland</td>
<td>2</td>
<td>0.3</td>
<td>UK</td>
<td>47</td>
<td>8.1</td>
<td>No response</td>
<td>8</td>
<td>1.4</td>
</tr>
<tr>
<td>Italy</td>
<td>91</td>
<td>15.8</td>
<td></td>
<td>37</td>
<td>6.4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Latvia</td>
<td>1</td>
<td>0.2</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>537</td>
<td>93.1</td>
<td></td>
<td>40</td>
<td>6.9</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: CSES Survey

Table 3.7 How many chemical substances did you place in the market in 2010 (including substances contained in articles)?

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>14</td>
<td>2.4</td>
</tr>
<tr>
<td>2-10</td>
<td>72</td>
<td>12.5</td>
</tr>
<tr>
<td>11-50</td>
<td>81</td>
<td>14.0</td>
</tr>
<tr>
<td>51-100</td>
<td>54</td>
<td>9.4</td>
</tr>
<tr>
<td>101-1,000</td>
<td>60</td>
<td>10.4</td>
</tr>
<tr>
<td>1,001-10,000</td>
<td>26</td>
<td>4.5</td>
</tr>
<tr>
<td>&gt;10,000</td>
<td>7</td>
<td>1.2</td>
</tr>
<tr>
<td>Don't know</td>
<td>34</td>
<td>5.9</td>
</tr>
<tr>
<td>Not relevant</td>
<td>118</td>
<td>20.5</td>
</tr>
<tr>
<td>No response</td>
<td>111</td>
<td>19.2</td>
</tr>
<tr>
<td>Total</td>
<td>577</td>
<td>100.0</td>
</tr>
</tbody>
</table>

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Overall 22% of respondents’ firms are in the <50 employee category, 20% in the 50-249 employee category, and 58% employ 250 or more.

Table 3.8 Company size of respondents by category in terms of employees.

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;50</td>
<td>126</td>
<td>22</td>
</tr>
<tr>
<td>50-249</td>
<td>118</td>
<td>20</td>
</tr>
<tr>
<td>250 +</td>
<td>327</td>
<td>57</td>
</tr>
<tr>
<td>No response</td>
<td>6</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>577</strong></td>
<td><strong>100.0</strong></td>
</tr>
</tbody>
</table>

Source: CSES Survey

The majority (46.6%) of respondents were units of a multi-site, multi-country enterprise group. Single-site independent firms make up the second largest category (40.8%).

Table 3.9 Please indicate what kind of business you are in and where your headquarters is based:

<table>
<thead>
<tr>
<th>Options</th>
<th>EU 27/EEA based (HQ)</th>
<th>Non-EU/27/EEA based (HQ)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Nº</td>
<td>%</td>
<td>Nº</td>
</tr>
<tr>
<td>Single site – independent</td>
<td>226</td>
<td>39.2</td>
<td>9</td>
</tr>
<tr>
<td>Multi-site - single country</td>
<td>60</td>
<td>10.4</td>
<td>3</td>
</tr>
<tr>
<td>Unit of an enterprise group/ company (multi-country, multi-site)</td>
<td>182</td>
<td>31.5</td>
<td>87</td>
</tr>
<tr>
<td>Dedicated REACH unit</td>
<td>25</td>
<td>4.3</td>
<td>2</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>No response/ correction*</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>493</strong></td>
<td><strong>85.4</strong></td>
<td><strong>102</strong></td>
</tr>
</tbody>
</table>

*18 respondents indicated they are a REACH unit + another

Source: CSES Survey

As regards shares of turnover spent on R&D, the largest share of respondents (26%) indicated that they spent between 2-5% on R&D in 2010, but most firms spent less than that (32.2%). Some 20% spent more. The specialty and consumer chemicals businesses tend to spend 2% or more of turnover on R&D.
**Evaluation framework and research tools**

**Table 3.10**  Approximately what percentage of your turnover was spent on Research & Development (R&D) in 2010?

<table>
<thead>
<tr>
<th>Percentage</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;1%</td>
<td>63</td>
<td>15.5</td>
</tr>
<tr>
<td>1-2%</td>
<td>68</td>
<td>16.7</td>
</tr>
<tr>
<td>2-5%</td>
<td>106</td>
<td>26.0</td>
</tr>
<tr>
<td>5-10%</td>
<td>53</td>
<td>13.0</td>
</tr>
<tr>
<td>&gt;10%</td>
<td>30</td>
<td>7.4</td>
</tr>
<tr>
<td>Don't know</td>
<td>87</td>
<td>21.4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>407</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Source: CSES Survey

Most respondents indicated that their main source of innovation is from within the enterprise or enterprise group.

**Table 3.11**  What would you say the sources of your innovations are in general? If more than one, please rank in importance (1st as most important, 3rd as least important).

<table>
<thead>
<tr>
<th>Options</th>
<th>Mainly your enterprise or enterprise group</th>
<th>Your enterprise or enterprise group together with other enterprises or institutions</th>
<th>Mainly other enterprises or institutions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Nº</td>
<td>%</td>
<td>Nº</td>
</tr>
<tr>
<td>1st</td>
<td>205</td>
<td>62.7</td>
<td>98</td>
</tr>
<tr>
<td>2nd</td>
<td>58</td>
<td>17.7</td>
<td>106</td>
</tr>
<tr>
<td>3rd</td>
<td>28</td>
<td>8.6</td>
<td>27</td>
</tr>
<tr>
<td>Don't know</td>
<td>36</td>
<td>11.0</td>
<td>35</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>327</td>
<td>100.0</td>
<td>266</td>
</tr>
</tbody>
</table>

Source: CSES Survey

As far as the statistical robustness of the responses is concerned, the German and Italian responses can be considered robust at Member State level (representing some 35% of EU chemicals sales), while those of the UK, France, Belgium, Spain and the Netherlands can be considered to be representative, although to a somewhat lesser extent.

Importantly, the responses in terms of roles is statistically robust, with 192 (33.3%) being manufacturers of chemical substances and 121 (21%) formulators (mixers) of chemical substances or mixtures.

In addition, as nearly 58% of respondents are large firms (employing more than 250 people), and as large firms are responsible for most innovation in the chemicals industry, this result also contributes to the representativeness of the sample.

This suggests that in terms of the main targets of the REACH Regulation from the point of view of innovation the survey findings are based on a sound foundation.
3.6.4 The case studies

The case studies look in greater depth at a number of issues concerning the effect of the implementation of the Regulation on innovation. They are presented in Annex 7. The topics selected are:

1. **Innovation linked to substitution of a substance placed on the candidate list.** One of the expected findings from the study on the impact of REACH on competitiveness and the internal market is that there is strong pressure from downstream users to not use chemicals on the candidate list and even the SIN list. One rationale for the REACH Regulation is that this should lead to innovation to find substances to substitute those substances. The case study considers the question in more depth and looks at two examples from industry.

2. **The effect of the REACH Regulation on innovative clusters in the chemical sector.** Innovation activity tends to concentrate in specific areas or clusters. At this early stage in the implementation, clusters in the chemical sector are expected to see the first effects – if any – on innovation of the regulation. In this case study we made contact with the Axelera cluster (Rhone-Alpes, Lyon) to consider the impacts of REACH on cluster activities.

3. **This case study looks at the impact of regulatory framework for innovation in the US, China, India and South Korea.** While new REACH-like legislation is being considered in other economies in the world, existing legislation has an impact on innovation. The aim of this case study is to consider the effects of REACH-like legislation in those jurisdictions. This is done through desk research, contacts with companies, and discussions with chambers of commerce and industry organisations.

4. **Development of a market for chemical data as a result of registration and its use/ role in R&D and innovative activity.** A large amount of data is being created and gathered as a result of the introduction of REACH. While in the early stages innovative companies have been busy dealing with the compliance demands of REACH, the data gathered is expected to play a supportive role for innovation in the Union in the future. This case study considers what is being done with this information, how useful it is, if it is accessible (physically/financially) and asks if a market is developing and what its use is. It is based on desk research, the survey, an additional mini-survey, and discussions (including some additional in-depth interviews).

5. **REACH and marketing and organisational innovation change.** The definition of innovation (Oslo, Community Innovation Survey) includes marketing and organisational innovation. Early discussions have shown that REACH has affected the way companies operate in a variety of ways. The aim of this case study is to follow up with some firms in more detail and depth to see in what forms REACH has driven organisational and marketing innovation. This is based on the survey results and further interviews with a selection of firms.

6. **The effect of the PPORD (product and process oriented research and development) exemption.** To help achieve the objectives of REACH, a reduced system of notification is available for new substances used in research and development. This approach is the focus of one case study. We obtained feedback from the survey, interviews with companies and additional data from ECHA for this case study.
7. **The impact of REACH on highly innovative SMEs.** Alongside large, highly innovative companies, SMEs, often present in high-value-added or niche markets, play an important role in innovation in the chemicals industry. This case study uses survey data and targets a limited number of highly innovative SMEs to gather their views on the current and expected future impact of the regulation on innovation.

8. The last case study considers the **protection of Intellectual Property (IP)** under REACH as regards development of new substances (new registrations) and patent law, and the impact on innovation. Issues as regards SIEFs, Safety data Sheets and Authorisation are also be explored, as are links with Confidential Business Information (CBI). This is based on feedback from the survey, company interviews and interviews with IP lawyers.
Evaluation of findings

In this section we analyse and consider the results of the research in relation to the key evaluation questions examined in the study. The section is based on the information collected from desk research, the interview programme, responses from the survey and the case studies.

This part of the report follows the order of the evaluation questions as set out in the terms of reference. In the pages that follow, “small firms” refers to companies employing less than 50 people, “medium-sized” enterprises to those employing 50-249 people, and “large” to those employing 250 or more.

4.1 Relevance

4.1.1 The REACH objectives and innovation

In this sub section we ask how the REACH regulation’s objectives regarding the innovativeness of the EU chemical industry are standing up as compared to the initial needs identified in the White Paper and current needs as expressed in more recent EU strategic documents (EU2020 /Innovation Union).

(a) The REACH Regulation’s innovation objectives

The White Paper of 2001 stated: “It is essential to promote the competitiveness of the chemical industry and encourage innovation, and in particular the development of safer chemicals. Regulations are a major factor in shaping the innovation behaviour of firms in the chemical industry. The Commission proposes to increase the current thresholds for notification and testing of new substances, to extend the conditions for derogation for research and development and enable test data to be used and submitted in a flexible way.”

The Regulation would also require the registration and testing of existing substances.

According to the Commission’s impact study, it was envisaged that the Regulation would influence the pace and the direction of industrial innovation at product, process development and organisational level. Specific measures were to increase the testing threshold from 10 kg/y to 1 t/y, and to exempt product and process oriented research from registration for a period of five years (renewable for an additional five years). Requiring registration of both new and existing substances would ensure a level-playing field, rather than existing substances being favoured.

In the short-term, the view was that the impact on innovation would depend on the impact of REACH on the resources available for R&D which would result from the interaction of several factors listed below.

- Carrying out tests requires highly skilled personnel, which may limit the personnel available for R&D activities, especially in SMEs.

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41 Ibid., p.8
Evaluation of findings

- Reduced profits could restrict the finance available for reinvestment in R&D spending. It was estimated that the direct costs of REACH would be equivalent to around 3% of current expenditure on R&D.
- If chemical companies were prepared to recruit additional staff or to contract out testing then no negative impact on R&D should be expected. However, if companies decided to leave their R&D budget unchanged, there would be opportunity costs in form of reduced traditional R&D.
- If companies were to sacrifice their R&D budget, direct costs would only occur in terms of opportunity costs in the form of less R&D and innovation. Double counting of these effects should be avoided.

The view was that, especially in the longer term, the modifications made to the chemical R&D regime would facilitate R&D. The new system might also lead to induced innovation in the chemicals industry to develop new and safer products and processes. In addition, the greater certainties given by the proposal in terms of implementation timetable may promote uniform incentives to innovate. The collection of information at the first phase of implementation of REACH as well as the sharing of information across the supply chain may have considerable influence over the way the chemical industry works and how strategic decisions are taken. Closer contacts between users and suppliers, better external linkages and access to external sources of knowledge, and the ability of European industry to project a more attractive image for its products vis-à-vis international competitors could improve the direction and pace of innovation as well the development of newer and safer products.

Enterprises were expected to benefit from the lighter requirements for new substances produced or imported below 10 tonnes a year, especially for production or imports under 1 tonne, which would no longer have to be registered. This was expected to have a significant impact, given the fact that more than half of their notified new substances are below this threshold.

The substantially lighter registration requirements for new substances were expected to significantly reduce the concern that REACH could increase the average time-to-market of chemical substances not in continuous production. Substances on the former existing substances list can still be produced in quantities less than one tonne on an immediate basis. Moreover, provided that such a substance had been marketed, manufactured, or imported in the EU sometime in the 10 years prior to the entry into force of REACH, it would be treated as a phase-in substance and therefore benefit from not requiring any registration before the relevant registration date.

As mentioned in 3.2 concerns expressed about the effects of EACH on innovation from compromising the confidentiality of business information were addressed by tightening up the protection of confidential business information.

A number of reports and case studies looked into the impact of the pre-REACH legislation (Directive 67/548/EEC) on innovation. One report collected the main recommendations on how to improve innovation stemming from these investigations and compared them with the REACH provisions. The results are summarised in the table 4.1.

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43 The impact of REACH on innovation in the chemical industry DG JRC-IPTS27, p. 27
Table 4.1 Overview of recommendations and REACH provisions relating to innovation

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>REACH</th>
<th>Expected impact on innovation</th>
</tr>
</thead>
<tbody>
<tr>
<td>A risk-oriented notification system might reduce costs and time-to-market</td>
<td>Prioritisation of testing for high production volume substances, reduced requirements for intermediates, and the exemption for polymers all implement risk elements, but REACH is no real risk-contingent system.</td>
<td>+/-</td>
</tr>
<tr>
<td>EINECS and ELINCS should be unified to move innovation to new substances</td>
<td>REACH comprises all substances and replaces the existing split system. Incentive to use new substances for R&amp;D makes old substances costly.</td>
<td>+/-</td>
</tr>
<tr>
<td>R&amp;D exemption too narrow defined (max 2 years, with volume thresholds)</td>
<td>R&amp;D exemption can be extended up to 10 years, no volume thresholds. Promises trigger for innovation.</td>
<td>++</td>
</tr>
<tr>
<td>Polymers exemption too rigid</td>
<td>Polymers are exempted. Strong push for innovation</td>
<td>++</td>
</tr>
<tr>
<td>Intermediate exemptions</td>
<td>Slightly extended exemptions foreseen. Impact on innovation may be positive but low.</td>
<td>+</td>
</tr>
<tr>
<td>Volume thresholds too low</td>
<td>Volume thresholds have been increased 100 times. Creates more space for R&amp;D.</td>
<td>++</td>
</tr>
<tr>
<td>Phase-in time</td>
<td>Reduces burden caused by adaptation to new regulation and keeps resources in R&amp;D.</td>
<td>+</td>
</tr>
</tbody>
</table>

Source: The impact of REACH on innovation in the chemical industry DG JRC-IPTS27, p. 27

The Regulation specifies its aim and scope as regards innovation in Article 1:

(1) The purpose of this Regulation is to ensure a high level protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.

The Regulation also includes the following further point:

(8) Special account should be taken of the potential impact of this Regulation on small- and medium-sized enterprises (SMEs) and the need to avoid any discrimination against them.

(b) REACH, EU 2020 and the Innovation Union

The objective of the REACH Regulation as regards enhancing innovation in the EU chemical industry is as relevant as ever in terms of policy context and measures. Innovation features prominently in both the EU 2020 strategy and the Innovation Union.

Innovation is central to the three priorities at the heart of Europe 2020:

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Evaluation of findings

- Smart growth – developing an economy based on knowledge and innovation.
- Sustainable growth – promoting a more resource efficient, greener and more competitive economy.
- Inclusive growth – fostering a high-employment economy delivering economic, social and territorial cohesion.

Within this Europe 2020 strategy, one of the seven flagship initiatives is the "Innovation Union"\(^{47}\), of which the aim is "to re-focus R&D and innovation policy on the challenges facing our society, such as climate change, energy and resource efficiency, health and demographic change. Every link should be strengthened in the innovation chain, from 'blue sky' research to commercialisation". In view of the importance of the chemical industry in innovation in the EU and the focus of REACH on safety and health, there is a clear synergy between the aims of REACH and those of the “Innovation Union”.

The Regulation also emphasises that SMEs should not be discriminated against, and thereby is aligned with the “Think Small First” approach, seen as a key driver in EU industrial policy. For example, there are certain dispensations for SMEs built into the Regulation, such lower registration fees, and also lower fees are payable by SMEs upon application for keeping certain business information confidential. However, it should be pointed out that this is a statement of principle. The practice is examined in the pages that follow, and it is clear that there are areas where SMEs are placed in a disadvantageous position vis à vis larger firms.

Overall therefore we consider the innovation objectives within REACH still to be highly relevant. They identify and address key areas for intervention at firm, industry and EU level to drive the pace and direction of research and innovation in chemicals.

4.2 Effectiveness in achieving objectives

In this sub section we evaluate the effectiveness of the Regulation in achieving its objectives in terms of a three stage approach to the innovation process: conception (idea generation and evaluation), implementation (development/prototype, pilot application, testing) and marketing (production and market launch). This approach is reflected in the diagram below, reflecting a “typical” innovation project. Stage 1 in the diagram corresponds to conception, stages 2 and 3 to implementation, and stage 4 to marketing. It is appreciated that innovation does not always occur in such a structured manner in companies, especially SMEs, but this is used as a useful framework for presenting processes and findings.

The diagram emphasises that there are different stages that the project manager responsible has to take the project through to get to commercialisation, and at each stage the project has to pass through a “gate” or “hurdle” in order to be able to proceed. Different factors are at play at each gate, as the diagram demonstrates. This model structures and informs the discussions that follow.


\(^{47}\) Ibid., p.10
4.2.1 Conception stage (idea generation and evaluation)

“Conception” as used here refers to the generation and evaluation of innovative ideas. When considering the conception stage, the first step is to look at generation and capture of information about substances and their uses, information transfer mechanisms and institutions created by REACH (such as Safety Data Sheets, Chemical Safety Reports, SIEFS and Consortia). Then we ask to what extent new information or knowledge has been created, captured and disseminated, and to what extent this has given rise to new ideas on products and uses. Next attention is turned to the effect of the Regulation on openness and scrutiny of the industry and what the consequence have been on the willingness of the industry to innovate. Finally, it is asked to what extent REACH has led to a diversion of resources from companies’ planned (“true”) innovation to REACH compliance-related filling of gaps in information that could potentially lead to new innovations.

(a) Industrial information generation and transfer institutions and mechanisms

The innovation objectives of the REACH Regulation are informed by the view that the ability of an industry to generate new ideas is a function of multiple variables. It is believed that innovative ideas emerge at the interfaces between industries and within industries at different stages of the value chain. Therefore the more the industry is interlinked with other branches of the economy and the greater the communication at different stages of the value chain, the more likely it is for innovative solutions to
emerge\textsuperscript{48}? This presupposes the existence of information to transfer, and the processes within REACH are designed to generate and capture information about chemical substances and their uses to this end. REACH introduced a number of institutions and mechanisms to foster industrial information generation, capture and transfer. The main ones are the SIEFS and Consortia, the SDS and eSDS, and the CSRs.

Interviews with companies have suggested that processes of information generation, capture and transfer in the SIEFS and consortia can be problematic, as is to be expected when people who may be business competitors, or do not know each other at all, meet and are expected to share information. Issues about intellectual property and confidential business information tend to arise (see below, 3.5). In this situation REACH advice units in different Member States usually advise companies that come to them for advice on how to deal with SIEFS to make data as vague as possible with the aim of disclosing the minimum. On the other hand, some SIEF members, such as for example some large firms, are quite open, especially when dealing with older, well-known substances, and when they are not trying to recover costs made in the past in generating that data. In addition to costs, an issue affecting data sharing that comes up is that firms (large and SMEs) are not always happy about the way SIEFS are run by Lead Registrants who may be dominant firms or suppliers, or both, and who may dictate conditions and have access to confidential business information or intellectual property of participants. SMEs may not be in a position to complain or go public due to fear of “reprisals”, and there are also sometimes issues between companies who have traditionally been competitors, sometimes for generations, and are now expected to collaborate and share information in a highly artificial setting, maybe in a language that they do not fully understand.

\textsuperscript{48} Innovation takes place in the context of overall business strategy development, whether formal and structured or more ad hoc. A wide range of factors driving innovation is mentioned in the interviews and the survey. Within different industries and different sub-sectors there are different drivers of innovation. For example: formulators often have to respond to changes in fashion at short notice; downstream users such as the aerospace industry are driven by highest standards of customer safety with very lengthy testing periods where product life cycles can be up to 40-50 years; refiners seek new catalysts to comply with legislation about pollution; ICT companies need quick innovations for products that may have very short life cycles; basic/ bulk chemicals producers may focus on process improvement or marketing and distributional innovations. Below is a selection of examples of factors driving innovation in the chemicals industry based on feedback from the Innovation Survey. There are many more and they include, for example: placement of metal processing liquids in the metals processing industry, improved applications of products manufactured with existing substances, improved product properties, developing process technology, meeting demands of legislation, fashion trends in the textile apparel furnishings, increased microchip performance, energy saving molecules for the performance chemicals, novel visual effects, trends in automotive production, regulation requirements, green chemistry, latest successful perfume launches, global megatrends (such as population growth, increasing urbanisation, rising demands for resources and energy), costs, efficiency, safety, taste experiences, FDA/ AMA approvals of new chemical entities as active pharmaceutical ingredients/ investigational drugs, bio-pharmaceutical research on new pharmaceutical compounds, environmental, health and safety impacts, odour reduction, colour printing, new therapeutic treatments, green cosmetics, solvent to water-based products, replacing CMRs with less dangerous substances. Much of the feedback for realizing innovation is obtained by in-depth, long term contact with customers (both upstream and downstream) and research organisations. Firms depend on these for their future. To this end chemical companies have field sales/ development/ service engineers out meeting and interacting with customers on a continuous basis to identify new products and niches. This is part of the normal doing “business as usual” for companies to survive and is a major source of innovation.
Evaluation of findings

The process of creating the SDS or eSDS can also be difficult. But as far as information on the SDSs is concerned, some firms spoken to say they are not always sure of the quality of that information when they receive it, because the tests involved have not always been carried out yet (although most seem to be happy in this respect as results from the case study on the development of a market for data in Annex 7 indicate). When they produce SDSs, firms may also try to make them as vague as they can without going against the spirit of the Regulation to protect confidential business information or intellectual property. As a consequence one survey respondent likened the process to “getting blood out of a stone”, especially from non-EU suppliers. Having said that, many companies are quite forthcoming with the required data. SMEs that we have spoken to tend to be perplexed by all the information contained in the SDS and find them very hard to deal with – which limits their use as an information transfer mechanism along the supply chain. There is so much information that firms do not always have the time to go through all of it to find what is relevant. Some small firms do not have the appropriate human resources to understand all the information and its implications, so nothing is looked at. SDSs have also not yet become widely available throughout the whole supply chain. As one survey respondent put it: “We have received very little communication from within our supply chain. We expected 700 eSDS and have received 40.”

As shown in the case study on the development of a market for chemical data (see Annex 7), the data banks and information developed out of the REACH process tend to reside within the appropriate SIEF or Consortium secretariats and member companies where members of the respective organisations can have access to it, either by paying for the studies to be undertaken themselves or by buying a Letter of Access. Data can be accessed by SIEF or consortia members through the IUCLID files, registration dossier and CSR’s. Only some of the information is made publicly available through the SDSs (including exposure scenarios where applicable) and the ECHA website. Although made publicly available, much of this data is still owned by the consortia member companies. In the course of meetings and discussions related to the substances in question ideas are transferred and knowledge is gained. However, much new data has still had to be created through various tests.

A further point made quite strongly by many trade associations and companies is that, particularly as the first registration has involved predominantly large volume phase-in substances that had been in use for some time, many firms and organisations considered that very little was being gained in terms of knowledge from the process, although it was at a high cost. Often then the view has been that costs and administrative burdens are caused by REACH that bear no relation to the result. (The question as to what extent new knowledge was gained (“gap filling”) is dealt with in (c) below).

The view expressed in the course of interviews with many firms and associations was therefore that while the encoded knowledge base of the chemical industry has grown, much of the information that was captured and has become available was already known and is of limited value for innovative purposes. Having said that, the view was also widely expressed that with the next two registration deadlines the situation may be very different as then lesser known chemicals will be in question.
Evaluation of findings

The survey asked respondents whether the development of, or access to, information from the key information-related processes and institutions within REACH acted as a stimulus to product conception and innovation. Responses are set out in the table 4.2.

4.2 Has the development of, or access to, any of the following sources of information acted as a stimulus to product conception and innovation in your organisation?

<table>
<thead>
<tr>
<th>Options</th>
<th>Registration dossier with Technical dossier and Chemical Safety Report</th>
<th>Development of the Safety Data Sheets (SDS)/(eSDS)</th>
<th>Substance Information Exchange Forum (SIEFS)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>№</td>
<td>%</td>
<td>№</td>
</tr>
<tr>
<td>Yes</td>
<td>65</td>
<td>17.3</td>
<td>102</td>
</tr>
<tr>
<td>No</td>
<td>293</td>
<td>77.9</td>
<td>284</td>
</tr>
<tr>
<td>Don't know</td>
<td>18</td>
<td>4.8</td>
<td>12</td>
</tr>
<tr>
<td>Total</td>
<td>376</td>
<td>100.0</td>
<td>398</td>
</tr>
</tbody>
</table>

Source: CSES Survey

Overall about one sixth of respondents indicated that they acted as a stimulus to product conception and innovation. The SDS and eSDS proved most valuable in this respect. Analysis of the survey results suggest that small firms have tended to gain more often in terms of product conception and innovation as compared to larger companies, and especially from the SDS and SIEFs. Manufacturers of chemicals tend to register least benefits.

Companies indicated various ways in which they have innovated as a result of these processes. These include: as a result of having better information about substances, and as a consequence increased internal competence, it is possible to have a better dialogue with major customers; learning new information about substances on the ECHA site; based on the CSR for one of their solvents, new applications can be realized in a better and safer way (for the customer); SVHCs were detected from suppliers in the supply chain which were substituted with another substance which turned out to be less costly, resulting in improved margins; new insights in certain metallic compounds led to development of products without those compounds; and, a good overview of the available Tox and EcoTox information for registered substances has increased the possibilities to use a given substance for other applications.

Companies with a more neutral position as regards the effects on product conception resulting from the REACH information generation and transfer processes made comments such as the following: some developments are so unique and innovative that no relevant data is available yet, as when innovations are based on very detailed specialist processes, with this level of detail, the descriptions of REACH are not required, not relevant and are not published; also, the quality of the information remains low and non-specific; and, REACH is a task for specialists - corporate management and marketing departments are not always familiar with REACH – so they don’t know how to use the data for conception of new innovations..

However, most companies responding to the survey highlighted negative impacts of the industrial information generation and transfer processes vis à vis innovation. Costs and the administrative aspects involved are often emphasised. Companies responding to the survey question mentioned points such as being “pestered” by DUs and customers with 30-page questionnaires (that R&D staff had to respond to);
processing “senseless masses of data” (SDS grew from 20 to 200 pages) which detract from innovation and just create bureaucracy – whereas innovation requires non-disclosure of knowledge until products are ready for the market or a patent has been registered; research people being compelled to stop work on new products (“just do substance mixing now”) to work on regulation driven matters; and, that the complexity of the Regulation is such that it generates bureaucracy rather than innovative ideas.

As regards the value of the data, the following comment was made: “there are processes that require the use of certain chemicals. Of course, if a huge risk potential is determined this must be communicated accordingly (see DDT, etc.) so that corresponding measures can be introduced, however, questionable test results (boric acid) do not in any way improve the data records!”

In conclusion, it can be said that based on the interviews and survey findings data generation and dissemination have, to date, been a source of conception of innovations - although this has not been a wide ranging phenomenon. The majority of firms have suggested that the bureaucratic aspects of data generation have inhibited conception of innovative ideas. However, it may be that once compliance with processes has been achieved, the situation could change, and that with the coming deadlines for substances used in smaller volumes, there may be a greater impetus to conception of innovative ideas.

(b) Openness and scrutiny over the chemicals industry – and industry's willingness to innovate

There is a view that the REACH regulation introduced a higher degree of openness in and scrutiny over the chemicals industry than existed previously. The idea behind introducing openness and scrutiny was that this would mean that more knowledge about substances would be accessible, which would in turn drive innovation. Here it is asked if there has in fact been an increase in openness of and scrutiny over the industry as a result of REACH. Then it is considered what (if any) effects (benefits) this has had on innovation and what the impact on the industry’s willingness and determination to innovate has been.

Openness and scrutiny

Availability of data can favour the identification of innovation opportunities aimed at, for example, using safer substances. It can also act as a form of pressure on industry to replace SVHCs or unsafe uses with safer alternatives. In the survey companies were asked if they thought REACH had led to increased access to and scrutiny of information about chemical substances. 72% of respondents considered that there had been an increase, and 18% that it had increased a lot, although 26% thought that there had not been an increase. There was no particular trend in terms of firm size that held the opinion that there had been an increase, nor in terms of sector, but in terms of respondents’ roles, manufacturers and formulators tended to be presented in a higher share than the average for the survey as a whole.

Firms were asked if this has meant that they were able to benefit from increased openness to and scrutiny of information about chemical substances as a result of REACH by identifying new ideas that could lead to innovations in products, processes, etc. 69% said “no, none at all” but 24% indicated that there had been some benefit (22% “yes - moderately”, about 2% said “yes, a lot”). The majority of such benefits related to properties of substances (81%), but benefits as regards uses were also identified (36%). Benefits were obtained both through the firm’s supply chain (60%) and other sources (56%). Examples of the types of benefits firms obtained, as indicated in survey responses, Are: improvements in health and occupational safety (in a formulator), clearer understanding of substance properties, better toxicological information (properties of substances, classification, identification), and more information
of use of products in the SDS so that risk is reduced. However, survey responses suggest, at least at this stage of the implementation of the Regulation, that what is seen as a costly exercise in information creation and gathering (much of which was already known) has led to an information overflow that many firms are not able to digest and use for the conception of innovations, or that the degree of bureaucracy required to deal with compliance can have a dampening effect on innovative activity. The complexity of the information (who in the firm can understand it?) may also limit its usefulness from the point of view of conceiving new ideas. In addition, it is commented that information requested is not always available.

A further aspect of openness and scrutiny concerns the access by NGOs to data at substance and company level. For many firms this is a major concern, as it could have very negative impacts on their share value if they are targeted for various reasons and do not have time to adjust, substitute or reformulate from for example use of substances in the candidate list.

On the other hand it has also been argued that scrutiny is not yet fully open and transparent enough by ChemSec and Client Earth who initiated proceedings against ECHA and alleged the agency of several violations of European laws designed to promote transparency, democracy, and legitimacy in EU policy-making. ECHA has refused to disclose the names of the facilities producing certain dangerous chemicals and the amounts in which they are placed in the EU market. However, the matter is under review. Revelation of such details was not the initial intention of REACH, and this degree of openness will have presently unknown implications for innovation in Europe.

Therefore, while there is increased openness and scrutiny of information about chemical substances, there is not as yet evidence of an overwhelming stimulus to conception of innovative ideas, although there have certainly been some benefits.

Industry’s determination and willingness to innovate

Related to the conception of innovative ideas driven by access to data, openness and scrutiny, is the question of industry’s determination and willingness to commercialise these ideas. In addition to the effects of the Regulation, a range of factors internal to the firm (e.g. knowledge, capability, profitability, product life-cycle stages, etc.) and external (e.g. market conditions, competition, regulation), which may differ at sub-sector and firm level, and with views on risk and uncertainty, drive profitability which drives the investment decision. 40% of survey respondents consider the effect of REACH as of some degree of importance in driving innovation. However, there are many other factors involved as well, both in terms of how the Regulation itself evolves and is implemented and the current immediate impact.

The evidence from surveys and interviews (see also (c) below) suggests that much of industry is determined to continue innovating, even if this implies having to carry an increased administrative burden. For many firms innovation determines their future success, and without it they will not survive.

(c) Phasing in of REACH: diversion from planned ("true") innovation or "gap-filling" to identify new potential?

The phasing in of the Regulation involved a comprehensive exercise of the testing and assessing of over 4,000 existing substances and chemical products. The Commission’s EIA thought that this could divert resources from companies’ planned (‘truly’) innovative research activities. On the other hand, it was also believed that the information gathered from this phasing-in stage and data sharing could fill gaps in knowledge about the properties of existing substances/uses and thereby lead to benefits by revealing hidden potential in these currently available substances. This question is considered here, and we comment on where the balance between these two expected effects could lie.

A diversion of resources from innovation to compliance?

Industry representatives and firms expressed strong views about the extent of the diversion of resources from firms’ planned, “truly” innovative activities, to activities required for compliance with the Regulation, often seen as of limited use to the firm. It was pointed out that although much of the activity could be considered administrative and bureaucratic, in fact it generally required input from staff with a solid grounding in chemistry and toxicology (so sometimes specialist external resources had to be used). Even when replying to relatively simple administrative enquiries from downstream users about substances in articles for example, invariably they were referred to R&D staff with knowledge of chemistry. We were told, for example, of a research group of 40 people being transferred wholesale to REACH activities, and one major petrochemical company at one stage had 60 people working full-time on REACH. In addition, resources were often allocated to fund consultants for support in compliance.

The impact of these requirements was felt differently by firms. For those that had resources available, additional staff could be recruited so that R&D programmes under way were not negatively impacted. However, in more financially constrained firms it lead to very high demands being placed on staff to try to maintain essential innovative work as well as to ensure compliance with the Regulation. The economic environment in which the Regulation was introduced and developments in subsequent years have not favoured innovative activity.

The survey asked respondents whether the introduction of the Regulation had led to staff being shifted from R&D and innovation related activities to activities related to compliance with the Regulation. 63% of respondents indicated that in fact this had been the case, including 19% who indicated that the shift had been substantial.

Among the firms that said the shift was "substantial", 32% were small, suggesting that small firms were particularly affected in this respect, as opposed to the situation with large firms where the share was 40% ). Among those affected formulators were relatively more present than in the overall survey group. Responses from the survey include the following from a large manufacturer: “We, and most of the chemical industry, operate on a very low margin on sales. Increased costs for REACH will generally be offset by reduced expenses within our operations, and R&D is one variable cost which can be diverted. REACH had a substantial negative effect on our R&D staff. Rather than doing productive research on new innovations, we used 10-15% of our R&D staff time to support REACH in substance sameness discussions, selection and synthesis of test substances, spectral analysis, polymer analysis, purchased
Evaluation of findings

product chemistry discussions, substance production information, SCC restrictions for Intermediates, and a dozen other topics.” Another said it meant diverting 33% of people at an economically difficult time and reduced new product development opportunities. One firm mentioned future requirements for staff to create eSDSs for formulations that might be composed of 15 substances, each with an exposure scenario, in a company with 1,800 raw materials and 20,000 active formulations.

A further important question is whether the shifts are considered to be permanent or temporary. Was there a bulge before the registration deadline which will level off and decline to a low “maintenance only” level, which will allow resources to be transferred back to R&D and innovative activities, or will the resource requirements remain permanent – at whatever level?

The view from industry associations and firms is that there was indeed a “bulge” leading up to the 2010 deadline, but what happens subsequently will depend on various other factors such as the extent to which tests are required to be carried out, and administrative requirements for development and updating of SDs, exposure scenarios, and monitoring, for example. Some R&D resources will also continue to be drawn into innovative activity related to compliance with the Regulation (e.g. removal of SVHCs from mixtures) that is not part of planned innovation programmes and therefore in a sense detracts from firms’ planned innovative activity. In addition, some have started preparing for the 2013 deadlines. So while it is unlikely that there will be a return to a pre-Reach scenario, various firms will experience the post 2010 registration deadline differently.

In the survey 25% respondents thought the shift in activities away from R&D to compliance would be temporary, and the remainder permanent. The distribution in terms of size of firm among respondents that expected the shift to be temporary mirrored that of overall responses, but in terms of REACH roles the presence of formulators and manufacturers was lower than in the overall group. Among those that saw the shift as permanent, small firms represented 41% of respondents, compared to 22% representation overall. Firms interviewed thought that the on-going requirements of REACH related to industrial information transfers and updates would have a lasting impact on smaller firms. Survey responses received in this respect emphasise the on-going requirements of the Regulation as regards on-going diligence and review, draining resources from real value-added activities; and also expected increased REACH legislation. Several respondents highlighted the increasingly globalised aspect of innovative activity offering more location choices for innovation, leading to their R&D effort being focussed on non-EU areas, and gradually transferred out of the EEA.

In the survey respondents were asked what the effect on the level of expenditure on R&D and other innovative activities was. 46% of those that answered the question said there was an increase in expenditure on R&D and other innovative activities (18% said this increase was substantial), 31% saw no effect and 14% that it would decrease. 40% of those who thought that there would be a substantial increase were small firms. Some companies interviewed indicated that the additional REACH work was a major strain on staff as the current economic climate precluded additional recruitment (often there have been headcount freezes) which has meant that the REACH work resulted in much longer working hours. 69% of respondents thought that the increased expenditures would be permanent. Survey responses from firms show that they have often recruited additional people to cover additional laboratory tasks, or for product safety, and see those positions as permanent; but some R&D staff temporarily transferred to help with the registration process are now back on R&D. Some make the point that despite increased costs they will continue to invest in R&D; others say that their companies’ development projects are no longer targeted for Europe.
Evaluation of findings

In the course of the company interview programme some very large global companies also said they will be increasing overall expenditure to maintain their long term R&D programmes. This is important from an innovation point of view as overall these large firms are responsible for the greatest part of innovative activity in the industry. So they are not reducing expenditures on innovation, although their cost base would increase to accommodate regulatory compliance.

Filling in knowledge of gaps on existing substances and/or uses, uncovering hidden potential?

The overall conclusion from industry is that as the first registration period dealt with large volume substances many of which have been in use for a long period of time, their properties have tended to be well known, so there was in those cases not much gap-filling and uncovering of hidden potential. Thus it was said that the dangers of the substances in steel have generally been known for a very long time and completely new findings have not been determined by REACH, while the printing ink industry uses primarily substances known and proven over a long period of time. Another example is that of lime producers, where it was suggested that it would have been much more effective to encourage innovation if instead of some thousands of companies paying ECHA a registration fee this money was used to set up a lime research trust to carry out new research on lime. Some associations say, as the survey results above suggest, that there has definitely been a shift from R&D/ NPD to compliance to meet data gathering, generation, creation and codification requirements but the problem is compounded by the fact that it is expected that compliance costs related to this registration will continue to draw resources in the future as well, as ECHA starts to evaluate dossiers and additional tests may be required. It is expected that gap-filling might be more of a factor with the next cut-off dates when substances marketed in smaller volumes about which less is known are registered.

At present the focus therefore seems to be on compliance rather than identifying new potential. We have only heard of a few instances of new product development as a result of REACH processes but this was not necessarily the result of filling gaps in information, rather it has been linked to issues surrounding the candidate list, the SIN list and withdrawal of substances.

A further point is that data created so far has not yet been evaluated by ECHA, so there are some uncertainties as to its acceptability. We have also been advised that Competent Authorities of some Member States are keen to obtain very robust data that sometimes requires further testing, so there may be more gap-filling expected in the future.

Finally, it was also pointed out that while there will be some gains in knowledge, some will be lost, as companies withdraw from working on some substances withdrawn and on the candidate list.
4.2.2 Implementation stage (development/prototype, pilot application, testing)

This stage includes prototype development, pilot application and market testing. The following questions are considered:

- The REACH Regulation has shifted the centre of gravity in terms of the safety assessment of existing chemicals to manufacturers/industry. Has it upheld certain barriers for research activities on new substances? Have changes impacted the balance of interests for research activities and what is the current centre of interest (new substances vs. new uses for old substances)?
- What has the experience of various measures within the Regulation to support R&D been?
- What has been the effect of measures in the Regulation intended to limit the number of animals used in testing stages? Did the requirements related to the reduction of animal tests impact the industry capacity to introduce new substances or to develop new uses for existing substances?
- Are there any implications for the supply of laboratory capacity?
- What has been the impact of REACH on the development of business cases for innovation projects (e.g. rates of return, risk, uncertainty).
- Have these factors led to better products?

(a) The shift in terms of the safety assessment of existing chemicals towards manufacturers/industry.

Questions dealt with in this part are: What has been the effect of the shift in terms of safety assessment of existing chemicals toward industry? Have some barriers to research on new substances been upheld? Where is the balance of interest for research activities? What is the current centre of interest (new substances vs. new uses for old substances)?

The shift in the centre of gravity in safety assessment of existing chemicals to industry

Companies and industry associations interviewed point out that for them (and their supply chains) safety has been a major, if not a key, driver of innovation since well before the REACH Regulation came into force. Examples mentioned include aerospace, where very powerful statutory bodies exist to enforce passenger safety. The safety of chemicals used in those industries is also highly controlled in terms of risk reduction in both manufacture and disposal from a human and environmental health point of view. In other industries such as automotive, toys, personal care and detergents, health and safety are also crucial, and when anything approaching an issue emerges the industry concerned tends to respond very quickly. The printing ink industry uses substances that have been known over a long period and has its own list of substances that are not to be used due to HSE related requirements. Also, in some industries there is already a great deal of knowledge about safety and related matters, but there are not major innovative activities being carried out either as the substances are well known and managed accordingly.

However, as is well known, independent tests carried out by authorities found that there was a need to test existing as well as new substances. Before REACH existing chemicals were exempt from safety assessment. Only the relatively few chemicals marketed after September 1981 (about 3800 listed on ELINCS) were subject to safety scrutiny. This dual-track system led to a situation, where of 2465 high
production-volume chemicals only 14% had the equivalent of the base-set of tests as required for new chemicals, and 21% had no data at all\(^\text{50}\).

As the burden of risk assessment of chemical products had rested with the authorities, lack of hazard data, coupled with a poor data on the handling and use of chemicals, led to very slow progress on the assessment and control of chemicals. Since 1993 only about 150 high volume chemicals had been identified for risk assessment, of which about 30 completed the evaluation process under Regulation EEC 793/932. Since 1976, restriction on marketing and use (according to Directive 76/7693) has been applied to only about 100 substances, along with about 900 substances classified as carcinogenic, mutagenic or toxic to reproduction. These data indicated that there was a need for additional safety assessment of chemicals.

In the survey it was asked if the additional testing costs for new substances – as opposed to existing substances – was a disincentive to innovation before the implementation of REACH. 39% replied “no, not at all”, while 47% said “yes”, including 18% that said “yes- a lot”. 45% of those that responded “yes” were manufacturers and 42% of those that said “no” were manufacturers.

### Table 4.3 Was the additional cost for testing of new substances (as opposed to the situation for existing substances) a disincentive to innovation for you before the REACH Regulation was implemented?

<table>
<thead>
<tr>
<th>Options</th>
<th>Nº</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes - a lot</td>
<td>56</td>
<td>17.9</td>
</tr>
<tr>
<td>Yes – moderately</td>
<td>90</td>
<td>28.8</td>
</tr>
<tr>
<td>No, not at all</td>
<td>120</td>
<td>38.5</td>
</tr>
<tr>
<td>Don’t know</td>
<td>46</td>
<td>14.7</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>312</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Source: CSES Survey

The survey then asked those that responded “yes” whether the requirement that both existing and new substances must be tested eliminated the disincentive to develop new substances. 33% said “yes”, including 29% who indicated “partly”, while 65% said “no”. There was a higher share of SMEs in the “yes” group than present on the overall survey (58% compared to 42%).

### Barriers to research activity on new substances

Interviews with companies, industry associations and Competent Authorities indicated that REACH has brought new boundaries to development of new products, processes and prototypes, while some have not been removed. In this latter category there is still a difference between "existing" and "new" substances under REACH where for "new" substances between 1-10 t/a, one has to provide the standard test data of Annex VII, whereas for "old" substances one doesn’t have to, according to Annex VII (a) (b) and (c), unless according to Annex III they are likely to cause a risk.

\(^{50}\) http://ec.europa.eu/environment/chemicals/reach/background/docs/finrep_occ_health.pdf
In addition REACH has brought new factors into play that create barriers for research activities on new substances. These include the costs of registration, both for materials from within and outside the EU, for manufacturers and importers also when new to the company; constraints in supply chains, and IPP issues. One respondent pointed out as follows that testing costs are only part of the equation, and other parts have been affected by the Regulation: “Specific comments on impact of: 1) "Testing Costs": For high volumes (>10,000 or 20,000tpa) costs are not an issue, and there are usually many Registrants to split the costs. For substances in the 100-300tpa range, testing costs could eventually kill all but the highest margin substances. EU R&D on these lower volume substances is significantly affected even now because of REACH. 2) Dossier Preparation: Not an issue when we prepare our own, but has been a major impediment to buy a LoA, which are often over-priced. 3) Access to new market opportunities: REACH has reduced our supply chain options for raw materials and increased EU costs. At the sales end we’re not able to recover REACH costs from DU’s. This discourages R&D for the EU market. Even more important, we see our customers shifting their focus outside the EU. In particular we are now dealing with EU based global companies in Asia. Since REACH, we have opened new technical centres, with Asian staff, in India and China. While REACH was not the only driver, it was a factor in the decision to relocate some R&D to Asia”

Companies were asked to list any details about new substances developed due to the change in testing requirements between old and new substances. A few were provided: new pigment additives a new substance expected to be more biodegradable than what exists on the market (it was almost stopped due to registration cost – currently proceeding in the lowest volume scale for the time being); 2 substances within the PPORD framework - implementation of projects will be investigated at the end of the exemption period; substituted a substance with another having the same characteristics; replacement of carcinogenic products by less hazardous substances; utilisation of tensioactives of natural origin ECOCERT products and introduction of the ECOLABEL in the near future. So while barriers to new substance research still exist, some innovation has resulted from the changes in testing requirements.

The balance of research interest between new uses for existing substances and new substances

When considering the overall impact of the equalisation of registration costs on the balance of research interest between existing and new substances, most organisations spoken to suggest that it is still quite early to say where the balance is now. The position has probably not settled down yet, and the current economic climate is also probably playing an important role in research funding and innovation programs. However, as has been mentioned, some of the large firms interviewed do see the shift favourably, and they tend to be major spenders in the field of R&D and innovation.

The survey asked if respondents have any additional comments as regards the factors influencing the balance of innovative activity between existing versus new substances. Analysis of these responses suggests that comments fall into three categories: market resistance against introduction of new substances; costs of registration; and other factors related to new substance registration. A further challenge to EU-based innovation mentioned again is that of increasing locational choices in other parts of the world.

As regards market resistance the point is that there is a bias to known substances, and change also involves some risks for suppliers, as the following survey feedback comments demonstrate: “The replacement of an old product by a new one is frequently an occasion for our customers to test several
competing products in parallel and hence increases the risk of seeing our market share taken by a competitor”. Companies also “profit from sales of substances which we had in our offer earlier on. Costly registration of new solutions is very risky because when new products are not recognised by the customers – they bring losses and the registration is pointless.”; “the market wants to work with the old substances as long as possible. New substances often take a while to get going”. DUs may have to incur costs to adapt their products and processes if new product are developed and marketed by their suppliers. It may of course be that new substances (or uses) are safer, which could counter this bias to some degree.

One point made in relation to costs was that equalisation of costs means that whereas in the past some development could take place with existing substances, now even that will be too expensive. Also, under the previous regime returns from investments in existing substances could be used to fund other new development, now this has been constrained. Issues surrounding uncertainty about budgeting for testing costs (e.g. will waiving arguments be accepted?) are considered in more detail below. Another point raised is that of the possibility of reducing testing costs for industries producing non-toxic and non-ecotoxic substances (e.g. in oleochemistry). As one respondent said: “The cost of testing for existing substances is going to become an increasing tax on business, especially for SMEs the closer we get to 2018. We could not afford the cost of significant innovation under EINECS, and any resource we can afford will now even more be directed towards paying the cost of preserving the current product range. We envisage future innovation will be restricted to purchasing new items within Europe from major producers/importers, who will thus have commercial leverage over our business.”

The new registration regime under REACH also presents some barriers for research into new substances. These are looked at in more detail in 4.4 (a) below, but points raised by firms in the course of the research refer to time to market that has increased due to administrative processes (inquiry) and testing needs, which contrasts with using well defined and established data for existing substances. The CLP Regulation requirement on classification also causes — to some extent — problems in product development (due to IP issues).

Several respondents also highlighted the increased locational options for R&D and innovative activity outside the EU: “Most global companies shifted their 'new substance' introduction to non-EU regions back in the 1980's and 1990's. EU doesn't get the new and innovative substances until years later, after a profit has been made outside the EU to justify the high new substance costs." Another explained the relationship between markets and costs as follows: “market acceptability and hence profitability of a new substance must be sufficient to warrant the test costs of REACH. For specialty chemicals the margins are not high. As a consequence any new substances are developed and trialled outside of the EU to assess their commercial viability. If successful these may then be imported into the EU. Thus much early innovation work is carried out outside the EU. Overall our company has moved away from extensive research on new molecules to formulation of existing substances. The legislative burden on new substances and the corresponding risk is high - for us especially for the 100-1000 t/y band.”

In sum, although some of the big players in the market view the equalisation of testing costs relatively favourably, it is too early to draw an overall conclusion on where the balance lies, or is moving towards at this stage. Closer to the 2018 dead line it may be clearer where the balance of research spending on innovation as regards existing and new substances is moving to. However, at this stage of the REACH process the interviews and survey suggest that there are still many factors other than equalisation of testing costs between existing and phase-in substances that result in a bias against research on new
substances, some of which are unrelated to the Regulation, and some of which are. As a result there are still many factors that favour research on existing substances. Nor does the general economic climate contribute to research on and development of new, commercially unproven substances.

(b) Measures in REACH to support research activity

The Regulation introduced some measures to encourage R&D and innovation. These are: the volume exemption; for product and process oriented research and development (PPORD); and those for isolated intermediates and polymers. They are considered in turn. Some REACH-related EU and national schemes that can contribute to research for innovation will also be mentioned.

- The volume exemption:

Substances used in scientific experimentation, analysis or chemical research in a volume less than 1 ton per year are exempt from REACH registration, authorisation or restriction. The survey asked if this led to increased R&D activity, and if this ceiling was sufficiently large to enable the additional R&D the firm wishes to undertake. 6% of respondents indicated that this had led to increased R&D activity at their firm, and 29% thought that the exemption was sufficiently large to enable the additional R&D the firm wants to undertake, 50% that it was not and 21% indicated that they don’t know).

Survey responses suggest that the volumes in question are often only considered sufficient for laboratory synthesis, not for pilots, trials and early production introduction. As one respondent put it: “We have developed a substance. We are thinking of patenting the product, however the production, and related marketing, will commence directly abroad because with one ton we are not capable of doing a test of a significant market and, to make a larger quantity, we have to commit the company to great expense without knowing if there will be a return. For this reason we will produce some tons abroad and test the market in China and SEA. Results: We are teaching others to make products that should be made here seeing that they are high value-added, the finished product will first be made abroad and this means giving a competitive advantage to the Chinese and SEA producers”.

- The PPORD exemption

Substances manufactured or imported for the purposes of product and process oriented research and development are exempted from registration requirements for a period of five years (or more on application). The survey asked respondents whether the PPORD exemption was sufficiently long to enable the additional R&D their firm wishes to undertake. 48% of respondents think that the exemption is sufficiently long to enable firms to carry out the additional R&D that it wishes to undertake, but 23% do not while 29% don’t know. However, it does seem that that a low share of firms has applied for PPORDs (15%). The PPORD exemption is subject of a case study in Annex 7, of which key findings follow.

- 43% of PPORDs on the ECHA database at September 2011 are of German origin, 11% French, 7% each from the UK and Italy, and 5% each from Belgium, Ireland and Austria.

- The number of PPORDs completed seems to be declining or levelling off (but this may be due to economic circumstances).
Interim evaluation: Impact of the REACH regulation on the innovativeness of the EU chemical industry  
Final Report.

**Evaluation of findings**

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**Table 4.4  Statistics on successfully completed PPORDs per year**

<table>
<thead>
<tr>
<th></th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
<th>2011*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total dossiers</td>
<td>230</td>
<td>210</td>
<td>208</td>
<td>147</td>
</tr>
<tr>
<td>of which:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of PPORDS in the database</td>
<td>229</td>
<td>194</td>
<td>175</td>
<td>121</td>
</tr>
<tr>
<td>Spontaneous updates</td>
<td>1</td>
<td>16</td>
<td>33</td>
<td>26</td>
</tr>
</tbody>
</table>

Data per 13/9/2011. Source for 2008 and 2009: R-IT.  
Source for 2010 and 2011: BO report 01_REG_DossierSubmissions_v.1.8_PPORD  
Source: ECHA

- The survey responses suggest that the following are the main reasons why companies do not apply for PPORDs:
  - Time to market: the development phase in the industry is too short so PPORDs don’t help; the development phase in the industry is too long (20 years); they only use REACH compliant substances for research so that production can go ahead immediately after R&D.
  - Administration and cost issues: the process is too complicated and over-elaborate for small and micro-firms.
  - Costs: the focus is on using existing substances because they do not want to incur additional costs.
  - The non-EU option: places like China, USA, Saudi Arabia and India are quicker and cheaper.
  - Confidentiality: companies do not want to provide customer lists.
  - Companies prefer to register as they will have to register anyway later.

Firms that did use the PPORD tend find it very helpful because it helps overcome the 1 tonne volume barrier and is said to be an improvement on the previous Substance Directive 67/548. However, interviewees also suggested that PPORD is treated as a discretionary item by ECHA whereas it ought to be automatic as long as the required data sets are completed.

- Isolated intermediates

Isolated intermediates (on site or transported) are exempted from REACH registration in quantities up to 1 ton per year. Beyond that ceiling data to be provided by the manufacturer is still less than in the standard registration procedure. The survey asked if this has contributed to increased innovation, and if it has enabled the additional innovation the firm wishes to undertake. 11% of respondents said “yes” it has contributed to increased innovation, and 83% that it did not. 19% said it has enabled the additional R&D the firm wishes to undertake, while 50% that it did not and 30% did “not know”.

Respondents were asked if they have any comments to add as regards this exemption. There was a good deal of feedback. Key points raised are: the additional costs and operational requirements of ensuring that substances stay under strictly controlled conditions (SCCs) can lead to problems for innovating firms (e.g. in multi-stage synthesis), resulting in losing business to overseas suppliers if customers are not prepared to pay for the works required to comply with the Regulation - as one respondent stated: “Exclusive registration of substances as intermediates has a very negative effect on research and innovation. R&D users should be able to use transported and isolated intermediates WITHOUT restriction by Art. 18. (General exception of R&D, transfer via the supply chain to R&D users would then be possible without Art. 18 certification.)” Laboratory applications are often not covered by intermediate
regulation. (For example, use as solvent; controlled conditions in the laboratory but not strictly monitored (\textit{\textasciitilde} completely closed) as required in Art. 18).” Changes in ECHA’s guidance after December 2010, even countermanding valid licences issued by the German authorities of many years’ standing, has also caused some problems for innovation.

- \textbf{Exemptions for polymers}

Under REACH, polymers are exempt from registration. The survey asked if the exemption for polymers has contributed to increased innovation, and if the exemption is sufficient to enable the additional R&D the firm wishes to undertake. 8% of respondents said it does contribute “substantially”, and 21% that it does “partly”, while 67% said it does not. 39% though the exemption enough for to enable the firms to do the research it wishes, 31% that it “does not” and 30% replied “don’t know”.

There were very many responses to the open ended question on polymers. The main points raised refer to the trend to try and “squeeze everything into the polymer definition” (oligomerisation – see text box 4.3):“I know enough companies who have their reaction resins produced in the Far East and oligomerised to so-called polymers or pre-polymers so that they can be imported into the EU. Everyone is desperately trying to squeeze everything into the polymer definition. Yes, many hours are spent in the laboratory in order to resolve these formal problems. But it is still not innovative since the final properties are not improved. In the Far East people are laughing and thanking ECHA. At the last raw materials show Chemspec it was a joy to see how REACH is relocating thousands of jobs to the Far East. We produce a binding agent for EUR 16 / kg cost price. A Chinese manufacturer declares it as a polymer and imports it for EUR 11 / kg. How are we as a manufacturer with 12 employees and no legal department supposed to cope?” Companies also questioned the “disproportionate” impact on costs of having to fully register monomers when they are chemically converted immediately with no HSE dangers. The fact that only component monomers of polymers need to be registered, rather than the many polymer variants, is however seen as an advantage.

One highly innovative non-EU headquartered multinational company established in the EU producing polymers also mentions supply chain issues arising when companies from abroad supplying non-standard exotic monomers may not want to register. Firms based outside the EU will not face this problem, and can then export the items in final articles, placing innovative EU industry at a disadvantage.

\textbf{(c) REACH and animal testing}

The Regulation introduced measures intended to limit the number of animals used in testing stages. This has implications for costs and time as animal testing tends to be costly and time-consuming. Measures include the principle of data sharing and joint registration, as well as use of QSARS and read-

\begin{itemize}
  \item \textsuperscript{51} According to Article 6.3: Any manufacturer or importer of a polymer shall submit a registration to the Agency for the monomer substance(s) or any other substance(s), that have not already been registered by an actor up the supply chain, if both the following conditions are met: (a) the polymer consists of 2 \% weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);(b) the total quantity of such monomer substance(s) or other substance(s) makes up 1 tpy.
  \item \textsuperscript{52} Article 1 of the Regulation underlines the importance of developing alternative testing models.
  \item \textsuperscript{53} Quantitative Structural Activity Related models, used for testing.
\end{itemize}
Interim evaluation: Impact of the REACH regulation on the innovativeness of the EU chemical industry Final Report.

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across. Here we ask if provisions within REACH have led to a reduction in the needs/ costs for testing and if requirements as regards animal testing have had an effect on the firm’s capacity to introduce new substances.

The survey asked if read-across, had led to a reduction in the need/ cost of testing. 49% indicated that it had, including 15% that said it had done so “a good deal”. 26% said it has not changed and 14% that “it did not know”. Most firms that responded were large – well over the 58% of the respondent group in this category, and also mainly manufacturers. This is not surprising as they make up the majority of firms that were involved in the first registration, so they have most experience in this area.

In some cases use of read-across has meant that companies do not have to commission new tests to register some substances, or it has led to a reduction in costs for testing. One firm indicated that if it had not been possible to use read-across and waiving it would not have been possible to meet the registration deadline.

Some companies did express caution as regards the use of read-across, as dossiers still have to be evaluated and there is as yet little experience of ECHA’s views on the matter, which will be critical for cost reduction for 2013 and 2018. Also, it is argued that the methods of read across, QSAR, etc. still include a strong element of uncertainty, so certain significant safety factors have to be allowed for and an advantage may turn into a disadvantage; and that for generating the basic data set (1-10 tonnage band data requirements), read across is not useful because one needs the basic data set for comparing the target substance with the read across substance. Only in the higher volume bands might read across become applicable. One firm mentioned that the cost of building up a case was so high it might have been easier to commission the tests themselves from scratch.

Companies have pointed out some areas where problems are being experienced with read-across. These include costs of access to SIEFS for read-across information only for importers or formulators who use multiple substances and do not manufacture, and would have to join potentially hundreds of SIEFs; what many consider to be the often very conservative interpretation of requests for waiver by ECHA; technical issues concerning for example extrapolation (absence of rules), known risk, or building up of sufficient data; and problems experienced by SMEs such as costs of Letters of Access and inability to check exemptions for waiving animal tests or use of read-across due to absence of expertise and low visibility in SIEFs. One respondent put the case as follows: “As a SME we are dependent on others to operate as SIEF facilitators and Lead Registrants, thus we have no visibility of the detailed costs or how read-across is used. Only one textile dye has been registered to date, and the proposed cost of data-sharing was prohibitive. We have test reports on a large number of substances which could be used directly by the SIEF for registration of that substance, or for read-across to similar substances, but to date no SIEF has paid us for any of that data.”

54 Theoretical models that can be used to predict in a quantitative or qualitative manner the physicochemical, biological (e.g. (eco) toxicological) and environmental fate properties of compounds from knowledge of their chemical structure. A QSAR is a qualitative relationship that relates a (sub)structure to the presence or absence of a property or activity of interest. A QSAR is a mathematical model relating one or more quantitative parameters, which are derived from the chemical structure, to a quantitative measure of a property or activity. (ECHA, 2011, The Use of Alternatives to testing on Animals for the REACH Regulation, p. 7.)
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According to some interviewees, relatively little use had been made of QSARS at the stage of the first registration date. The view is that there was not yet sufficient experience and certainty in their use and application to satisfy the stringent requirements of public sector toxicologists. However, a great deal of work is currently under way to improve their usefulness in preparation for the next registration cut-off dates, in particular under the Antares Programme (Alternative Non-Testing methods Assessed for REACH Substances) and VEGA Programme (virtual models for evaluating the properties of chemicals within a global architecture) mentioned above.

Animal testing

As regards whether the provisions of REACH have led to a reduction in animal testing, interviews with leading chemical industry firms indicate that their experience is that ECHA has used a very conservative interpretation of their testing results and tends to request full 90-day testing which involves animal tests when the companies have indicated that weighted 28-day tests are more than sufficient. According to survey responses (below), several factors have a bearing on what happens in practice.

22% of survey respondents thought that the provisions of REACH have led to a reduction in animal testing (15% “somewhat” and 7% a good deal”). 34% thought it has not changed and 32% that it had increased.

Issues surrounding animal testing foreground the interplay of the many factors involved in the interaction of the Regulation, its interpretation and implementation, the relationship of the Regulation with other EU policy directives, as well as the behavioural interactions of firms participating in SIEFS and consortia. Several respondents comment that the approach adopted by ECHA as regards animal tests is conservative (e.g. vis à vis use of alternative test methods) and biased towards testing, although interviews suggest that CAs of MS exercise an important influence on the level of testing required as this is seen as a source of data for them; companies are surprised that some studies for existing substances are considered too old; and regret the consequences for costs and unnecessary animal suffering resulting from different approaches of EU policy (e.g. Cosmetics Directive and REACH). It also seems that consortia or SIEFs may adopt animal testing approaches even if not necessarily required; and SMEs do not always challenge the approaches adopted in SIEFs as they do not have a strong voice there. Clearly there is a complex interaction between a set of regulatory, technical and behavioural factors relating to how SIEFs and Consortia work, firms of different sizes, the role of ECHA, foreign firms, and so on, that influences the level of animal testing and has resulted in some survey respondents reporting an increase in such tests.

Animal testing and the impact on industry’s capacity to introduce new substances.

The survey results suggest that provisions within REACH as regards animal testing have not had a major influence on firms’ capacities to introduce new substances – 60% see them as having no effect, although 23% of respondents indicate that it has been negative (2% positive, 17% don’t know). Where present, the negative impact is related to the costs involved and the additional time taken to conduct tests.

(d) The use of external laboratories

In the course of the interviews with firms and associations it emerged that problems had been experienced by some companies as regards access to laboratories for testing in the run-up to the 2010
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deadline, both for Regulatory testing and standard work. The survey asked respondents to what extent they used external laboratories for testing. 89% indicated that they did: 52% “sometimes” and 37% “always”. Among SMEs 93% said they always or sometimes used external laboratories; the equivalent figure for larger firms was 88%. The main reasons given for this are: the requirement for specialised skills and equipment (e.g. for tox or eco-tox, or animal tests), the need to use GLP facilities so that results can be accepted as independently verifiable (e.g. for SIEFs, legal purposes or Third Party accreditations), and the scale of needs – they are too infrequent to justify investment in in-house facilities. Only really large firms can afford their own in-house labs for testing.

Firms who use external laboratories for testing were asked if they had experienced any delays in access to laboratories for testing due to capacity constraints at such laboratories from demands to meet REACH-related testing requirements by other companies. 48% said “yes” (9% “a good deal”, 38% “somewhat”). Comments on the question suggested that some trends may be emerging. There have been increases in delays and prices, which even for non-REACH-related work, has had knock-on effects in delaying product introductions, sometimes by several months; delays are particularly experienced in finding slots for higher tier studies (annex VIII, IX and X) and some testing is yet to begin, while there may be a decline in quality of interaction resulting from more focus on throughput. Respondents from some MS report specific problems: “Since REACH was introduced queues in the only available toxicological laboratory in Poland were enormous and then it turned out that in order to register we were going to buy the research results as part of the consortium which we are a member of instead of doing them on our own. We also had to deal with enormous queues when certifying our products for transport. A small number of suitable research centres in Poland and queues lasting even 2 years entirely exclude a new product from sales”; however some adopt a different approach; “We do not do our testing in the EU. EU labs are too expensive and slower than U.S. labs which provide better service at a lower cost. US Labs are not yet overloaded, and have not yet begun to increase their prices.”

Interviews with firms and laboratories suggest that good toxicological and eco-toxicological laboratory staff – those with some experience – are becoming increasingly hard to recruit.

Interviews with Member State institutions and industry associations have also revealed some issues. In particular it seems that newer and smaller Member States have been negatively impacted as, for example in Estonia there are no GLP approved laboratories, so tests have to be sent abroad to be carried out which has cost (e.g. translations and related liabilities) and time consequences. This does not help innovation in Member States that are trying to get their chemical industry to catch up with that of other Member States by moving their industry up the value chain, and favours established players in the industry with the required physical and human infrastructure, such as those with firms located in the leading chemical industry clusters in the EU.

In Italy there was also concern expressed about availability of laboratory facilities. A survey was carried out by the Competent Authority which identified all laboratories that can perform analysis on the substances to be registered and they have defined centres of excellence capable of analysing samples from the inspections. One has been created in Biella (Piemonte) for textiles and

55 In the experimental (non-clinical) research arena, the phrase good laboratory practice or GLP specifically refers to a quality system of management controls for research laboratories and organizations to try to ensure the uniformity, consistency, reliability, reproducibility, quality, and integrity of chemical (including pharmaceuticals) pre-clinical safety tests
leather, and others for the analysis of PAHs in Venice and the analysis of chromium in cement six in Calabria. Federchimica also produced a list of GLP qualified laboratories. It has been suggested that testing laboratory capacity may be a problem in other countries, especially those with high shares of SMEs in their chemical industry.

(e) Other programmes to support REACH-related research and innovation

In the course of the project we tried to identify programmes specifically aimed at supporting REACH related innovation. The only one identified was the FIT_REACH programme in Italy. However, REACH-related projects are also carried out in the framework of other programmes such as FP-7 and SUSCHEM. The text box below sets out a short summary of the FIT-REACH programme that is operating in Italy.

**Text Box 4.1 FIT REACH**

In Italy a programme has been set up to support adapting to REACH and identify and exploit opportunities that may arise as regards substitution. Funding for the programmes was 80% for elimination of SVHCs, 20% for significant reductions in products, processes or exposure to such SVHCs. The main characteristics of the programme are set out below.

- €120m was put aside for the programme as a whole, €80m for whole Italy (Fondo Speciale Rotativo per l’Innovazione Tecnologica) and €40m for the Southern regions – from the structural funds (Convergence)
- It has been mainly used by companies from the North
- Funding is for both experimental research and industrial research
- Funding is for obtaining robust results, pilot and demonstration projects, prototypes, new products, services or processes.
- Projects must involve major, not routine development.
- Must be projects worth more than €1million projects, but can be more than one firm, and can also be universities or research centres.
- Projects must take between 18 and 36 months to complete.
- There is a long evaluation process for applications. It was launched in March 2009. Up to now, of 124 projects put forward, only 33 definitely approved.
- The programme is only for Art 57/ Annex XIV substances

At present it is still too early to evaluate results.

**Source:** CSES Interviews

There are also EU driven programmes such as Subsport [http://www.subsport.eu/](http://www.subsport.eu/) (the substitution support portal), the Antares Programme (Alternative Non-Testing methods Assessed for REACH Substances) [http://www.antares-life.eu/](http://www.antares-life.eu/) and VEGA (virtual models for evaluating the properties of chemicals within a global architecture) [http://www.vega-qsar.eu/](http://www.vega-qsar.eu/). Some clusters are also beginning to focus on REACH related work (see below, and case study 2 in Annex 7 for more detail, that looks at Axelera). In the past, Denmark and Sweden have also had programmes to support substitution.

Axelera is a “pôle de compétitivité” (a chemicals “cluster”) that receives public funding. It is based in the Lyon-Rhone-Alpes region, one of some three dozen or so chemical clusters in the EU. It focuses on sustainable chemistry and firms in the cluster do research related to REACH, especially as regards substitution of substances. The approach is holistic: it does not just look at substitution substitution on its own but sees it as part of the total material recyclability, green chemistry, the firm of the future, and the chemistry-society relationship. They have been doing specific REACH-related projects in recent years such as NESOREACH and developing R&D tools for use in research on substances. The 2011 ANR call for
proposals specifically mentions solutions for substances on the authorisation list as a major axis. Axelera companies are also engaged in FP7 projects, but interviews suggest more outreach activity on the part of the Commission could produce further results there.

**(f) REACH and the rate of return on innovation, risk and uncertainty**

In the process of prototyping, developing pilot applications and testing, the results are assessed from the point of view of developing a business case – including a capital and cash budget - for continuing with the project. At various stages in the innovation process a “gate” could be reached (see chart 4.1), and there might be a “hurdle”, such as an expected rate of return, or several hurdles for the project to get over in order to continue (e.g. links to strategy, etc.).

*The rate of return on innovation (ROI)*

The ROI requirement usually appears quite early on in the process. While there are questions about the role and use of the idea of ROI in the context of innovation, it does play an important part in innovation projects. At the Chemrawn conference, for instance, it was mentioned that a 5% yield from R&D is fairly typical for most chemical companies (although some report better than 20%). To finance such a low yield is a challenge for SMEs, leading to R&D becoming concentrated in the multinational companies. Implementation of innovations on an industrial scale requires more and more investment due to the global capacities of the industrial units (e.g., BP Chemicals’ first plant of fluidized bed process for vinyl acetate monomer has a capacity of 250 000 t/year).

The survey asked respondents how REACH had affected the expected rate of return on innovation in their firms. 37% said that it had reduced the expected rate of return on investment, 30% said there was no effect and 24% responded “do not know”. This is not surprising, given the increased costs related to REACH on the one hand and uncertainty as to whether costs would be recovered through higher prices or greater sales on the other.

ROI is impacted through: costs of studies, testing costs, development of documentation, and delays in registration - sometimes enough to put off further investigation into what could be a promising substance, in addition to not always being able to increase prices so as to absorb costs especially when competing in export markets, and has effects on location of innovation activity. One respondent put it as follows: “REACH costs have a direct impact on margin/profit, as the costs have generally not been recoverable in EU pricing. The inability to recover this in pricing is probably because we export a high percentage of EU production, and foreign competitors don't have REACH expense. In addition we believe that importers are able to avoid REACH costs by either not registering at all, or by using a series of Legal Entities to keep their import volumes below 1000tpa. Foreign manufacturers would also not have REACH-type costs on their Intermediates. The Bottom Line is that REACH is directly related to reduced profits and rates of return”.

56 See for example: Morris, L. (2008); Innovation Metrics. The Innovation Process and How to Measure it, Innovation Labs LLC,

57 See annex 1.2
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Business risks and uncertainty

A key element in the decision calculus as to whether an innovation project should go ahead or not to a “next stage”, in addition to estimates of ROI, is the level of business risk and uncertainty associated with the financing and outcome of the project. Interviews with firms suggested that this is one way in which REACH influences business innovation decisions at quite an early stage of the business planning for the project.

The survey asked whether compliance with the Regulation had had any impact on business risk and uncertainty related to innovation projects. 49% of respondents indicated that risks and uncertainty related to innovation had increased as a result of the Reach Regulation (13% said “substantially”), 20% that there was no effect, 8% said it had decreased and 17% that they did not know. In terms of firm sizes, small firms were highly represented in the “yes, increased substantially” category (41%). Respondents were asked to explain in a few words why they answered as they did. This open question elicited one of the highest number of open response replies in the survey.

Risks

A wide range of business risks have been affected and survey responses suggest that on the whole risk has increased. This influences a wide range of costs, including, importantly, costs and availability of finance, with differential impacts on large firms and SMEs. In the survey, the following areas where risks have increased were pointed out by respondents: in addition to investments in projects as previously required, an investment in registration was now also needed, which increases risk; the general lack of information at the customer side increases risk, while in addition customers, as downstream users, shift the responsibility on to supplier; liability risks due to unclear data records relating to the legality of chemicals; unwillingness of business partners from outside the EU to release new developments in Europe - risks and costs are transferred to e.g. distributors; companies also indicate that there is some lack of clarity and ambiguity in the Regulation which causes risks for the company and decision makers; all of which means that overall REACH risk is an additional element to be integrated in the business case.

Many factors come together in influencing the overall level of risks. As one survey respondent put it: “Fixed personnel costs are tied up which will not rise or fall in relation to projects. We use an external consultant for REACH who is unfortunately also active for competitors; a conflict of interest occurs. How can we prevent a SIEF member giving one of our competitors information which is damaging to us? In Germany in GmbHs (limited companies) the end of year accounts are published and made available on the internet. In the Far East this is utilised by the state authorities to correlate the operating figures of a company with the tonnage ranges and products which that company has pre-registered. During my last trip to the Far East I was talking to a divisional head and was confronted with the fact that they could supply me with product X at a good price up to 100 t per annum. How did my interlocutor know about our product and the tonnage range: it was pre-registered by us but not bid for in the market?”

Uncertainty

The main areas of uncertainty as regards innovation relate to: substance identity; unpredictability of candidate lists (when, what, how) and authorisation; testing (and perceived unfairness of having only 5% tested by ECHA) and other registration costs; time delays in the inquiry/registration process; issues surrounding transparency in SIEFs; availability of materials in the supply chain (possible withdrawals); lack of certainty (ambiguity) in parts of the Regulation; and, questions about market surveillance and
enforcement. This makes it difficult to plan for cash flows (timing), capital budgeting, setting up production and distribution facilities, training staff, etc. One example: “Total REACH registration costs are not clear at the time when the decision to register is made, but majority of the costs may come via the testing proposals and following testing for Annexes IX and X. This makes the business planning and justification of expenditure very difficult as the cost may vary between 200 k€ to 2M€ which may totally change the business case”. Also: “All toxicology tests give a high rate of ‘false positives’, which can stop a product in its tracks. You can't always predict outcomes of many studies, and this means that there is no 'product certainty' until all the tox testing is completed. Even when the test is completed, the results may be a 'false positive'. Under REACH the on-going 'test plans' will prolong this uncertainty for years”.

On the other hand, as one firm put it: “more certainty exists about substance toxicity and there is lower likelihood of subsequently finding adverse effects. Greater availability of toxicological information has increased acceptability of our products (though this has not produced any benefits other than feel-good factor, and competitive products are similarly impacted)”.

These risks and uncertainties have an influence on planning innovation. As one multinational firm told us - when developing a business plan for a new product, within the EU a new budget line appeared for REACH that was not present in other locations where product development could potentially go ahead. It was also difficult to insert numbers for cost and timing in the EU to compare with other locations as a result of uncertainties created by REACH.

(g) **Better products**

A key question related to the impact of REACH on innovation is if the effect of a change in the balance of research into new as opposed to old products has translated into better products? From the preceding comments several points have emerged in this respect:

- The economic environment since 2007 has, generally, not been supportive of new product launches.
- The 2010 registration did not lead to extensive creation of new knowledge about substances – although there certainly has been some. However, new knowledge has not always been of a nature that is relevant for developing and launching new products or different uses.
- Although some major companies have indicated that the rebalancing has been received in a positive light, major research programmes in the large companies that drive most research in the chemicals industry can take some time to get set up and running, and their results may take some time to materialise.
- There are still many factors that are not supportive of research into new substances – some REACH – related; others to do with products and markets.
- Companies in the survey have provided some examples of developments that have occurred as a result of the rebalancing of research between old and new products – but there has not been a significant response as yet.

Based on the preceding points it is probably fair to say that some better products have emerged as a result of the “equalisation” by requiring testing of old and new substances, but as yet the response has not been overwhelming.

As an overall conclusion, as far as the 2010 registration deadline is concerned, it would be fair to say that the balance has been towards compliance, with a relatively low level of gap-filling which has not as yet generated substantial innovation and better products.
4.2.3 Marketing stage (production and market launch)

Turning now to stage three of evaluating effectiveness of the Regulation as regards innovation, we look at the effect of the Regulation on products that have successfully made it down the innovation pipeline to production and market launch. Here we consider to what extent the costs associated with the REACH Regulation impact the landscape of innovative companies, and especially, the impact of these requirements on the costs of setting up new companies (start-ups/ spin-offs). Then we consider the effects on two further production and launch factors: toll manufacturing and time-to-market.

(a) The cost of REACH and its impact the landscape of innovative companies

First, costs are considered: where they arise, their nature, etc., and how this could influence production and marketing decisions in the firm. Then impacts on the wider landscape of innovative companies in the chemicals industry are considered.

REACH costs

REACH costs affect companies that fall within the ambit of the Regulation, to a greater or a lesser extent, throughout their value chain activities. In some cases, such as, say a manufacturer of chemical products, the impact can be very deep and wide ranging, while in others, such as in a retailer of articles that contain chemicals, it could be quite minor. However, all resources – property (including IP), labour, capital and entrepreneurship - come at a cost, and/ or an opportunity cost, and this also influences returns on funds invested. Costs can be direct and indirect. The REACH Study dealing with the impact on the competitiveness of the EU chemical industry and the Single Market deals in some detail with the various costs related to the Regulation. Annex 4 sets out in some detail where impacts on costs can be felt as a result of REACH in innovative companies.

The interviews and survey bring out some key aspects related to costs. In the first place there is their cost, in the second there are opportunity costs, and in the third place there are the uncertainties and intangibles related to costs and timing.

The first category includes, for example: registration fees, SIEF/ Consortia membership fees and participation costs such as travel and subsistence, research on substances, testing, development of REACH documentation (SDSs, CSRs, etc.), training, IT costs, consultancy, plant modifications (e.g. if need for SCCs or SHE matters), research and development costs for substitution, supply chain audits, responses to customer enquiries, etc.

Costs such as these can, generally speaking, be worked into a business case for an innovation project. They are higher than would have been the case without REACH and as result will have an impact on the expected rate of return on the project. In addition, some are very new in the sense that a company that wishes to use a substance although registered but which has not registered for it, has to incur an

58 See: Interim Evaluation: Functioning of the European chemical market after the introduction of REACH, March 2012.
Interim evaluation: Impact of the REACH regulation on the innovativeness of the EU chemical industry

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additional registration cost that will have to be absorbed by the innovation project it is intended for. As was seen from the survey responses above, more than a third of firms that responded indicated a negative impact on rate of return (nearly half if the “do not know” responses are excluded). The fact that many of the costs are up front also means that they have a relatively strong effect on discounted returns. The results here can be either go/ no go for innovation projects, or it can mean that they will be carried out in non-EU locations.

In the second place there are opportunity costs. As noted above, there is considerable evidence from the survey that R&D personnel have been transferred to regulatory activities, but also that this has led to nearly half of the survey respondents increasing expenditure on R&D activities. This means that that those expenses have to be recouped from some products or services, or firms will suffer reduced profitability. The net outcome on innovation, at such a high level, is not determinate.

The third group of costs falls in the category dealt with under the heading of risk and uncertainty above. These include matters related to delays in the inquiry process, increased time to market, changes in guidance about the Regulation, differences in enforcement regimes throughout the EU, timing of – if required – further testing and the costs involved, the effect of ECHA selecting the dossier for evaluation, possible changes to do with toll manufacturing arrangements, developments to do with the candidate list, risks related to REACH liabilities, increased risks due to having to carry increased REACH costs, and the like.

The feedback from the research suggests one very important general conclusion: innovation projects are more highly scrutinised in terms of costs, risks and returns before they are launched on the market than was the case before the implementation of REACH. Specific comments from the survey related to: issues around registration costs –especially for SMEs - “Several new molecules have not been put on the market due to the high registration costs (mainly testing costs)/ We have stopped production of certain substances, since the cost for registering them would be too high”; withdrawal of ‘harmless’ chemicals; the cost “jump” when moving out of the PPORD; and uncertainty about rates of return due to uncertainty about costs, time delays associated with costs.

The key point about the preceding comments is that these costs are omnipresent through the organisation – whether innovative or not – and have an effect on the rate of return/ risk and uncertainty of innovation and if they cannot be recovered the investment is either less profitable or it cannot go ahead. Also, many of the costs are not certain, which increases the risks related to the investment decision, which in turn has an impact on the willingness of suppliers of funds to finance the innovation in question – whether it is an internal or external source of funds.

Impact on the landscape of innovative companies

Turning now from the situation in an individual firm to a wider landscape of innovative companies, it is useful to think of such a landscape in terms of the model of innovation in the chemicals industry developed in 2.3 above.

Increasingly these organisations are working together in networks, clusters, communicating informally in open innovation models. Cost changes have different impacts on these firms. Below we present some examples of the effects of REACH on innovation in firms in these categories.
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Text Box 4.2 REACH costs and the landscape of innovative firms: Global chemical company

For this global diversified chemicals manufacturer REACH has meant significant additional costs but due to their size and strong position in the financial markets they are able to recover these by obtaining additional funding if necessary or they can spread the costs over or recover them from some of the other product lines in the firm. REACH has also provided new opportunities for them in that they can develop new long term research programmes to identify and exploit new opportunities – and they have the funding (internal and external) to finance these. They see the “equalisation” of registration costs for new and existing substances as a positive development, but they are also very concerned about losing funds invested in IP and their CBI through the REACH “data generation” and information sharing mechanisms and do not consider REACH processes as patent-friendly.

Medium-sized firm: high tech paints

This highly innovative SME specialises in providing high tech (eco-friendly) paints to EU and non-EU markets. It has very few product lines. They have between 50-100 employees and several thousand substances are involved, each of which may have a SDS of 100 pages (which has to be kept up to date). Some are imported from outside the EU which creates problems as regards registration. Some former importers have closed down as they could not recover registration costs from the non-EU suppliers. All these additional costs have to be absorbed by the paint product lines as they do not have other products that can help absorb them, and therefore either impact profit margins or they lose market share in highly competitive markets where they compete.

Small consultancy specialising in advice for formulators

One advisor that specialises in advising formulators said that there is a group of formulators that has decided to remain under the one ton production limit so that they do not have to incur REACH costs. If they develop interesting substances and formulations they have large firms with whom they have long standing collaborative relationships that then pick these products up and can afford the development, marketing and launch. The small companies do not want to understand REACH or get involved with it, they want to do research. Large companies often have their own “internal” venture funds to finance such developments, but generic VC funds can also become involved (e.g. Emerald Technology Ventures or DFJ Mercury).

An innovative marketing firm bringing new innovative products into the EU from the USA.

This flexible, sole trader with low overhead –costs has a business model which consists of visiting the USA on a regular basis to identify innovative products to sell in the UK market. When the company became aware of the REACH requirements it went to its US trading partners to obtain information about the chemical composition of the preparations that went into the products being imported. This immediately created problems as the principals were reluctant to disclose the formulations they were using. So it became necessary to consider inserting an intermediary into the good business relationships that had been built up over the years (Only Representative) that might add an additional layer of cost, reduce profitability and added no value to the business. (At the time of the interview the situation had not yet been resolved. The US supplier does not want the UK client to become its OR due to IP and CBI issues. The UK client is a micro firm, selling from a warehouse at a port direct to hardware shops - the notion of being an “OR”, while intellectually of interest - is completely alien to this business model.)

A micro firm that specialises in development of solutions for surface treatment

This company with four members of staff was established 11 years ago. They are a university spin-out with little cash – the business is based on innovation and their know-how. They would like to grow and up to the present have been funded by debt and private investment from the owners. They are a potential venture capital candidate but that would require them to expand outside the EU. The business revolves around its IP - the trade secrets that underlie its formulations. They were not brought into the scope of REACH through the 2010 registration deadline but are now becoming concerned as the raw materials they use have not yet been registered and they may have to be registered (mainly sourced from within the EU). In addition, they are unsure about what the situation will be as regards their trade secrets. They have heard rumours that they will have to “reveal all” because of REACH, whereas in the past this was provided on a “need to know” basis. The components are not hazardous so they are unsure why anything needs to be divulged at all. In their patents they are able to
hide some details by specifying ranges and not having to identify what is optimal usages, etc. which gives their IP some protection. As a result they are beginning to have to invest their time (and / or hire a consultant to help, which reduces the time spent, but does not eliminate it) looking into these matters. They have speculated about moving out of the EU or to the USA or Canada, because they have global clients and could conceivably be located anywhere, and are aware of several other firms in a similar situation. The protection of their IP is essential as it provides the incentive/ business case for continued investment into the firm - describe the situation as “extremely worrying”.

Source: CSES Interviews

These examples illustrate some of the impacts of REACH costs on business models of different players in the landscape of innovative firms. The general view from interviews is that the larger the firm, the more it is able to adapt to the requirements of REACH, and the less the impact is of costs on innovation. On the other hand, very small firms that operate in volumes below REACH registration requirements, are, similarly, not directly affected although of course they might be if they have, for example, to pay more for raw materials.

An example of a response to REACH costs by a highly innovative firm, which amounts to avoiding them by reformulating, is presented in text box 4.3 (see also 4.2.2 (b) under “Polymers”)

**Text Box 4.3 REACH costs and the landscape of innovative firms: Registration, substitution and a small innovative firm.**

This company with about 150 employees and a turnover of between €20-30 million, selling its outputs mainly in its domestic market also sources its supplies domestically – one key bulk ingredient was produced by one large firm in the market who would not assure them that they would register. The company then had to decide whether to register themselves or not. Thinking through the situation they considered that their molecule in question was not very common and that they probably would not have a very large SIEF, so the registration might become very expensive as there were few to share costs with. They therefore decided to rather invest in reformulating.

To this end they recruited an additional chemist, realising that they would not be able to recover the cost involved (some €50k plus per annum). Once they had developed and tested the reformulation (oligomerisation – so that it became a polymer)), they had to train the sales team to be able to sell it. They also had a few major customers where they had to get the product accepted. None of these were keen to try the new product “why fix it if it isn’t broken?” who were very conservative in this respect as if the processes at their plants go wrong they could lose €100’s of thousands in a very short space of time, and they in turn sold to a few very demanding big-ticket clients who would not be tolerant of failure. With the one customer this involved evening trials over three weeks and week-ends when the plant was shut down, with another it took more than two years to make the switch.

One key point from this is that there was nothing “wrong” (e.g. SVHC) with the chemicals involved. The whole exercise was precipitated by issues surrounding continuity of supply related to registration costs. Also, the person who provided the materials for this is well connected in the industry and said that developments such as these were taking place in many firms in addition to theirs. The change affected several layers in the supply chain as well and incurred substantial costs.

Source: CSES Interview

Innovative companies are of course found outside the narrowly defined chemicals sector, and because chemicals are so widely used throughout the economy, the impacts of REACH costs are felt in such firms as well. Interviews and the survey responses indicate that in fact some highly innovative sectors supplying products to for example the aerospace and defence, nuclear, information and communications technology, the building, automotive and textile industries have been affected by costs related to compliance, substitution, the candidate list, and authorisation. In general the principle here
has been that the larger firms are more able to absorb costs, but at the same time they often have, where relevant, more freedom as regards where they want to carry out operations, so some work may be de-localised from the EU as a result.

(b) Toll manufacturing

Some firms use toll manufacturing as an aspect of their product development/pilot plant development and marketing process. Toll manufacturing is a common feature of the chemical industry and is an agreement whereby a manufacturer agrees to provide a principal with a substance or other end product that it will manufacture. There are very many forms in which this can occur. For example, the principal can provide some or all the raw materials, it may involve packing or shipping, and may have varying degrees of involvement in the process itself. The key thing is that the principal owns part or all of the IP involved. The ultimate customer may never know of the role of the manufacturer who in turn may never know who the ultimate customer is.

Chemical companies use toll manufacturers for a variety of reasons. From the point of view of innovation the main reasons would be:

- To reduce time to market – by using the facilities as a pilot plant without having to construct from scratch, or for tests. As one respondent to the survey put it: “Tolling is a perfect tool to jump-start a new product”.
- Flexibility (capacity) to meet short or medium terms needs without having to make major new investment in capital equipment.
- To reduce risks – by not requiring capital investment in new plant.
- Access to specialised equipment: orders may require specialised equipment the acquisition of which is not justified in economic terms for the principal.
- Access to different process technologies: the toll manufacturer may have a different process technology to that of the principal for producing a product which is required for various reasons, e.g. client or regulatory related.
- Access to specialised staff or other support or facilities
- Reduced costs: for example by having inputs manufactured at lower cost locations within or outside the EU (e.g. export processing/“free zones” or low cost locations).
- Access to markets: a toll manufacturer may have a plant in a target market geographical area which means that transport costs may be reduced when accessing that market through the toll manufacturer.

There is no specific separate provision for toll manufacturing in the chemicals supply chain in REACH. So its registration requirements are the same as those of other manufacturers. In the survey we asked if the requirements under REACH for toll manufacturing had an impact on their firm’s innovative activities. 31% of respondents said that there had been a negative consequence, 38% that there had been no impact and 28% did not know.

59 Toll manufacturing in general is the subject of a case study in the Competitiveness and Single Market study. Here the focus is just on innovative aspects.
Main issues of concern mentioned in the interviews and survey related to manufacture and launch are the cost of dual registration; time delays due to negotiations required and lack of ability to use the toller as a quick pilot or supporting manufacturer for product development and launch; costs of having to set up own operations if necessary; and issues about loss of IP if data and knowledge has to be shared with the toller for registration.

The consequences as regards developing and launching of new innovations on the market of the REACH Regulation on toll manufacturing seem to be a reduction in options for trial, production and launch. This applies not only between separate firms but also within a network of subsidiaries of the same firm, giving rise to some anomalies.

(c) Time-to-market.

One of the key hoped for impacts of the REACH Regulation identified in the EIA of the Commission was that it would help to bring about a reduction in time to market for new substances. The view was that the former system was cumbersome, fragmented, inefficient and slow – different Member States had different systems, testing requirements, and there was a general lack of uniformity which also tended to inhibit not only innovation but the development of the single market.

Time to market in the sense used here refers to the whole process from conception to launch (including ECHA processes). In some fast-moving industries a speedy time to market is a key competitive factor, more important than being able to protect IP. Even in more slow moving sectors with longer time horizons, once a product has been defined it is important to get it to market as soon as possible.

In the survey firms were asked what the effect of compliance with the Regulation had been on time to market for their firm’s innovations, as compared to the pre-REACH situation. 41% of firms considered there had been an increase (16% “substantial”), 32% no change and just over 12% a reduction. 35% of those that indicated a “substantial” increase were small firms. Of these 16 small firms 3 had a percentage share of R&D to turnover of >10%, 3 of 5-10% and 6 of 2-5%. Research for the UK Intellectual Property Office (UKIPO) suggests that time to market is a relatively important strategy for SMEs who do not invest in long term research and patenting. Importers of chemical substances and mixtures, formulators and manufacturers were most affected “substantially”.

Interviews suggest that that some of the larger firms that would have submitted multiple enquiries across several countries in the past have been able to benefit by not having to deal with cases on a country-by-country basis; and smaller firms, where a personal relationship with the relevant authorities in a handful of Member States may have been more important, may have been more negatively impacted.

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60 Hughes, A. Mina, M.; The Impact of the Patent System on SMEs, UKIPO (undated, but 2010 or later)
61 In the Competitiveness and Single Market project it was asked: “Has the implementation of REACH and the various procedures involved affected the time required to bring your products to the market? Some 51% of the 743 respondents indicated that there had been no change. The remaining 49% indicated that there had been an increases ranging from up to 2 months to more than 12 months.
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In the interviews with firms the most mentioned factor as regards increased time to market has been the inquiry process at ECHA. It was indicated that it can take too long to obtain a reply, there is no legal time limit on ECHA for providing a response, once a response has provided, if ECHA has a question, the inquiry seems to have to go to the “back of the queue” again, there is no way to track progress of the inquiry, individual persons are not allocated to specific dossiers - so working with ECHA here is described as working with a “black box” (in the past it was possible to develop a relationship with the person handling one’s inquiry which made communication easier), and testing requirements are uncertain. All this can create business uncertainty as regards timing, costs and ultimately, returns on innovation and the decision to go ahead with a project or otherwise. Delays in the inquiry and registration process mean that decisions as regards the design and commissioning of plants are more difficult to make, recruitment is delayed, and the overall attractiveness of the project declines and customers may cancel orders. Companies do appreciate the importance of technical accuracy, and having good scientific data to support product marketing, but there is a view that on the other hand there is little appreciation of the commercial realities of innovation at ECHA. As one firm put it: “Timing is very important. Full inquiry process takes about 5-6 months: 1 month for the analytical characterisation, 4 months to have the feedback from ECHA and other 2 months to join the registration. From marketing point of view this is unacceptable”.

The view from ECHA is that a major cause for delay in the inquiry process is due to companies that do not submit thoroughly prepared documentation and seem to expect ECHA to provide the research resources to carry out searches and fill in missing information for free. ECHA’s target response time for enquiries is set internally and has proved difficult to attain. It may be revised downwards due to resource constraints.

Other causes of increased time to market identified are related to the need to use R&D staff for compliance issues, and requirements of technical staff to monitor developments in various regulations and directives (REACH, CLP, Food Safety, etc.) and the time it takes to find out if data exists and negotiate knowledge sharing fees. This is particularly the case for imports. The result, for one firm: “Our company tends to place more and more research outside the EU... due to the fact that new products can be released faster in the most important markets”.

In the interviews with firms we were told that requests for new products to major global firms from major customers have been turned down, they were told, due to staff being preoccupied with REACH compliance. Of course, this is anecdotal, but would seem to fit the pattern presented by the survey responses.

(d) Market acceptance of products

In the context of the impact of REACH on launching innovative products on the market, we asked if, based on experience, compliance with the REACH Regulation contributed to a better acceptance of new products and technologies (for example by providing for better safety and/ or communication with customers and society). Industry associations and firms spoken tended to reply, overall, in the negative. However, in the survey 24% of respondents indicated that this was in fact the case, while 57% said “no” and 19% did not know. Feedback from companies was mainly in from the “no” group. The main reasons for their responses can be grouped as follows: lack of awareness by customers, ignorance about the procedures, and/ or lack of scientific understanding; the price focus of buyers, especially in international
industrial markets, and their lack of interest in HSE factors, as one manufacturer put it: “Our DU/customers generally aren't focused on any improved EHS/product safety aspects from REACH. Their focus is whether we will continue to supply them and continue to supply at the same price. In fact, we were one of the first suppliers in our segment to send REACH/CLP 'compliant' eSDS’s. As a result we were inundated with DU questions about the new eSDS’s, as DU's were generally ignorant of the changes in the regulations (since they don't prepare eSDS’s for registered substances). In this example, 'compliance' was a competitive disadvantage as we had to be the ones to explain things like the new ES Annex.; and because in many sectors products were already “safe” before REACH came into force (e.g. agricultural pesticides, Plastics Regulation, Cosmetics Directive, exempted phytosanitary products, pharmaceuticals).”

(e) Impacts on the costs of setting up new companies (start-ups / spin-offs).

One of the hoped for impacts of the REACH Regulation is the fostering of innovative new start-up companies to exploit opportunities (e.g. in R&D or production) provided by the increased amount of information about chemicals, as well as it being more accessible and open to scrutiny. However, compliance with REACH does involve incurring additional costs that companies have to absorb, or try to recover from customers. (Some aspects have already been touched on above when dealing with the impact of REACH on “the landscape of innovative firms” above.)

The impacts of REACH on costs of setting up new companies (start-ups/ spin-offs) depend on the nature of the start-up or spin-off in question. For example, does it intend to focus on R&D and remain relatively small, maybe making use of some of the exemptions in REACH to avoid having to incur REACH costs directly; or does it intend to grow (in terms of its use of volume of chemicals), using phase-in or new substances?

If the spin-off is part of the network of a major chemicals company, the costs may have little impact if the firm in question is in a position to provide funding and support with a full knowledge and appreciation of the factors involved, and provide support and funding accordingly.

If the company is a start-up that has developed relatively independently, or it is a university spin-out, it might face more difficulties in dealing with costs and obtaining funding from for example a general bank. There are however a wide range of funding support mechanisms available throughout the EU and national governments for innovative SMEs that might be able to provide access to finance.

There is also venture capital available, but this is often targeted at other sectors, such as biotech, or pharmaceuticals, and venture capital funded work in the chemical industry is often more in areas such as biochemistry, or linked to bio-areas such as nanomaterials where exceptional profits could be realised. Interview feedback from venture capital providers suggests that REACH as such has not been a driver for VC funding – there are very many other factors involved of more importance.

All companies using raw material inputs, where those raw materials are chemicals that have to be registered under the Regulation, might have to incur slightly higher costs if the supplier is in a position to

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62 In the Interim Evaluation: Functioning of the European chemical market after the introduction of REACH, March 2012, extensive data as regards REACH costs such as, for example, registration is presented.
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pass them on to customers. There may also possibly be problems of access to specialised laboratory materials if they have not been registered for research organisations, or larger manufacturing operations product withdrawals could lead to them having to incur costs to either find or develop substitutes.

Location of the start-up will also have an influence on costs: if it establishes in a leading chemical cluster in the EU, while establishment costs may be higher due to higher property costs and staff costs, availability of external support services for the REACH processes such as laboratories, consultants, legal advisers, staff trainers, etc. will probably be greater than if the start-up located in a more isolated area, or where there was not such a strong chemical industry support network. Accessing such services could then be more costly for those outside the main chemical clusters that can provide REACH support.

In addition, there are other REACH related indirect cost factors that are possibly unfavourable to new entrants, for example in the inquiry process which is not only time consuming (and can therefore have a very negative effect on cash flows in a new firm) but where Lead Registrants are notified if a company wished to enter a substance market, as are other companies with similar substances which has CBI-related implications.

If the firm is intending at some stage to produce in volume bands that mean it has to register, those cost implications need to be worked into the business plan and implications for cash flow and financing be mapped out when doing the three-year business plan. The relevant cost elements would include a selection from those identified above and may imply an increase in operating costs once REACH registration is sought, and more registered items are part of the normal daily operating environment. Consequential risks and uncertainties may have an impact on availability, timing or process of finance if that is sought from an external organisation, whether a bank, a business angel or a VC fund. As one survey respondent put it: “The costs for innovations are higher than before: they can only be passed on through the chain to a certain extent. The risk for investors has increased (planning reliability has been lost)”. For example, even the translation of a SDS from one language into another has implications as regards liability that probably need to be assessed with the company’s insurers.

However, in general, for the majority of cases, unless firms stay small and pass under the volume bands of REACH, it is probable that the costs of doing business will increase, and market entry costs will be higher. Some dynamic and highly innovative research companies are expressly following a strategy of staying small and passing on their innovations to larger multinationals with whom they have relationships and who will do piloting and marketing, so that they can stay under the REACH volume bands.

If the company is created as a spin-out or buy out, and is already an operating going concern, it will probably already have absorbed the REACH costs involved, unless it wishes to enter new markets requiring additional registrations or incurring of other REACH obligations.

One area where there is quite strong agreement among firms and associations interviewed is that the increases in costs associated with REACH compliance will in general act as a barrier to entry for new firms, particularly small firms. Large firms will continue to drive innovation in the chemicals market. This view is appropriate for companies at all stages of the value chain: researchers, importers, distributors, manufacturers, downstream users, end-users, formulators.
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4.3 Efficiency of the processes introduced

The data generation mechanisms present in the REACH mechanisms came at a significant cost to industry. In this subsection the question of how efficient the data generation mechanisms have been in increasing the innovativeness of industry is considered.

(a) The efficiency of data generation mechanisms in increasing the innovativeness of the industry.

As indicated in previously, a great deal of data has been generated and captured systematically in the REACH process. This has occurred in compiling registration dossiers, doing research, participating in SIEFS and Consortia, for example in the form of test results, development of SDSs and CSRs, and specifying exposure scenarios. Many organisations have participated in this exercise. They include, among others, chemical firms (within and outside the EU), laboratories, downstream users outside the chemical industry (narrowly seen), ECHA, Competent Authorities in Member States, and the European Commission. Data generation is an on-going process and will continue as dossiers are evaluated and requests for further information and or tests are made, and new substances are brought into the ambit of REACH.

One point that has been made by many interview and survey respondents is that companies still need to find out how to use the data. At present they are still, in many instances, gathering and collating data, rather than in a position of attempting to digest the great volume of data that has become available with a view to identifying opportunities for innovation. In other instances, particularly as regards the effects of the first registration, much of the data that was generated by REACH was already known, as in the case of some older well-established industries. How much of it is really new has therefore been questioned.

The effectiveness of this data in terms of various aspects of innovation has been considered in subsection 4.2. The overall conclusion there might be summarised as saying that there is no direct or necessary link between data generation and innovativeness. In fact, in some circumstances it is easy to conceive that data generation takes place at the expense of innovation, especially in the short term. Either way, it appears that at present there is as yet little in terms of concrete evidence of extensive patenting or innovation as having occurred as a result of the data generation processes.

At this stage there is a good deal of scepticism in the industry about the efficiency of these data generation mechanisms in increasing innovativeness – except maybe in the medium to long term, which extends to after 2018. Other factors, not just REACH drive innovation. Availability of/ access to data may be a relatively more important driver of innovation in some circumstances than others, but there is not an immutable, direct, causal link between availability of data and innovation. We have only been able to identify a few instances in the course of the interview programme and survey where an innovation has been driven by a purely REACH related consideration.

Interviews carried out and research accessed so far suggest that the costs of implementation of REACH have been higher than foreseen in the Commission’s EIA\(^63\). However, we have not been able to identify a valid metric for measuring the change in the innovativeness of the EU chemicals industry that can be

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\(^{63}\) See: Interim Evaluation: Functioning of the European chemical market after the introduction of REACH, March 2012.
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linked in a meaningful way to the costs incurred in implementing the Regulation. There are too many other factors involved in the development and registering of patents at the European Patents Office, or even of new substances at ECHA, for any quantity to be tracked or related to the coming into force of REACH. The results in terms of innovations in response to REACH reported in this survey have also been very few, and are either related to a substance or its use or qualitative such as setting up new supply chain management measures to ensure future supplies of critical substances.

Therefore in order to evaluate how efficient the data generation mechanisms in REACH have been in increasing innovativeness we have adopted the following approach. On the one hand costs have been identified elsewhere\textsuperscript{64}. On the other, to obtain at least a high-level view of results, we asked survey respondents how important they saw REACH in driving innovation at their firms, and then asked what they consider the effect of REACH has been on innovation at their firms as compared to the pre-REACH situation. This should give a qualitative assessment of the relationship between costs and outputs.

The importance of REACH in innovativeness

The survey asked “Overall, how important would you say the role of REACH is as regards innovation in your firm as compared to other factors driving innovation?” Some 8% indicated “very important”, 33% “somewhat important” and 50% “not important”. This suggests that while REACH is not a key driver for innovation, it can play a role. Interviews with firms have indicated that for some years, and increasingly, REACH is and has been a matter discussed at Board level, especially in larger firms. There could be strategic decisions about joining up with foreign partners involved, setting up new operations, or divesting certain product lines, all of which have implications for innovation. Impacts will differ in different industries, depending for example on their use of SVHCs.

Feedback from firms suggests that REACH can play an important role, as one global EU-based manufacturer of specialty chemicals that has an R&D ratio of 50\% put it: “I have been in the chemical industry, globally, for 30 years in Regulatory management. REACH is easily the most disruptive and Innovation-killing legislation ever. We are seeing that there is little or no REACH induced market shifts to "innovative" products. Innovation is driven by many other factors, including energy utilization, sustainability and cost-efficiency, but REACH should not get any credit even for 'green' product improvements”; it can lead to major corporate repositioning in terms of markets and suppliers, and may have negative effects, although the situation may change I the long term for some firms. On the other hand others say REACH will not impact their innovativeness because that is driven by product customisation for key accounts, new growing market segments, technology development and other regulatory developments related to climate change, ozone depletion and energy usage.

The effect of REACH on innovation compared to the pre-REACH situation

When considering what the effect of REACH has been on innovation at their firm as compared to the pre-REACH situation, most respondents in the interview programme suggested that it was too early to say what the effect has been, but either had reservations on the matter, or were quite sceptical, except as regards the long run, which would be some years after 2018. When asked this question in the survey, 13\% saw the effect of REACH on innovation at their firms as positive when compared to the pre-

\textsuperscript{64} See above
REACH situation. 44% saw it as negative (of which 14% “strongly negative”) and 29% thought it had no effect. In terms of firm size, some 38% of respondents (20) indicating a “strongly negative” effect were small firms. In terms of roles, manufacturers and formulators, as well as importers of chemical substances and mixtures were presented in higher than the average ratios for their presence in the survey as a whole. Feedback suggest that industry perceives the changes as placing a much greater emphasis on evaluation of costs, benefits, risks and uncertainty than was the case in the pre-REACH situation, and that this, among other things mentioned throughout the report, has discouraged even small, incremental innovations from coming about.

Survey respondents were asked to identify the factors within the Regulation most supportive of innovation. They were invited to group them into three categories, with 1 being most important.

Of the 153 responses for category 1, more than half said “none” (or equivalent). Among factors identified, the following were mentioned in declining order of frequency: PPORD, read across, discovery of new hazards, SVHC list, updating of the SDS, candidate list substances that have led to replacement programs, replacement of substances with uncertain future, restriction of uses for substances, substitution, increased availability of toxicity data, development of existing product, improved business conditions as many competing importers did not register, customer relationship (retailers).

In Category 2 the following appeared (30 replies): the SVHC list, followed by a wide variety of other points such as higher awareness of environmental impact of chemicals has led to new applications and reputation risk management. There were 16 replies to Category 3 (including 3 “none”) that include those listed in 1 and 2.

Respondents were also asked to indicate which factors had the most discouraging effects on innovation and to group these into three categories (1 as most discouraging). By far the largest group was that of the costs and time absorbed by bureaucracy and administration. This was followed by time delays, complexity of the regulation, and uncertainty in interpreting the Regulation and business uncertainty as a consequence of the Regulation. This pattern was repeated in Categories 2 and 3.

The future

Firms were asked if they see the position (as set out above) changing in the future. 10% saw it as becoming more positive, 24% as becoming more negative, while 38% thought it would not change and 28% did not know.

(b) The ratio of costs of the system to the number of new products/patents/solutions.

Based on the preceding remarks it should be clear that there is as yet no ready direct relationship emerging between numbers of new products/patents/solutions and the costs of the REACH system. It also seems unlikely that we will find such evidence as the link between a regulation such as REACH and any number of patents, new products or solutions is very difficult to establish. As has been mentioned previously, there are many factors that drive innovation. Also, there are different kinds of innovation, and the impacts of different innovations can be widely different. It may be more important to consider these factors than to postulate a purely quantitative relationship between costs and numbers of patents, new products/solutions. The closest we have been able to get to something approaching this is
the composite of variables that are captured in the IUS as is set out in 3.3 and the section on conclusions and recommendations (5.2).

It may also be more useful to look this relationship in terms of short, medium and long term perspectives. The immediate short term relationship is quite obscure, and may not be positive, as companies are concerned with compliance issues. Some innovations may take several years to come through, and longer term programmes take time to come on stream, so over the medium to longer term it may be possible to think of a relationship because as firms develop their research and new product development paths or “visions” they may build in more REACH-related criteria and in this way link innovative activities more to REACH requirements.

In the survey, respondents were asked if REACH has signalled a direction for R&D or other innovative practices related to health, safety and environmental protection that would not otherwise have taken place in their firm. 40% said “yes” and 5% (of the 40%) said that a “fundamental reappraisal or research orientation” had occurred. 54% said that there had not been any change.

For the 40% that said yes, responses to the survey suggest that this was usually linked to other drivers present that influence HSE considerations, rather than uniquely due to the Regulation alone. Many firms do point out that such an orientation is not new for them.

We understand from interviews with Industry associations that there is at least one long term research programme under way which looks at a fundamental reappraisal of the underlying materials and their relationships; and that this is at least in part driven by REACH.

In sum, it seems that from a short term perspective, there is some, if little, evidence of efficiency of the data generating mechanisms in improving the innovativeness of industry, but in the longer term there may be more as more lower volume substances about which less are known are registered and research programmes get under way.

4.4 Utility of the outputs of the processes

In this sub-section the utility of the substitution mechanisms: registration, the candidate list, authorisation and restriction - are considered as drivers of innovation. Central to the notion of substitution from the point of view of innovative activity and impacts on the economy is just what “substitution” involves. One point of view is that it involves the replacement of, in the context of this discussion, a SVHC with a non-SVHC, and the outcome is a “safer” product. Alternatively it may involve the reformulation of a mixture so that it contains less of the SVHC and is no longer necessary to notify it under the REACH Regulation. A more nuanced approach is to define it as: “replacement or reduction of hazardous substances in products and processes by less hazardous or non-hazardous substances while achieving an equivalent functionality via technological or organisational measures”65. In this approach, if

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there is not functional substitution, or if there are insurmountable technical problems, it is not a case of successful substitution.

Oosterhuis identifies the following factors that will usually play a role in the realisation and outcome of a substitution process:

- The availability of the substitute (i.e. it should be sufficiently developed and tested);
- Availability of information on the substitute and its consequences (including risks, uncertainties, and gaps in knowledge);
- Awareness in the organisation of the problems related to the currently used substance, and preparedness to change;
- The costs (investment and operational) of the substitute (these should be affordable and acceptable for the innovating firm, even though they do not necessarily have to be lower than the costs of the current practice: considerations such as better product quality, consumer demand, anticipated regulation or a ‘green’ company image may justify higher costs);
- Environmental performance of the substitute (for a substitution to be environmentally desirable this performance should be unequivocally better than the current practice; tools such as life cycle analysis or substance flow analysis may be needed to determine this);
- The risk of other negative (side) effects, both for the firm itself and for others (these may include indirect, cumulative and long term effects).

Chemical substitution can be a very complex process. For example, if a substance is replaced by another (less hazardous one), it may be that for some uses downstream it works, but not for others, whereas the substance that was replaced worked for both. Or the processes involved may have to change as well, which can, again, have implications for downstream users.

Substitution processes can take time – there are different periods for different types of products and different types of innovation. In the meantime firms have to bear the costs of REACH compliance, fund substitution programmes and deal with customer issues related to substitution. For example, Orgalime has pointed out that substitution of Cadmium in switches under RoHS took some 7 years to complete. Some of the ex-ante REACH impact assessments specifically highlighted substitution costs, for example the one carried out or Finland66, and that of the CEPE. A recent report by Alcimed for Anses (France) also found that substitution of CMRs remains a complex challenge67. Companies cannot always copy each other when substitutions are invented due to differences in products and processes, and levels of performance might suffer, especially in surface treatment. Case study 1 in Annex 7 deals with substitution, and considers some of the definitional issues involved when talking about “substitution”. For example, should something be considered a substitution if performance is reduced, and should that then be considered an innovation?68

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66 KTM Rahoitettut tutkimukset (2004); The Impact of the New EU Chemicals Legislation (REACH) on Industry and Economy
67 Alcimed, Produits CMR (cancérogène, mutagène, reprotoxique) 09/09/2011
68 It is also clear that issues about performance have knock-on effects – e.g. ESTAL mentions the case of surface treatment of aluminium for use in the building industry. Builders are expected to warrant a product for some decades, but if the product that is used in treatment of aluminium to be able to coat it so that can have such a long life is withdrawn due to its presence on the candidate list, this becomes problematic and matters of product
4.4.1 The effect of the substitution mechanisms (registration, restrictions, authorisations and candidate list) on innovation in the market

(a) Registration

The prospect of registration can lead to a decision to substitute a substance with another for various reasons, but from the point of view of REACH if the substance is a SVHC, firms might strongly consider alternative options. There may of course also be unintended consequences if for example through oligomerisation (conversion into a polymer) companies avoid registration costs, or rather select an already registered substance than develop a new one so as not to incur time delay in the inquiry process if tight delivery deadlines need to be met.

First registration of phase-in substances will be considered, then that of new substances.

• Registration of phase-in substances

Firms may decide to substitute a substance rather than register it for a wide variety of reasons, of which the main ones are cost, the substance might be a SVHC and the firm wants to withdraw it, uncertainty as to whether the substance will be placed on the candidate list at some stage which would then create problems, or the substance may in fact be at the end of its life cycle and not justify additional investment. Whether a substance is, or will be, registered or not, can have a major impact on the innovation activities of a company.

The impacts will be primarily on the producers of the substance or the downstream users. Producers will probably do this on the basis of return on investment calculations, and this has led, according to survey respondents, to “perfectly harmless” substances, or even “eco-friendly” substances that embody substantial R&D investment from the past being withdrawn from the market purely due to registration cost considerations. However, in such circumstances, firms will be basing their decisions on planned actions and strategies for which they can plan and prepare themselves.

In the case of downstream users the consequences can be more problematic as the inputs may be critical for development of formulations or substances, or in R&D work, sometimes in very small quantities. The whole issue has taken up a great deal of time, and is continuing to do so, and creates a good deal of concern among highly innovative companies based in the EU.

The nature of the registration can also have an impact. For example in the case of one distributor of laboratory chemicals the registration is for an intermediate (to reduce registration costs), but they receive the substance, repackage it and then send it to various laboratories that use it throughout the EU. But they are not in a position to confirm that the labs that use it will use it under the strictly controlled conditions required. Nor can they develop a separate CSR, and a full registration would be too expensive. While at present some 10% of such a firm’s business may be affected, which is manageable, in the future it could easily rise to 30% which could be very problematic not just for itself but also in terms of the knock-on consequences for R&D in the EU.

liability for those companies arise. The chemical industry provides new products, new names, but builders are not sure about performance, yet customers demand is for high performance.
Firms may also reduce the volume they are manufacturing or importing to avoid the 1000 tons registration band, and it is understood that firms from countries outside the EU have set up new legal entities within the EU each of which can take up less than a 1000 tons to circumvent this. It remains to be seen what the effect of the 2013 registration will be.

Some firms have also reformulated their preparations in such a way that they can avoid having to invest in registration. One such an example is set out in text box 3.26 – this was done specifically in response to uncertainty about whether a key supplier would register or not.

The volume exemption of R&D also has limitations in this respect as if one importer or supplier can be exempt from registration but has to provide many organisations even with a little at a time, it can lead to rationing, or possibly the need to open another representative office for the firm in the EU (which will incur additional costs for the supplier, even if they do not register). One company saw the unwillingness of others in the industry to register as an opportunity and registered – becoming the sole supplier into the EU.

Finally, if a firm wants to use a registered substance that it has not used before – that is, effectively, enter the market - it has to go through the registration process for that substance. This incurs costs, time, and results in the Lead Registrant becoming aware that the firm is now entering that market, which may be a sensitive business issue.

Firms have expended substantial resources mapping out their supply chains and trying to obtain commitments from their suppliers that they will continue to supply in the future – these have become parts of the REACH costs associated with production and new product development. In situations where supplies are uncertain, firms have to take business decisions on how to proceed.

- **Registration of new substances**

If companies do decide to develop new substances or uses, for example due to withdrawals of substances from the market or to replace SVHCs, registration of new substances has also had some consequences on innovative activity in the EU in the sense of whether they will occur or not, or what influences such registrations. Here costs, volumes, and timing are important factors in making a decision.

In addition, IP issues emerge in the course of the inquiry process that could have an influence on whether substitution through new substances/uses occurs (for example by revealing a substance identity a direction of research may be revealed to competitors). These are considered more in 4.5 below.

**(b) The Candidate list**

The majority of trade associations spoken to expect the effects of the placing of substances on the candidate list to have an impact on substitution of substances, and some concrete examples were mentioned of impacts already being felt. In this respect the candidate list has a similar effect to the SIN\(^{69}\) list. Companies spoken to have indicated that there is already a strong effect being felt even though there is not yet always a “scientific” reason for the demands made upon them. Understandably,

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\(^{69}\) One survey respondent suggested that the CoRAP (Community Rolling Action Plan) list is also having a similar effect. This list specifies the substances to be evaluated over a period of three years. The first list of 90m substances was adopted by ECHA on 29 February 2012.
companies often do not publicise the fact that they have SVHCs in their production process (that they may be trying to remove), nor that they have removed some if that is the case, due to adverse publicity or unwanted attention that may attract.

The view from one association (BEUC) is that the candidate list (and the SIN list) is useful to start and drive processes and consultations that will lead to removal of those substances and development of substitutes. For example ChemSec is making contact with retail associations throughout the EU to encourage them to encourage their members to demand that all SVHCs, or even substances on the SIN list, be removed in the articles that they sell. The overall response we have had from interviews suggests that the candidate list is currently acting as a major, if not the major, driver for change.

In the survey responses the group most affected, in terms of REACH roles, by substances entering the candidate list is formulators (35%), followed by manufacturers and importers of chemicals (22% each) and distributors (18%). Within these roles, the sectors most affected were:

- Specialty chemicals (adhesives, powders, etc.), sector code 2029
- Specialty chemicals (paints, varnishes, coatings, inks) sector code 2022
- Basic metals (chemical manufacture) sector code 24

Substances often identified are: the various chromates (e.g. sodium chromate), chromic and boric acid in plating, cobalts, and siccatives for wood processing

In the survey companies were asked what the effect of placing substances on the candidate list was as regards innovation at their firm. Responses are presented in table 4.5. At this stage it appears that reformulation was the most often chosen response, followed by withdrawal from portfolios and a request for substitution of such substances from suppliers, and then launching of initiatives to develop new substances to replace them with. Reformulation was an approach of manufacturers or formulators, and chosen quite a bit more often than developing new substances. There can be expensive technical/scientific challenges involved in developing new substances, and feedback from interviews and the survey suggest there are also regulatory and market factors that favour using existing substances that are already registered. Withdrawals can be made by producers as well as importers or distributors, while substitution requests will have been made by DUs and retailers. From a technical, financial and regulatory point of view, development of new substances for substitution is the most challenging option.

A further result has been the “blacklisting” of substances used in sectors such as metals, construction chemicals, printing inks, or paints and coatings. Companies decide to remove substances or not use them to avoid the extra costs of compliance related to use of those substances. It has been suggested that even products on the registry of intentions are affected. In this respect it seems there is a great deal of unease in the industry about the candidate list as we have been told repeatedly that DUs and final customers often have very little understanding of what the candidate list actually means: the substances in question have not yet been evaluated but they are considered unsafe. So there are often “unwarranted” requests for their removal, and often also requests to remove them completely from articles – below the 0.1% limit. This has led to reformulation or substitution above and beyond what was foreseen in the development of the Regulation, and what firms consider to be unnecessary costs related to compliance.
Table 4.5  What has been the effect of the placing of substances on the candidate list for innovation at your firm?

<table>
<thead>
<tr>
<th>Options</th>
<th>We launched initiatives to develop new substances to substitute them</th>
<th>We launched initiatives to find alternative formulations of existing substances to substitute them</th>
<th>We withdrew them from our product portfolio</th>
<th>We requested substitution of those substances by our suppliers</th>
<th>We took no special action</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Nº</td>
<td>%</td>
<td>Nº</td>
<td>%</td>
<td>Nº</td>
</tr>
<tr>
<td>Yes</td>
<td>61</td>
<td>26.6</td>
<td>161</td>
<td>60.3</td>
<td>124</td>
</tr>
<tr>
<td>No</td>
<td>161</td>
<td>70.3</td>
<td>101</td>
<td>37.8</td>
<td>108</td>
</tr>
<tr>
<td>Don’t know</td>
<td>7</td>
<td>3.1</td>
<td>5</td>
<td>1.9</td>
<td>6</td>
</tr>
<tr>
<td>Total</td>
<td>229</td>
<td>100.0</td>
<td>267</td>
<td>100.0</td>
<td>238</td>
</tr>
</tbody>
</table>

Source: REACH Innovation Survey

One major area of concern for firms relating to the candidate list is how substances qualify to appear on the list. This is very important from the point of view of developing substitutes as companies are concerned about embarking on major research and development programmes only to find that the substances they are working with are also to appear on the list. The view from industry seems to be that the list is a “political” one and it is not driven by scientific logic. Comparisons are drawn with the approach adopted in the USA where there is considered to be more transparency and predictability which can guide industry more effectively in its search for substitutes. Companies do not understand, for example, how many substances will ultimately be on the list or how that number was arrived at, and when they will appear on the list.

ECHA however argues that it should be quite clear from the provisions within the Regulation which substances can be expected to appear on the candidate list. Either way, this does suggest that, if the situation is clear from the point of view of the regulator, but not industry, at least a communication exercise to improve understanding and clarity would be of value to support and encourage innovation so that companies can invest their resources appropriately.

Open-ended responses to the question of what the effect of the candidate list has been on innovation can be grouped into the following categories: benefits, de-selection, administrative burdens, technology and pricing, negative effects, “nothing new”, uncertainty and “other”, as presented in the following text boxes.

Some companies have benefited from the candidate list as a driver of substitution as they produce alternatives to SVHCs on the candidate list already. Others are able to do work in this area to help companies substitute. It involves not just developing substances but production technologies. Usually it is easier if uses are of such a nature that lower performance is acceptable. However, if innovation activities commence, they do not always lead to success.

Companies are also keen to point out issues surrounding premature market de-selection or “blacklisting”. Some DUs request a complete absence of SVHCs in the products, or assume they will be regulated out of existence and therefore request immediate substitution. This is not always possible and
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creates problems for suppliers of those substances or products that contain them. It may be that as a result those products disappear from the market for reasons based on no scientific foundation.

For many firms the most immediate effect of a substance appearing on the candidate list has been a flood of paperwork which incurs costs to manage. Customers request certificates and paperwork documenting that the SVHCs are not contained in the relevant products, and with each update of the candidate list this is repeated. However, the information is not always readily available from the supply chain, especially when it is a long supply chain and includes non-EU countries. These requests are also made to firms that do not have substances on the candidate list. Overall these effects have a negative impact on innovation as it absorbs the relevant manpower in administrative tasks.

A further question surrounding the candidate list and its impact on innovation is that of performance. Some substances on the candidate list are not readily substitutable without a loss in performance. While this does trigger new research for substitutes, in many cases the argument is that firms have been searching for substitutes for some time and of they were available they would have been in use. Also, in some cases where substitutes exist, those substitutes may be considerably more expensive. Some firms have lost market share and major drops in turnover.

Some candidate list substances are also used in research, analysis and diagnostics (e.g. acrylamide, boric acid, sodium borate) and are not found in consumer products. There is a concern that it will be difficult to procure these substances in the future, which can have very negative effects on innovation in the EU.

A major issue surrounding the candidate list is the increased uncertainty it has created in the industry. Innovating firms are concerned that the substances they are working with to substitute those on the candidate list with will themselves go on the candidate list at a future time. Alternatives to candidate substances in the less than 1000 tpa tonnage band are being promoted as substitutes when their end points have not yet been assessed, which could lead to them having to be replaced in the near future as well.

Companies express concern about entire industry sectors such as the galvanic industry relocating out of the EU and re-exporting into the EU. This would also stop innovation in the EU in those substances. Some exporters have been forced (e.g. in flame retardant plastics), to split globally standardised products into US and EU variants. One respondent said their company has moved marketing and production out of the EU. However, some firms have said that clients do nothing and hope that authorisation will be obtained and economically acceptable.

Two examples of how two very different firms (one a long established global player, the other a small highly innovative highly specialised firm) have adjusted to substances they use appearing on the candidate list are provided in case study 1 in annex 7. In both cases it has led to major turbulence in and threats to the survival of the business unit and business in question.

The candidate list has elicited a substantial number of responses and is an important substitution mechanism driving innovation – in its various guises – in the chemicals industry. Among the various substitution mechanisms within REACH, it currently probably has the greatest impact, both in a positive sense of driving innovation, and in a negative sense of creating administrative burdens and uncertainties that companies need to comply with.
(c) Restriction

Restriction regulates the manufacture, placing on the market or use of certain substances if they pose an unacceptable risk to health or the environment. Restriction is designed as a "safety net" to manage risks that are not addressed by the other REACH processes. Any substance on its own, in a preparation or in an article may be subject to a restriction if it is demonstrated that risks need to be addressed on a Community-wide basis. A restriction dossier needs to justify that the proposed restriction is the most appropriate risk management measure to address these risks. Proposals for restrictions can be prepared by Member States or by ECHA on request of the Commission.

At present restriction is not attracting as much attention as the candidate list and authorisation. However firms seem to support restriction rather than authorisation, and see this as a relatively rational compromise to authorisation.

Most of the existing entries in Annex XVII are from the “Marketing and Use” Directive 76/769/EEC which was repealed on 1 June 2009. Since then Annex XVII has undergone several amendments. A substance under Restriction can be subject to a partial ban, such as in certain product types or applications, or have specific limits, such as concentration thresholds or release rates from articles (e.g. nickel in earrings and other jewellery). For some substances restriction is a total ban on its marketing and use, including when present in articles, for example polychlorinated biphenyl (PCB) Ugilec 121 (EC No. 400 140 6).

Once restricted under REACH a substance is not exempt from Authorisation. However, once a substance is added to Annex XIV its use will no longer be subject to new restrictions. Only the presence of the substance in articles may attract further control via Annex XVII.

One restriction that has recently occurred under REACH is cadmium, which is a carcinogenic substance and toxic in an aquatic environment. In 1988 the Council adopted a resolution for an action program to combat environmental pollution by cadmium. Cadmium was used as a colouring agent or stabilizer in some plastic articles and has been prohibited in the EU in a number of plastic articles since 1992, but was still allowed in some rigid PVC as at that time alternatives were not available on the market. Since alternatives became available the European PVC industry decided to phase out cadmium from all PVC as part of a program called “Vinyl 2010”.

Following the repeal of Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances by REACH in June 2008, cadmium and cadmium oxide were identified as priority substances for a risk assessment.

The risk assessment pursuant to the Regulation, performed by Belgium, was completed and a risk reduction strategy for limiting the identified risks adopted in 2008. Communication 2008/C 149/034, together with the corresponding Commission Recommendation 2008/446/EC5, provides the results of risk evaluations and strategies for limiting the risks for the above mentioned substances. The conclusion of the assessment of the risks to consumers was that there is a need for specific measures to limit the risks in brazing materials and jewellery. The Scientific Committee on Toxicity, Ecotoxicity and the Environment (SCTEE) has been consulted and has issued opinions with respect to the risk evaluations carried out by the rapporteurs. These opinions, which have been taken into account during the formulation of the risk reduction strategy mentioned above, can be found on the website of the Scientific Committee.
Following the provisions of REACH and as a consequence of the risk assessment and the risk reduction strategy adopted in 2008, the Impact Assessment\textsuperscript{70} assessed the need for a draft Commission Regulation amending Annex XVII to REACH as regards the restriction on cadmium.

As a result of these preceding processes, the European Commission banned cadmium in all jewellery products, plastics and brazing sticks from December 2011. High levels of cadmium have been found in some jewellery articles, especially in imported imitation jewellery. Consumers including children risked being exposed to cadmium through skin contact or through licking. The new legislation prohibits the use of cadmium in all types of jewellery products, except for antiques. The Commission has also banned cadmium in all plastics as from December 2011. The ban will protect the environment by reducing cadmium pollution. The new rules also promote the recovery of PVC waste for use in a number of construction products.

The study team has not been able to obtain any feedback on the effect on innovation of this most recent restriction on cadmium. Interviews with trade associations (Orgalime) suggested that it took some seven years to develop substitutes for cadmium under the RoHS Directive. Most of the cadmium now used in the EU is imported, with some manufacture remaining in the UK. However, the cadmium manufactured is now mainly aimed at exports; the manufacture of mixtures or articles containing cadmium is done outside of the EU and re-imported. The International Cadmium Association advises that most of the world cadmium production (around 80\%) goes into manufacturing batteries (generally nickel cadmium batteries). The use of cadmium in batteries has been banned in the EU for non-commercial applications where the substance has been replaced mainly by lithium ion. A further 10\%-15\% of world production goes in the fabrication of pigments (from dark brown to light yellow).

Member States may retain more stringent restrictions than those within REACH until June 2013 as long as they are notified (Art. 67.3). This could serve as an additional driver for substitution, reformulation, withdrawal or relocation out of the EU.

\textbf{(d) Authorisation}

Substances subject to authorisation may not be used in the EU, unless a company (and their registered users) have been authorised to do so. This means that eventually these substances are phased out of all non-essential uses.

For each substance included on Annex XIV, a deadline will be set after which use of that substance in the EU must stop (known as the ‘sunset date’), unless Authorised. Some substances may be accompanied by a list of specific-uses that do not require authorisation. Once the sunset date has passed for an Annex XIV substance, only uses which have been specifically ‘authorised’ (or which do not require authorisation) will be allowed.

At present only a handful of substances have been authorised. However, the authorisation process for these substances has been accompanied by intense lobbying by the stakeholders involved, in addition to the costs incurred due to the process itself.

Some companies do however see having to enter into the authorisation process as inevitable and are gearing up for that. While large firms may have the required resources, as it is very costly, SMEs tend not to want to. For example, ESTAL (association for European Surface Treatment on Aluminium) which consist mainly of SMEs, is concerned that its members that use specially treated aluminium for building construction may be excluded from that market as a result of the costs involved in authorisation, which will mean they either have to pay more to buy from firms that are authorised, or they will have to import treated aluminium that has already been treated from outside the EU in order to meet the specifications of customers (as set out by for example architects) when quoting for work. This increases transaction costs and raises legal issues about product liability between EU Member States and 3rd countries.

In the survey respondents were asked what the effect of the placing of substances on the authorisation list has been for their firms. Responses are presented below. The trend in responses seems to mirror that in the candidate list. Reformulation and withdrawal were the most often chosen options, with substitution by developing new substances the least selected option. A large group also “took no special action”.

**Table 4.6 What has been the effect of the placing of substances on the authorisation list for your firm?**

<table>
<thead>
<tr>
<th>Options</th>
<th>No</th>
<th>%</th>
<th>No</th>
<th>%</th>
<th>No</th>
<th>%</th>
<th>No</th>
<th>%</th>
<th>No</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>We launched initiatives to develop new substances to substitute them</td>
<td>57</td>
<td>24.9</td>
<td>116</td>
<td>43.4</td>
<td>105</td>
<td>44.1</td>
<td>105</td>
<td>41.0</td>
<td>89</td>
<td>46.4</td>
</tr>
<tr>
<td>We launched initiatives to find alternative formulations of existing substances to substitute them</td>
<td>129</td>
<td>56.3</td>
<td>98</td>
<td>36.7</td>
<td>90</td>
<td>37.8</td>
<td>109</td>
<td>42.6</td>
<td>84</td>
<td>43.8</td>
</tr>
<tr>
<td>We withdrew them from our product portfolio</td>
<td>14</td>
<td>6.1</td>
<td>9</td>
<td>3.4</td>
<td>12</td>
<td>5.0</td>
<td>9</td>
<td>3.5</td>
<td>10</td>
<td>5.2</td>
</tr>
<tr>
<td>We requested substitution of those substances by our suppliers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>We took no special action</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>200</strong></td>
<td><strong>87.3</strong></td>
<td><strong>223</strong></td>
<td><strong>83.5</strong></td>
<td><strong>207</strong></td>
<td><strong>87.0</strong></td>
<td><strong>223</strong></td>
<td><strong>87.1</strong></td>
<td><strong>183</strong></td>
<td><strong>95.3</strong></td>
</tr>
</tbody>
</table>

Source: CSES Survey

Respondents were invited to comment about the effect of placing substances on the candidate list for their firm. Responses can be grouped in to the following categories:

- Most SVHCs on the candidate list are well-known and if economically rational technical solutions had been available they would have been used to replace the SVHCs to reduce hazards. The concern is that companies have been trying to find substitutes for decades but had not been able to, and did not expect to. The effect would be increased expenditure - not innovation.

- Concerns about the effect of substance withdrawal on the ability to carry out R&D: as is the case with the candidate list there is a concern that transfer to the authorisation list will mean that key substances used for research purposes will no longer be available.
  - Performance may be affected. For example, some alternative products introduced by the coatings industry to meet legislative requirements are technically inferior to those replaced, and will involve
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more maintenance, repair and/ or replacement. In other industries, such as building, reduced performance could have significant consequences.

- The implication of resources being directed from “genuine” R&D to deal with authorisation: the costs of authorisation are considered a major issue, especially when outcomes are not certain, and costs cannot be readily be recovered on small volume substances, even if high value. Costs are a particular issue for smaller firms.

- A few survey respondents have told us of production being stopped and plants of DUs being closed down as a result of the authorisation process, or of production being transferred out of the EU

A further key issue surrounding authorisation is loss of intellectual property, business information (and possible conflict with EU competition law). There is no provision for keeping knowledge about substances going through authorisation and the socio-economic impact assessment confidential. So while this may discourage firms that have developed the knowledge, it does reveal to others what is involved, which may trigger additional innovation (for example, as mentioned above with reference to the CNR funded Axeleria projects). It may also lead to non-EU firms learning how to manufacture and doing it themselves, for export back into the EU. It is understood that some EU-based firms are helping non-EU companies to do this with such a plan in mind.

In sum, there is a wide range of factors at work that influence the effect on innovation of the substitution mechanisms discussed. These vary by substance/ use (new or phase-in), REACH role and sector. The dynamics of these relationships can be complex.

4.4.2 To what extent can these ‘forced’ innovations be assessed as beneficial for society, the market and consumers?

The preceding pages make clear that a great deal of activity that can be grouped under a generic “envelope” heading of “innovation” as defined in the Oslo approach has resulted from the operation of REACH substitution mechanisms. This includes the activities listed under the bullet points below and some comments are made on the value for society, the market and consumers.

- Using different substances (e.g. taking SVHCs out) in processes to make products
Consequences will be related to matters such as the effect on risk and the performance of the replacement product, the costs of change and longer term knock-on effects such as implications for repairs, maintenance, waste, etc.
- Changing the nature of substances used (e.g. “oligomerisation”) so as to avoid having to incur REACH registration costs.
In this case there may not be a question of reducing presence of SVHCs in the substance, so the only result is an increase in costs for society to avoid registration costs with few other benefits, although of course it is conceivable that firms doing this might want to engineer other changes into their products while they are doing it.
- Substitution of substances in products that have been identified (or may be identified) as SVHCs with other substances that are not SVHCs – with different performance characteristics (better or worse)\(^2\).\(^\text{71}\)

\(^2\) As one respondent put it: “Finding alternatives for SVHC substances from existing substances is ‘change’ but not ‘innovation’. Frequently the performance/cost is not as good the SVHC material but legislation drives acceptance of a lower performance standard/higher cost.”
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In this case the costs of substitution would have to be weighed against benefits of a “safer” product, and the knock-on implications of having a better or worse performing product. In some industries such as printing a slightly lower performing dye may not have huge consequences, but in others such as building, rapid corrosion of structural supports may.

- Reformulation of chemicals so as to remove or reduce SVHCs to acceptable levels in terms of the Regulation or customer requirements.
  Reformulation is generally not a cost free exercise, and to gain benefits of such an exercise it would also be necessary that risk is reduced as well.
- Replacing substances (SVHCs) with other known substances that have not been used previously due to cost considerations.
  In this case it would involve weighing up the costs implications as compared to the reduced hazards of using SVHCs, again the assumption is that risk levels are the same or reduced.
- Improving products due to better knowledge of properties gained as a result of REACH processes
  This would be generally considered as a positive consequence, especially if it meant to reduction in SVHCs in products, once again though with the proviso that there might be opportunity costs involved, and that the improvements need to be commercially viable or there will not be innovation.
  Development of new substances or uses.
  The conclusions would be the same as in the case of “improving products” (preceding point).
- Involving different external actors more in the firm’s innovation processes (e.g. SIEF or consortium membership, consultants).
  This type of organisational innovation may be beneficial, if for example it leads to new ideas and new product development. If these relationships result in loss of IP or CBI and/ or just leads to cost increases it will have a negative impact on that firm (although of course the supplying firm obtaining revenue or knowledge will benefit and may use that to drive its innovative activities). In the survey it was found that most (48%) new external relationships as a result of REACH were with service providers such as consultants.
- Setting up of new company systems and procedures to be able to deal with REACH compliance (see case study 5 on Marketing and Organisational innovation related to implementation of the Regulation).
  Processes in the firms such as developing SDSs or going through SDSs received could lead to new product ideas and innovation, or reviews of safety procedures may also result in benefits. In the survey it was asked if the organisational changes driven by the Regulation were considered to improve the innovative capacity of the respondents’ firms. 72% said “no”, while 14% said “yes” and 14% did “not know”.
- Setting up new databases and IT systems to deal with REACH-related matters.
  Developments such as these could have marketing as well as organisational consequences. While they do come at a cost, and will therefore have different impacts on different kinds of firms (e.g. micro as opposed to large), they could lead to increased engagement with customers and suppliers and as a result increased innovation.
- Relocating innovative activities to non-EU locations.
  Situations such as these can be very complex to assess and involves balancing the interests of those involved. Those losing jobs (existing or potential), for example, would probably consider this a negative

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72 Internal and external could be linked by for example the development of industry supply chain organisations that strengthen individual firms and link them to other firms and organisations.
consequence, but, from a different point of view, if SVHCs are taken out of the market it may lead to a safer environment. An industry or sector might lose its investment in human capital if its players move out of the EU, but the companies in question may be strengthened if they can retain their capabilities and access new markets as a result.

There is no simple overall answer to the question as to the extent to which all this has been beneficial to society, the market and consumers at this stage. Even answers to individual points very quickly become complex. In some cases, as evidence in the interviews and questionnaires suggests, there has been an unambiguous improvement in safety for people and the environment, which can be considered a beneficial development. However, in other instances, the changes have not had any impacts on safety (whatever way is chosen to define that term), and benefits range from equivocal (where for example there are trade-offs between the extent of REACH-friendliness on the one hand and costs versus benefits or performance on the other) to doubtful or even negative (e.g. in the case of reformulation to avoid regulatory costs).

### 4.5 Consistency

In this part of the report the focus is on the relationship between processes within the REACH Regulation and the requirements of the protection of intellectual property, patenting, and possible related impacts on to innovation. As pointed out in 4.1 above, this was one area of concern raised in the consultation on the initial version of the Regulation undertaken by the Commission in 2003.

Attention is also paid to the protection of CBI. In the REACH context there is often an overlap between IP and CBI, although formally they might be quite distinct. For example, the name of a supplier, a tonnage band and a basic formula identity can potentially reveal, or at least point a way, that leads to revealing IP. So when looking at IP it is also necessary to consider CBI.

In some ways the protection of IP is and restriction of access to knowledge is the opposite of the increased openness and access to data that is considered to be a key driver of innovation under REACH. But at the same time protection of IP provides an incentive to innovate by providing the opportunity of cost recovery and monopoly rents (at least in the short term, maybe longer). This is particularly important in knowledge intensive industries. (REACH and protection of IP is the subject of case study 8 in annex 7).

Creation and protection of IP plays a different role in supporting competitive advantage for different types of firm at different stages of the value chain and in different phases of company growth and development. For some, for example those involved in “blue sky” research, inventing and selling new substances, or protecting their IP for existing substances, is the key to their future growth and survival. For others, using those substances in various formulations, a different calculus is at work: the cost of protecting IP as opposed the benefits – it may be possible to stay ahead of the curve without having to invest too heavily in IPP through expensive patents. In some sectors (or sub-sectors) of the industry the focus may be on process improvements, rather than new product development. For some DUs new products come and go so quickly that long term protection of IP for their suppliers may be of little relevance. But then again, even in such cases there may be some core IP that needs to be protected.

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In this sub-section we first look at the responses from the survey as regards the role of REACH in IP and CBI. Then we look at patenting and how the IP issue has been dealt with by those in the market.

4.5.1 REACH, IP and CBI

(a) Protecting intellectual property

The Commission’s EIA identified possible loss of IP as a concern among registrants. To this end certain safeguards were built into the Regulation, such as the ability to apply, on payment of the prescribed fee, to keep some information confidential; the ability to register on one’s own in the case of truly new substance; and refraining from publication of data about plants and sites.

76% of survey respondents said that they had not encountered any conflicts with IPP from REACH requirements at registration and through the supply chain. Of the 24% that said “yes”, the largest share was manufacturers of chemical products (60%), followed by importers and formulators at 13% and 12% respectively - 63% are large firms.

Those who had answered “yes” were asked to indicate where such conflicts arose. The most frequently mentioned areas were the SIEFs and the SDS/CSR – major industrial information transfer mechanisms in REACH. But registration itself and dissemination through the ECHA website were also mentioned quite often.

Table 4.7 If YES, where have the conflicts arisen? multi response possible

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</tr>
<tr>
<td>Patenting new substances</td>
<td>10</td>
<td>10.8</td>
</tr>
</tbody>
</table>

Source: CSES Survey

Respondents were asked if they felt that REACH has provided sufficient protection for IP to promote innovation. 42% responded that they think not, and 18% that they do think so. 40% said they “don’t know”). Among those that replied “highly insufficient”, 28% were small firms, and among those that said “yes” (both “somewhat” and “completely”), the share of small firms was 14%. These results suggest that overall large firms see REACH as providing sufficient protection for IP to promote innovation more often than small firms.

The survey findings that 26% of respondents think there is a conflict between registration requirements and IP protection (74% do not), while 42% think there is insufficient protection of intellectual property to promote innovation, appear contradictory. This may be the due to the view that registration is seen as pertaining to phase-in substances, while innovation relates to new substances and uses. In the former case, especially for the first registration period, the view is that substances are better known and intellectual property may not be such an issue, whereas in the second case, by definition, creation of
new intellectual property is a different matter. However, the survey results are not definite on this point.

Respondents were invited to provide comments on the relationship between REACH and IP/P. These can be grouped into the following categories: the role of ECHA, the industrial information transfer mechanisms involved, problems specific to formulators, excessive disclosure requirements and competitive consequences.

As regards the role of ECHA, companies express concerns about ECHA’s dissemination plans and the security of the internet. There is also concern about the robust summaries being available in jurisdictions outside the EU. As regards the ECHA dissemination portal, a representative from one major firm said: “The ECHA website disseminates the dossier and on demand it may be possible also to have access to the chemical safety report. In 2012 all the registrant names and addresses related to the dossier will be available to the whole world. This is a perfect chemicals market overview: production sites, volume bands (as they usually correspond to registration time), a paradise for marketing people in the chemical industry in and outside the European Union.” There is also doubt about the ability of ECHA to follow-up and check on violations. Some companies are unhappy about having to pay additional fees to apply for protection of CBI while such protection might then not be granted. There are also new demands regarding production processes for intermediates and sometimes for customer details.

Companies invest a great deal of time in trying to make their data as non-specific as possible. Requirements for selection of alternative names are also considered to be quite strict and a 12 year protection period is considered too short by some firms.

Formulators highlight some specific issues: they say there are no ways to protect their “recipes” or “special tricks” that give them their competitive advantages and disclosure of chemical names removes some of the little protection available.

Firms also mentioned that there are excessive disclosure requirements - for example, having to declare novel use applications. Naming conventions C&L inventory and inability to use masked names have also impacted IPP. There are also difficulties in keeping specific studies confidential. Technical secrets are made available in the Chemical Safety Report, with details of manufacturing processes, impurities and hazardous substances are communicated in the SDS. Not all production processes are patented, which makes full disclosure very risky as loss of CBI can lead to the loss of a product or a whole business.

It was suggested in the course of company and association interviews that some firms try to protect their IP (for uses) by submitting separate Chemical Safety Reports (CSRs) for their substances, so the survey asked if any companies had done that and what they thought of it. 9% of companies indicated that that had done so. Over 80% of the firms that had done so were large (>250 employees). It may thus be that because large firms can more afford to use the processes within REACH to protect their IP they are happier with it (maybe explaining some of the results of the preceding section where it was found that small firms were disproportionately of the view that REACH did not provide sufficient IPP).

The survey also asked how many CSRs those that did submit submitted. 31 said 1-10, 14 said 11-30. They were invited to add comments, and a few were provided. These indicated that in fact CSRs were submitted separately for other reasons than IPP and that some respondents were not aware that this procedure could be used to protect IP.
Evaluation of findings

Competitive issues also emerge that have a bearing on innovation. As one survey respondent put it referring to the role of SIEFs: “Our sector sells catalysts based on metal concentration and the exact substance used to be a closely guarded secret between competitors. No longer”. Another said: “A major problem is that we have to share our regulatory, toxicological and risk assessment expertise with less competent competitors. If we didn’t the Joint Registrations would never be completed in the SIEF’s and consortia. There were Leads who without our help the JR would have missed the November deadline. We were forced to keep our competitor in business when they deserved to fail. Another problem is that we have to disclose what we’re making and in what tonnage band. This information was previously not readily discoverable.” Companies have also expressed concern about listing pre-Registration and full-Registration numbers on the SDS, as customers and competitors might then be able to identify specific substance identities of preparations. One survey respondent in fact said that they now know how to make formulations they buy from third parties, and added, “but frankly this does not seem correct to me”. Survey respondents have also pointed out that competitors can now see their product strategy as they can see which products are being registered and in which tonnage bands.

Companies question the value of identifying the product constituents when the aim of REACH is, ostensibly, to improve environmental protection, work safety and consumer protection.

(b) Confidential Business Information (CBI)

The survey asked if the provisions as regards protecting CBI have been supportive of innovation. 19% thought that they were, while 35% thought they were not. 46% said that they do not know. Among those that thought it was sufficient, small firms made up 15% of responses (which is quite low), while among those that thought it was highly insufficient they made up 26% (quite high) – or 7 out of the total of 27. Of these 7, five indicated that they spend >10% of their turnover on R&D.

The fact that 46% said they do not know is in itself an interesting finding. Are people giving away CBI without realising it? Although job titles are not always very accurate, the job titles of those that completed the survey includes very many with titles related to technical activities such as laboratory management, ecologist, quality, HSE manager, technical specialist, etc. It may be that such officials are not always aware about what is company IP or CBI in the context of SIEFs or consortia, and therefore the leakage of IP and CBI is greater than suggested in the survey findings. However we have no means of testing this hypothesis.

Comments made by survey respondents concern mainly fees and the process and problems of keeping certain information confidential.

As regards fees to retain confidentiality, companies expressed the view that they are too high, especially for SMEs, and so rather than incur the costs they often tend to go ahead and hope there are not negative consequences. This is especially the case as applications are not always granted – then fees are not refunded. Preparing a dossier for submission for CBI confidentiality also takes time. Furthermore, in a SIEF or consortium context, the question is asked as to how costs can be shared without talking about quantities and markets. Uses tend to be revealed. The Lead Registrant is aware of all in the group which could put that firm in a very strong position, and even more so if new firms wish to enter that market, as the inquiry process flags to others in the SIEF that a new entrant is emerging, as well some idea of what substance/ use is involved. While appointment of a Third Party Representative may enable some confidentiality in a SIEF, in general SIEFs or consortia will not share data unless the principal is revealed.
Appointment of an Only Representative by an exporter into the EU may to a point limit potential leakage of CBI, but such ORs may work for other firms at the same time or subsequently. Litigation can be complex, time consuming and expensive.

One further area to mention is what occurs in an authorisation process. In such a context IP can become public, and firms working together to prepare an authorisation dossier are expected to share so much information that there are concerns in terms of EU competition law. Appointing a Third Party may be a workable solution, but can be very expensive. Either way, the whole authorisation procedure leads to a haemorrhaging of CBI and IP. This could, as mentioned above, place useful information in the market and encourage other innovation.

4.5.2 REACH registration requirements and patenting procedures

For a patent to be registered, no-one other than the patentee may know about the specific patent knowledge before application for the patent. This has resulted in a potential conflict with the REACH provisions as to be able to put a substance on the market – even for trials or testing – it must be registered, and to register, information about the product or use in question must be made public which means that it cannot be patented. In particular, this is linked to the need for a CLP number which can reveal identity of the molecule in question, if it is a molecule or information on a safety data sheet if a use is involved.

If work on a new molecule or use (non-phase in substance) is being undertaken, there is a need to inform ECHA unless work is being carried out under the volume exemption or a PPORD, which is also exempt from CLP requirements. It is only if the product is supplied to another establishment, and it contains a harmful substance, when there is a need to inform, so that risk can be managed, but this does not require a full SDS so the IP can be protected.

Then, once the product is ready for commercial exploitation, it can be patented and a full inquiry can be commenced at ECHA that, once full registration is complete, may lead to publication on ECHA’s dissemination tool, with the use or molecule protected by a patent.

This procedure should mean that there is not a conflict between patenting and REACH registration requirements that could have a negative impact on innovation.

When there is a chance that a company can get a patent, subject to the proviso of the economics of the business case, companies will do so rather than first register it as a non-phase-in substance. Downstream users will also tend to register a patent on a specific use, and/ or use a separate CSR to that end. When costs of patenting are too high, then rather than trying to protect IP through a patent, SMEs might opt to use as generic as possible descriptions terms when registering. However, according to R. Barker, Head of Regulatory Affairs at CIBA, if firms that can afford to patent they will increasingly do so to protect their products and processes in the light of REACH obligations to share data.

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74 Masson, F. “Confidential Business Information (CBI) within the framework of REAC”, ETH Zurich.
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The feedback from the survey on volume exemptions suggests that the volume exemption may often be too low for the testing and piloting required. This means that issues about CLP labelling and public knowledge of the substances can re-emerge.

One comment from the survey in this respect follows: “For truly NEW Substances the pre-REACH situation was already fairly bad in the EU, so REACH couldn’t have made it much worse. For ‘existing substances’ which are EINECS/NLP listed, REACH has negatively impacted our introduction of ‘new’ uses of existing substances. The 100-1000tpa specialties are being pulled off the market by suppliers or being registered only as Intermediates which prevents our uses. This means we have to find other suppliers, or arrange for import in a lower, not yet ‘registerable’ tonnage band. This is only a temporary solution.

In addition, we are delaying EU product introductions until we file patents to protect new innovations. EU SDS’s require Dangerous substance disclosures which can be held CBI other places. While this was also the case pre-REACH, new REACH testing is making almost every substance &L as “Dangerous”, and hence subject to disclosure. We have to delay EU R&D sampling and sales until patents are filed. Note CLP Article 24 for CBI protection is practically worthless”.

We are of the view that as regards patenting, the relationship between the Regulation and the situation in practice is not yet fully clarified and resolved. The ECHA guidance is subject to different interpretations and overlaps with CLP increase complexity and reduce clarity. Large firms do not see REACH as patent friendly.

4.5.3 Has the intellectual property issue been resolved by industry players? What consequences for the innovation were observed?

As far as the main information transfer tools within REACH are concerned, it appears that IPP issues have not been fully resolved. Some companies have learnt to adopt an approach of disclosing as little as possible, while others with more at stake to get registration completed might be prepared to give more in order to “get the job done”, even if at potentially a higher cost. REACH advisory organisations generally counsel the former approach to companies going to a SIEF for the first time, or for submitting information into a SDS or even a CSR. One of the human problems inherent in the situation may be that those involved are often technical experts that are not adept at bargaining and might not always be aware of the business implications of the discussions taking place either. So from the point of view of the firms that have invested substantially in IP in the past and present the situation is not ideal.

While there are some avenues available to try and prevent loss of IP and leakage of CBI, these are often costly (for example appointment of an OR or a Third party Representative, signing a confidentiality agreement with a toll manufacturer, or a request for confidentiality from ECHA), and they do not always work.

4.6 Distribution of the benefits and costs

This sub-section looks at the distribution of costs and benefits as regards innovation of the implementation of the REACH Regulation to date in as much as it affects SMEs in particular, and considers whether any segments of the market have gained/lost disproportionally as compared to others in relation to their ability to innovate.
4.6.1 The effects of the regulation on SMEs in terms of access to market, innovation and intellectual property protection.

SMEs constitute a large and diverse group in the EU economic structure, and it is useful to set out some key features in the landscape of EU SMEs. According to the Eurostat figures (table A1.2) some 96% of firms in the EU chemical industry are SMEs, while they are responsible for about 28% of sales and 35% of employment. In terms of the EU average, SMEs are substantially less innovative than larger firms – with 34.4% of firms employing 10-49 qualifying as innovative, compared to 52.3% in the 50-249 employment category and 70.1% in the 250+ employment category (table A1.3). There are also wide ranges in innovativeness between EU Member States. Having said that, these figures are averages and within them there are potentially major differences between for example small contract research organisations creating IP and say, an importer of bulk chemicals. Small innovative chemical companies are a key part of the chemical innovation ecosystem.

Different EU Member States also have different firm structures in terms of employment categories. Thus for example Italy, Spain and Portugal have relatively more SMEs than the EU average, resulting in low average employment per firm. Therefore, if there are factors that have an impact on micro, small or medium-sized enterprises, they can be expected, in turn, to exercise a disproportionate impact on countries with high shares of such firms. In addition, this can have implications for the role of large firms in those countries where, for example in Italy, a large firm is at the centre of a very wide network of SME suppliers, and occupies a strategically critical role. So to look after the small ones it is necessary to look after the big ones too.

A further point of differentiation is in terms of REACH roles. SMEs can fulfil any of the roles envisaged by the Regulation, which further means that to the extent that REACH has a different impact on different roles, SMEs will accordingly also be affected differently. In the course of the interview programme it was also suggested that the chemical industry in different Member States have different profiles, and industry data tends to bear this out. Thus for example, the view was expressed that in Italy the industry tends to be more focused on the development side of R&D, that is formulating, which implies that REACH would impact many small importers and formulators, whereas in say Lithuania, average firm size is more than double that of Italy, Portugal and Spain, and REACH mainly affects DUs since there are only a small number of large manufacturers, mainly of fertiliser products, and not many formulators.

Furthermore, SMEs suffer from some well-known and widely documented challenges (“market failures”) which cannot be attributed to the effects of the Regulation, although they may affect how the Regulation influences SMEs. These include access to finance, access to specialised skilled labour, protection of IP/ barriers to innovation, dependency on local and regional markets, and dealing with regulation.

Notwithstanding these various differentiating factors within the landscape of EU SMEs, the majority, if not all, interview respondents, whether associations, firms, or innovation related or public sector organisations spoken to, expressed the view that compliance with REACH does impact different firm sizes differently, and is particularly onerous on SMEs. Here we consider the effects of the regulation on SMEs in terms of access to markets, innovation and IP.

(a) Access to markets

Access to markets can be considered in terms of access to input markets (existing and new, for inputs of labour, capital, IP, space in which to add value, access to raw materials, intermediate or final goods and
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services); and output markets (existing and new, intermediate – in the supply chain or final - local regional, national, EU and third countries).

Input markets

Turning first to access to inputs, costs for facilities required for production/ mixing can increase due to required changes on the SDS or the needs of SCC for intermediates, and use of GLP labs also adds additional costs. The potential flexibility of toll manufacturing may no longer be present without increased costs and IP risks. It may also be necessary to change production processes to for example reformulate or substitute substances which incurs costs.

There is a need to recruit highly skilled staff for the purpose of dealing with the Regulation or to outsource REACH activities to consultants to that effect (which might create an unhealthy “dependence” and constrain corporate learning). Either way staff costs will tend to increase, some of which will be of a regulatory nature, and not directly revenue producing, which is always an issue for SMEs. As one survey respondent put it: “REACH is much too complicated and much too all-encompassing for a small company like ours (7 people). We have to fight every day for orders and do not have enough money or manpower to delve into this difficult subject matter (which is also often written in complicated English text)” While this problem may vary in intensity between different member states and industries, due to for example different requirements in the Netherlands to allow people to work in the paints industry as compared to Italy, it is a general problem for SMEs throughout the Member States.

Questions surrounding IP will be dealt with separately below.

As regards acquiring inputs, whether for transformation, or storage before shipping out again SMEs are affected in several areas. In the first place there are the registration costs which, it has been argued, weigh more heavily on smaller forms. This is both for existing and new substances. In the course of the interviews and Innovation Survey we have obtained evidence of small firms having to reduce their business lines due REACH registration costs, and some have even closed down completely, or sold out to larger firms that have the resources to bear the administrative burdens of the Regulation. Small formulators for example may be strongly affected by having to obtain letters of access for the many substances they use in their products. Also, if they are importing from outside the EU their suppliers may be reluctant to register and withdraw from the EU market, or only select one importer in the EU to work through thus excluding them, or having to make additional charges. The reduction in suppliers could have an impact on market concentration and prices. Text box 4.3 provides an instance of how a SME dealt with issues related to supply and costs of registration.

Companies also sometimes have to incur increased prices for inputs when they have been altered or substituted to reduce or wipe out margins, e.g. an enterprise with 5 locations in the EU gets <1 tonne from each separately to use to use as an input to avoid registration costs, and for
exotic laboratory chemicals such "grey" activities have commenced where they had been registered as intermediates but may actually be used differently. These are of course only temporary solutions.

One SME that has registered gained the whole EU market as others on the market did not want to (although the consequences of this remain to be seen).

In addition there are the costs to be incurred as regards the various industrial information transfer mechanisms – institutions and processes. One survey respondent summarised the situation as follows: “the costs for REACH endanger the existence of some companies in the fine and special chemicals sector. Mostly there are only a few manufacturers per chemical so that the effect of cost-sharing is small. In addition these are mostly small or medium-sized companies without a large staff of experts (product safety, toxicology, etc.). In most cases there are only one or two employees who have to cover the whole field of product stewardship. Hence many tasks, such as compilation of CSR, exposition evaluation, IT requirements, have to be outsourced to external companies (e.g. consultants). This drives costs up enormously.” Importers and distributors often have problems in obtaining such information from non-EU firms, who are reluctant to share information about IP and markets.

As far as funding is concerned, the survey found that 40% of respondents that indicated that business risk and uncertainty had “increased substantially” were firms that employed less than 50 people. In addition to increased costs this is not an outlook that would readily attract additional funding. Venture capitalists spoken to also indicated that as such REACH had not attracted special attention as a wide range of other factors drive venture capital investment decisions. We were also advised that the banking sector as a whole is relatively unaware of REACH or REACH as an opportunity area.

Comments made in 2.3 can be repeated here: due to the generally low yield on R&D for most chemical companies (although some report more than 20% - Chemrawn) it is hard to finance such low yields for SMEs, so R&D has shifted to the multinationals. The increased costs associated with REACH will put pressure on return on investment margins in a sector that has not traditionally been the recipient of the kind of attention from Venture Capitalists and other forms of high-tech funding where blockbuster innovations can produce very high yields. Increased uncertainty due to REACH registration processes adds a further layer of complexity. Often, innovations also require larger capital investment to implement them, which again favours large firms. Finally, from the point of view of inputs, increased business risks due to potential liabilities from not meeting REACH obligations may further constrain the supply of funds and push up insurance premiums. This may however be offset, at least in part, by reduced potential product liabilities due to REACH compliance.

Therefore, it can be said that in general there is continued access to input markets for innovative SMEs, but that costs of access may be higher, and in the case of some raw material supplies there may be some constraints. These factors would tend to make innovation more difficult for SMEs.

Output markets

Output markets can be considered in terms of whether they are local, regional, national, EU, or outside the EU, and if they are for intermediate goods (e.g. in long complex supply chains such as in aerospace) or whether DUs are supplying final goods to retailers or direct to customers.

As regards access to output markets the key driver is costs. Can the increased REACH-related costs be recovered? What are the impacts on margins? For example in highly priced competitive non-EU industrial markets for innovative formulations it may not be able to raise prices. Depending on the role
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of the product in overall firm competitiveness, this could have a greater or lesser impact. Interview and survey responses suggest that the position of the EU’s exporting SMEs, where such a low percentage of SMEs actually export outside the EU, has weakened in those markets.

In intra-EU markets where all firms are affected by REACH costs, albeit to a different extent depending on their roles and in which Member States they are established, the relative competitive position between firms may not be so much affected. It appears that neither in industrial nor in consumer markets has compliance with the Regulation been a basis for charging higher prices, although there seems to be more scope for this in specialty chemicals. But other factors such changes in exchange rates and the oil price have had a greater impact on pricing than REACH.

So, as in the case of inputs, output markets remain accessible, it is just the cost and possible return on those markets that have been affected, and rate of return drives expenditure on innovation. Having said that, if substitute substances or articles are put on the market that do not have the same performance characteristics that those taken off have (e.g. due to candidate list or restrictions), it may affect market access if EU firms decide to import from outside the EU. In cases where firms are highly reliant on products that contain substances on the candidate list, or that have been authorised, the effect on market access can be severe, and could lead to firm closure, with concomitant loss of employment, capital invested, and the IP and know how. For example, we have also identified a few situations where a small firm that provides a critical component to a long complex supply chain has been acquired by their large customer as the small firm on its own could not pay for registration.

A small Italian company supplying the highly innovative Italian furniture industry with wood panels was burdened with additional costs because the end user wanted 0% SVHCs in the lacquers used in the laminates whereas they actually contained less than 0.1%. In the highly innovative paints and coatings sector where there are many highly innovative suppliers to EU markets as well as non-EU markets preoccupation with candidate list products and authorisation, and the large volumes and sizes of SDSs is using resources that cannot be recovered.

(b) Innovation

While SMEs on the whole tend to be less innovative than large firms, there is a group of SMEs that makes up a very important element of the chemical industry innovation “ecosystem”. They include micro-firms and SMEs such as those presented in text box 4.2. They carry out research and create IP, provide specialist facilities for customers, make highly innovative products working closely with their customers or contribute to programmes of major global players.

In the course of the preceding sub-sections looking at innovation in terms of product conception, development and marketing, it has been possible, based on interview and survey evidence, to make some points as regards impacts on SMEs. These are pulled together here.

Product conception (idea generation and evaluation)

The survey found that among those that indicated that they had found knowledge generated stimulated product conception and innovation, SMEs were more positive than large firms.

However, SMEs have been more affected than large firms in terms of costs of registration. SMEs have made extensive comments as regards the costs incurred in creating the SDS and responding to enquiries in support of such activity implementing the industrial information transfer mechanisms within REACH.
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Small formulators have regularly pointed out that having to buy Letters of Access from many consortia for their various mixtures is economically not feasible. They have also been strong in commenting about issues mentioned in dealing with behaviour in SIEFs where they are at a strong disadvantage when compared to Lead Registrants and other companies with more specialised resources that can operate in such an environment.

As regards increased openness and scrutiny as a result of REACH, the interview programme and survey did not find SMEs to be particularly affected, but it can be expected, based on the survey responses and interviews, that while SMEs may be willing and determined to innovate, their capacity and preparedness to do so may in some instances have been negatively affected due challenges related to the costs involved in REACH (direct and administrative).

Among survey respondents that indicated a “substantial” shift in resources from R&D and innovative activity to REACH compliance, the share of small firms was high (compared to the overall presence of such firms in the survey), especially in the case of formulators, and also for medium-sized firms, although the increase was not as marked. More SMEs also saw this shift as permanent than large firms, and indicated the response as one of having increasing expenditure on R&D to compensate for this in the long run.

Implementation (development/ prototype, pilot application, testing)

According to the survey responses, SMEs did not generally find the pre-REACH testing regime a major issue constraining research in new as opposed to old substances as compared to larger firms. Like large firms SMEs also considered that there are still barriers that remain for developing new substances.

The survey findings suggest that SMEs have benefited less, and made less use of, the various exemptions to stimulate R&D within the Regulation. SMEs have been less affected by provisions as regards read-across and or changes as regards animal testing – these are probably areas where large firms are more active, for example as Lead Registrants.

As far as use of external laboratories is concerned, there are no major differences in the extent to which they are used, nor delays experienced, between large firms and SMEs. As far as effects of REACH on ROI is concerned, SMEs and large firms are also not very different either,

However, there are major differences in terms of responses to the effects on risk and uncertainty between large firms and SMEs. In particular, for small (<50 employees) firms there is a high representation among the “increased substantially” response group, and for SMEs overall the share is high (some 60% as compared to 42% for the overall survey).

Marketing stage (production and launch)

While, as indicated above, the landscape of SMEs includes a wide variety of firm types, feedback from interviews and survey comments suggest that SMEs have been impacted more heavily by REACH costs than large firms. Changes in toll manufacturing arrangements have also had a negative effect, particularly on small firms, and this latter group has also experienced a relatively high rate of “substantial” increase in time to market, although SMEs overall reply that there has been an increase in time to market as a result of REACH – related factors.

These factors have also contributed to making it harder to set up or start a new firm, although importantly it does depend on what the aim of the firm is – to grow, to remain small, is it a one-person Only Representative, or does it plan to manufacture in large scale for export, etc.
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Table 4.8 presents a summary comparison of the perceived impacts of REACH on innovation between the general pool of survey respondents, and the group of highly innovative SMEs (2-5% or more of turnover spent on R&D) selected as the target group for the case study on highly innovative SMEs (case study 7 in annex 7).

Table 4.8  Overall, what would you say has been the effect of REACH on innovation at your firm to the present, as compared to the pre-REACH situation?

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<tr>
<td>Somewhat positive</td>
<td>12</td>
<td>10</td>
</tr>
<tr>
<td>Neutral</td>
<td>29</td>
<td>28</td>
</tr>
<tr>
<td>Somewhat negative</td>
<td>30</td>
<td>37</td>
</tr>
<tr>
<td>Strongly negative</td>
<td>14</td>
<td>21</td>
</tr>
<tr>
<td>Don’t know</td>
<td>14</td>
<td>3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

Source: CSES Survey

While there is not great deal of difference between the shares of the two groups that see the effect of REACH as positive, 44% of the whole survey group see it as negative, compared to 58% of the innovative SMEs. Table 4.9 sets out how these groups see future developments. The SMEs in question clearly have a more negative view of future developments than the group as a whole.

Table 4.9  Do you see the position changing in the future?

<table>
<thead>
<tr>
<th>Options</th>
<th>% All</th>
<th>% SME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes, it will become more positive</td>
<td>10</td>
<td>3</td>
</tr>
<tr>
<td>Yes, it will become more negative</td>
<td>24</td>
<td>38</td>
</tr>
<tr>
<td>No change</td>
<td>38</td>
<td>32</td>
</tr>
<tr>
<td>Don’t know</td>
<td>28</td>
<td>27</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

Source: CSES Survey

As one respondent to the survey expressed it: “I fear that I may not have understood the question because it seems to me that the latter implies that REACH increases the innovation rate. In my opinion it will lower it because it imposes costs such that small to medium enterprises may not best exploit their flexibility. A completely different discussion for large and strongly structured enterprises. Perhaps the legislator has not considered that the strength of the European chemical industry is its tailor made approach, and this is from the small to medium enterprises that depart from the large quantities principles and adapt to the various specific requirements. Considering our case, we prepare soluble colourings for companies in China, Iran, Brazil, Middle East, Indonesia, etc., and to do this we use a myriad of substances that we modify. To continue to excel we will be obliged to go and produce in China.” (Source: CSES Survey).

(c) Intellectual property protection (IPP)
Evaluation of findings

As indicated in 4.5, different firms may have different IP strategies depending on the role of IP in their business and costs of protection of IP. Feedback from interviews and the Innovation survey so far suggest that whether or not a patent is filed for, the costs of IPP related to REACH (for example if one wants a single registration for a new substance, or separate CSR) can be challenging or even prohibitive for SMEs. Firms can both gain and win IP or CBI in SIEFS or consortia.

Research for the UKIPO on protection of IP suggest that for SMEs time to market, or the use of “recipes”, are often more important in an IP context than formal filing of patents, which can be too expensive and time consuming, unless of course one is dealing with a specialist research organisation of which the core business is to invent and patent and then sell those patents to larger firms to develop. In text box 4.3 dealing with “Registration, substitution and a small innovative firm”, the company decided not to patent. In other cases where SMEs have registered substances that they do not want to have copied, they have tended to use as generic and unspecific descriptions as possible. The low level of evaluation of dossiers does provide some incentive to companies to use such an approach.

In the survey firms were asked if conflicts with IP factors had arisen in the course of implementing the REACH Regulation. Of the 25% that said “yes”, SMEs were not present in a particularly high or low share. Most that said “yes” were manufacturers followed by formulators. When asked if REACH had provided sufficient protection for IP to promote innovation, a slightly higher than expected share (28% as opposed to 22%) of small firms were in the group that said it was “highly insufficient”. The situation may change with upcoming registrations where it is expected more SMEs will be involved.

Closely related to the question of IP and IPP for SMEs is that of CBI. The survey responses to the question: “Have the provisions in REACH as regards protecting CBI have been supportive of innovation?” from SMEs in the category of “yes” (20%) contained a very low share of responses, and a high share in the category “highly insufficient”. These last responses included a disproportionately large share of companies with a higher share of turnover spent on R&D than average.

4.6.2 Have any segments of the market which gained/lost disproportionally as compared to others in relation to their ability to innovate?

The results of the interviews and survey suggest that the general conclusion that can be drawn is that small firms as a group tend more often than others to be at a disadvantage as a result of the workings of the Regulation. In general, the smaller a firm, the more it is, potentially, disadvantaged, always bearing in mind the proviso expressed earlier of course as regards small research firms producing IP that may have very little interface with the Regulation.

Other than that depending on the Regulation provision in question, different roles within REACH are affected differently. For example manufacturers and formulators are more vulnerable to IP issues, market intermediaries such as importers and distributors are more affected by the industrial information transfer mechanisms, while DUs and manufacturers may also be affected by SVHC and candidate list-related issues.

75 Hughes, A. Mina, M.; The Impact of the Patent System on SMEs, UKIPO (undated, but 2010 or later)
Evaluation of findings

In many ways the vulnerabilities of small firms set out in the preceding paragraphs (e.g., increased uncertainty, and the knock-on effect as regards access to finance; problems recruiting/ paying for specialist resources; reliance on narrow production lines; increased time to market) reflect the pre-existing problems that face SMEs in general. In the REACH context these weaknesses are accentuated. In general, it seems from interviews and the survey responses that larger firms have been able to absorb and deal with REACH-related costs and other challenges better than SMEs and at present seem to be in a position to benefit more.
Conclusions and recommendations

In this section we set out our conclusions and recommendations.

5.1 The innovation framework

(a) REACH, innovation and the prevailing economic and regulatory climate

Arguably the most important factor that has influenced the perceived impact of the Regulation on innovation has been the evolving economic situation. When the Regulation became active at the beginning of 2007 the world was on the verge of what was to become the greatest economic and financial crisis since the 1930’s, and at time of writing (2012) sustainable and meaningful recovery has been slow to emerge. In this context company finances have remained highly strained, especially for SMEs, and recruitment constraints have also impacted company operations. While such constraints can and do act as a spur to innovation, it is not generally considered an auspicious environment for the launch of new investments in innovative projects.

Firms have also reported that in recent years they are also often busy implementing a wide range of chemical industry and related initiatives both of EU and industry origin, for example: CLP, revision of the Seveso Directive, RoHS, Responsible Care and the Global Product Strategy, IPPC Directive, etc. in addition to REACH.

In view of the above comments, whereas the compliance aspects have had to be taken on board by firms, there are grounds to expect that what may be the “normal” time lag for innovation to occur as a result of an external factor such as regulation, may be extended, and it is probably too early to be able to assess the full impact of the Regulation on innovation.

(b) The Innovation framework

The Innovation Union Scoreboard’s structure as set out in 3.3 informs the presentation of conclusions and recommendations of this evaluation. There are some modifications in some of the points listed under those headings to ensure a meaningful interface with the evaluation topics, but the overall thrust will remain the same.

5.2 Identified impacts of REACH on innovativeness in the European chemicals industry

5.2.1 Impacts on inputs/ enablers

(a) Human resources

The survey findings and interviews suggest that there has been a significant redirection of skilled, sometimes highly skilled, personnel in firms from R&D and innovation-related activities to compliance work as a result of the implementation of the Regulation. The majority of respondents think the shift will be permanent. However, nearly half of survey respondents report that as a result there has been an increase in expenditure on R&D and related innovative activities. Interviews with large firms suggest those that were not financially constrained increased expenditure to maintain R&D activity. However, SMEs also reported increasing expenditure despite higher regulatory costs as often it is business critical.
Conclusions and recommendations

It is expected that the demand for highly skilled such labour, both regulatory and technical (e.g. with testing, toxicity and eco-toxicity skills, etc.) will increase as substances produced or imported in lower volumes come within the ambit of the Regulation and less may be known about these as they are used in smaller volumes and maybe less frequently.

Related to the abovementioned demand factors, supply changes are apparent as in several universities it is now possible to study for post graduate degrees in chemistry with a specialisation in REACH, or diplomas in REACH administration. A whole constellation of REACH-related service providers has also developed in recent years, ranging from providers of technical expertise, to legal, consultancy, insurance, laboratory and testing, Only Representative and Third Party Representative services, to support firms in dealing with the Regulation. (This is in addition to public sector provided help desks).

New career opportunities have opened up so while at present the changes can be seen as a drain on resources, it is envisaged that over time the number and quality of the supply of skilled human resources to industry will increase and be supportive of innovative activity.

(b) Open research systems

One of main drivers of the REACH Regulation has been the view that the gathering, capture and dissemination of data from the chemical industry will act as a spur to product conception, development and marketing. There is evidence that data has been created (e.g. testing results), captured (e.g. in SIEFS and Consortia) and disseminated (e.g. through the ECHA website), leading to an increase in the information base of the industry. Even if this is not the fully open system of for example a university environment, there has been an increased level of openness and scrutiny as a result, and some benefits have been evident, contributing to data generation and creation of IP. The SDS seems to have made the strongest contribution to stimulating new product conception, particularly among smaller firms.

As regards the creation of new knowledge, the view of interviewees and survey respondents is that although there has been a great deal of research and testing as a result of completing dossiers, etc. questions can be asked about how much of this has been really been new as it is claimed that much has been related to chemicals of which the properties are already well known, as for the first deadline of 2010 many of the large volume chemicals in question are well known and have been in use for considerable periods. While there certainly is truth in such assertions, additional testing, and bringing new substances into the net of the Regulation will lead to new knowledge creation, and probably more so for the next cut-off dates of 2013 and 2018. This exercise has taken place at great cost to the industry.

The evidence from the fieldwork also suggests that links with universities and networks developed by companies have tended to focus on the compliance/ regulatory elements of REACH. There is a great deal of activity throughout the EU in this respect. Many firms have established external relationships as a result of REACH, most of which have been with various service providers, especially consultants, but these have not contributed particularly to innovation.
Conclusions and recommendations

As pointed out section 2.2, innovation in the EU in chemicals is quite highly concentrated around some specific Member States and clusters. As yet we have not identified much REACH-specific innovation driven by these areas, although there has been some emerging, as evidenced in the case study on Axelera (part of the European Chemical Regions Network), and other environmentally oriented innovation programmes for example, do have REACH overlaps.

(c) Finance and support

As to the effect of the REACH regulation on the availability external funding from the private sector, there have not been, as far as we could identify, any funds launched or targeted specifically to support innovation or substitution initiatives (or compliance costs) under REACH. Companies have had to fund the extra cost requirements related to implementing the Regulation from their usual sources, and feedback from interviews suggests that this is easier for larger firms than smaller ones, especially in the current economic environment. Feedback from Venture Capitalists and REACH consultants with financial industry links suggest that REACH remains “one of many” factors that could influence funding.

REACH compliance costs would appear to have had a negative impact on rates of return on investment, while uncertainties about actual costs and their timing in the case of innovation projects have not helped financing decision-making in general. Here again the fieldwork suggests that in particular small firms have been negatively impacted.

The Regulation has also increased business risks due to increased investment needs (fixed and working capital) and various potential liabilities created by REACH obligations. This seems to have offset some potential benefits resulting from the value of chemical substances considered REACH-proof/ compliant being developed and marketed, leading to less risk for them to pick up problems as regards environmental or health and safety legislation later on in their life-cycles.

Other than through the REACH related public sector or industry led organisations set up in Member States that have tended to focus on regulatory issues, we have not identified any other programmes such as the REACH-FIT programme in Italy that deals specifically with innovation under REACH. In France the CNR does have a research programme with an axis specifically oriented towards REACH substitution research as well. One related European initiative that is getting under way is Subsport\(^76\) (part of the Commission’s “Life” programme), another is the Antares Programme (and VEGA) to develop QSAR testing methods. Some trade associations, such as Federchimica, are also providing a platform for firms who are engaged in substitution activities.

5.2.2 Impact on firm activities

(a) Firm investments/activities

\(^76\) [http://www.subsport.eu/](http://www.subsport.eu/)
Conclusions and recommendations

Respondents to the survey as well as some firms interviewed indicate that there has been some long term shift in the orientation of R&D and innovative activities towards more HSE related goals linked to REACH, however this is usually not just related to REACH but part of a general appreciation of movements in the market.

There has been some widening in the scope of innovative activities as a result of the Regulation to include more work on new substances, particularly among large firms, who are also responsible for most innovation in the industry, but barriers to R&D and innovation in new substances still remain.

The other substitution mechanisms within REACH: registration, the candidate list, authorisation and restriction, have had various impacts on innovative activities. Registration costs can have an impact on the decision to register a new substance or use, or use of an existing substance in innovative ways, as can delays involved in the process of registration, especially of new substances. This can in turn also influence the availability of substances within supply chains for future use in innovation. There are also unintended consequences as companies, for example, carry out product changes purely with a view to avoiding regulatory burdens of REACH, or perfectly harmless eco-friendly substances are withdrawn because of registration costs. It seems that the return on investment in new registrations needs to be more certain and possibly higher to compensate for increases in costs, risks and uncertainties, whether there are SVHCs involved or not.

The candidate list is a, if not the, major driver for change so far, although it is clear that there are unintended consequences in that for example, retailers or DUs request greater levels of absence of SVHCs than are foreseen within the Regulation, it generates excessive paper/administrative work, there is uncertainty about which substances may in future appear on the candidate list, and attention to the above matters and other candidate list issues can distract firms from their normal, planned innovative activities.

Authorisation has had a similar effect to the candidate list, although for a smaller group of firms which have been affected, but the costs involved for the firms and DUs concerned tend to be greater and thus the opportunity cost in terms of “real” innovation greater as well. The issue of restriction under REACH has not yet resulted in a great deal of activity, although the recent restrictions in the use of cadmium have indicated some potential effects, such as relocation of production facilities out of the EU and development of substitute materials.

As regards measures to support research and innovation are concerned, the research suggests that the effects of the exemptions in question, although valued where applied, have not had a widespread impact. The volume exemption is considered to be too low by many, and in reality not many firms use the PPORD. The position with intermediates is increasingly complex, and the situation as regards polymers, while highly valued by some also is not clear cut, limiting effectiveness.
The use of read-across has helped reduce testing costs but according to the survey respondents, there has not been a reduced need for animal tests.

One of the major, and most often mentioned, consequences of the Regulation has been to increase the administrative burden on firms which entails both costs and opportunity costs, both of which have an impact on innovation. Small firms have been most affected.

One further very important general conclusion is that now innovation projects are probably more highly scrutinised in terms of costs, risks and returns before they are launched on the market than was the case before the implementation of REACH.

(b) **Linkages and entrepreneurship**

The industrial information transfer mechanisms created by the Regulation (e.g. SIEFs, Consortia, SDSs) have, overall, increased supply chain collaboration and linkages between the various firms involved, often with industries other than chemicals. Some positive innovative results have been identified as a result, but at this stage the majority of respondents to the survey indicated no benefits and there are major concerns expressed about the administrative challenges involved in dealing with client enquiries related to candidate list announcements and/or dealing with large numbers of long SDSs and exposure scenarios. This is especially the case for SMEs. In this case the view is that benefits of collaboration are offset by compliance at the expense of innovation.

(c) **Intellectual assets**

The converse of the increased openness and scrutiny driven by the Regulation is concern over the ability to protect IP and related that the benefits associated with the creation of IP. A significant number of survey respondents – think that REACH has not provided enough IPP to promote innovation. Issues about IPP arise in the context of SIEFs, consortia, the development of SDSs and the ECHA dissemination tool. This has been particularly the case with small highly innovative firms. Firms also often think that the additional costs placed on requesting IPP are too high, especially when the requests may not be granted. Large firms that use patents to protect IP do not consider REACH patent friendly.

There are also widely held views that the protection of CBI within REACH remains insufficient, again, especially in the case of smaller firms.

5.2.3 **Impact on outputs**

(a) **Innovators**

The fieldwork has confirmed that extensive activity in the areas of product, process, marketing and innovation change is occurring as a result of the implementation of the Regulation. However, in many instances companies have considered these activities to ensure compliance with the Regulation as a distraction from their normal, planned innovation activities and to be unintended consequences of the Regulation. This view also holds as regards organisational and marketing innovation. The situation can
be described as quite turbulent, and it is likely to remain that way in the areas affected by the Regulation’s deadlines dates until after those dates have passed.

We have not been able to obtain specific quantitative data to measure “innovation” driven by the regulation. Companies often rely on other tools than patents filed to generate innovations – for example time to market and creation of custom “recipes”. However, the survey did ask firms to compare the current situation as regards innovation with the pre-REACH situation, and some two-fifths indicated that they thought it had worsened, as opposed to just over a tenth who thought it had improved. In addition, more thought it would worsen in the future than thought it would improve. Importantly, for innovative SMEs these responses were similar but more accentuated, with over half seeing the position as negative and a third expecting it to worsen.

Increases in time-to-market as a result of the Regulation and increased supply chain rigidities resulting from changes in toll manufacturing arrangements have not been supportive of innovation.

There has not been a discernible effect on the creation of new firms as yet. Many factors are involved in setting up of new firms and spin-offs, and the impact of the Regulation on such ventures varies greatly depending on what is envisaged.

(b) Economic effects

It has not been possible to identify any trends as regards for example employment, exports, sales or licensing revenues from outside the EU (other than the creation of a body of compliance and support services as mentioned above).

However, a point that has been made often about the effect of the Regulation is that the issues around compliance and related costs and constraints do make some non-EU locations more attractive for undertaking innovative activities. Based on the evidence provided, it appears that some such delocalisation of innovative activities has occurred, although REACH may not always have been the only or even the main driver.

As an overall conclusion it can be said that the impact of the Regulation at this stage of its implementation is much as was foreseen by the Commission’s EIA. In the short term somewhat negative effects identified there have certainly been present, and wider ranging benefits are only to be expected in the longer term, also possibly linked to regulatory developments on on-EU countries where it is hoped EU companies could in due course realise competitive advantages of the “first comer”. Issues around IPP and protecting CBI do remain though.

5.3 Recommendations

From the point of view of making recommendations it is apparent from work carried out in the course of the project that there are already many organisations, public and private, involved in support of innovation in the chemical industry. Having said that, we have found very little that is specifically REACH-related. The aim therefore to use as much as possible of established networks and to focus specifically on REACH – related innovation matters.
Based on the preceding conclusions, the following recommendations are put forward.

5.3.1 Enablers

From the point of view of human resources there is a need for a cadre of people who have good chemical knowledge but who actually want to be REACH managers/administrators, rather than chemists. There is also a need for highly skilled researchers and toxicologists – but who have a good necessary of REACH. The aim would be to ensure that very highly skilled resources are not drawn from their normal R&D activities to deal with REACH administration, while at the same time increasing the supply of those who can deal with REACH process work – in as much as such a split is practicable.

To put such a plan into action would involve a survey of what is being done at present in these areas and then finding organisations and/or networks that could help to fill the gap – preferably through their own resources – or by identifying if other EU funding is not available. Alternatively it might be appropriate to open talks with EU funding institutions to see if such support can become available. Some institutes of higher education may wish to initiate programmes or degree courses themselves, as might technical colleges. But the aim would be to identify and initiate such activities. In some cases this could be delivered by national or EU-level industry associations. It may be worthwhile considering development of an EU-wide recognised qualification, possibly at different levels, to this effect. There may also be scope, for example, to offer favourable rates to persons from small or medium-sized enterprises.

To increase the awareness of REACH-related innovation, there could be an opportunity to launch an annual competition for “REACH-innovator of the year”. A programme such as this could be managed by for example CEFIC and sponsored by the chemical industry, Member State governments and the Commission. It would draw attention to the positive aspects and highlight success that is possible, and sharing of knowledge among companies. There might be prizes in categories, for example for firm size, or the nature of the innovation. This would draw more resources to innovative activities.

A further way to support REACH-related innovation would be to see if there are similar initiatives to that of the CNR in France as regards funding research into substitution of substances on the authorisation list (as was found in the Axlera cluster), in other Member States, and if not, to highlight the possibilities of undertaking and supporting such programmes. As a first step, this would require a survey of MS research support programmes, followed up by a conference and development of an action plan. Where such initiatives are identified and already in place, knowledge sharing networks could be supported through for example the ECRN (European Chemical Regions Network). Continued support for EU funded projects such as Subsport should also be provided to ensure they are effective and appropriately resourced.

As regards encouraging private funding for REACH-related innovation, it would probably be best to work through an organisation such as CEFIC that could engage (a “road-show”) with suppliers of funding through venture or seed funds such as the European Venture Capital Association, or the European Business Angels Network, so that more awareness about the possibilities within REACH for innovation is raised. Initiatives towards the EY regulated banking sector should also be evaluated. The possibilities in public sector funding could be increased by making key national level funding organisations such as Oseo or the Scottish funds aware of possibilities within REACH. There may be scope for design and launch of specific programmes such as FIT-REACH in Italy.
Conclusions and recommendations

At **EU level** the profile of REACH could be increased in programmes such as FP7, and those organisations funding and supporting those programmes such as DG Research, could be encouraged to increase their outreach activities to identify more REACH-related projects.

### 5.3.2 Firm activities

As regards factors that could influence firm activities to improve innovation, we have identified the following:

The feedback obtained from a wide range of stakeholders, including firms big and small, as well as national, EU and worldwide industry associations, suggests that there are uncertainties surrounding the **candidate list** that could be addressed which will help firms in their REACH-related innovation activities. These revolve particularly around what it is that places substances in the candidate list, if there is any prioritisation involved, and if there is a target number of substances for the list, how that number is arrived at, so that when firms start to work with new, or different substances they can do so with some certainty that those substances will not themselves appear on the candidate list at some later stage thus wasting what may be some years of research. It is understood that ECHA considers the situation to be quite clear, but the widespread lack of clarity among firms suggests that at least there is a communication and explanation exercise required, if not more than that. This could be developed through for example establishing an industry-ECHA forum, or using one of the several organisations already in existence such as CARACAL to fully scope out the issue and develop a detailed action plan.

A further factor that could contribute to reduction in lost time for businesses and support innovation is to find a more efficient and effective way of dealing with SDSs and exposure scenarios. It is understood that there are initiatives under way in this respect. These should continue to be supported by key stakeholders with some urgency.

Continued and increased encouragement of the development of QSARS and similar **alternative testing methods** so that they can become a more important and more widely recognised testing technology. This is currently being done through, for example, the ANTARES and VEGA programmes mentioned in the report. A survey should be undertaken to see what the state of development of such tools is, what other such projects are under way, how effective they are, where delivery schedules are from the point of view of the 2013 registration deadline, and if they are effectively operated and appropriately funded.

The Commission, in consultation with industry and ECHA, should consider if it is possible, and useful, to develop a version of the **PPORD** that would make it more attractive for smaller firms, and also generally promote the use of the PPORD. This could be through, for example reducing disclosure requirements, and possibly extending its duration so that very long-running research programmes (e.g. 20 years) could be included. PPORD should be automatic as long as the necessary data set is complete, and not discretionary.

The Commission, in consultation with industry and ECHA, should also give consideration to raising the **volume exemption** to a level that would provide for higher volume testing and piloting.

ECHA should consider lengthening the **consultation times for animal testing** (with the proviso that this does interfere with speedy registration).
A pan EU survey of availability of GLP labs should be undertaken to identify bottlenecks in supply that can affect both the next registration and testing of routine innovations, and make recommendations if appropriate. This survey could be managed by the Commission through an open tender procedure.

Firms have indicated that there would be some benefit if ECHA were to clarify guidance as regards toll manufacturing (there are different interpretations in different Member States).

Further guidance from ECHA for firms on how to deal with patenting and IP issues in general – and how that relates to CLP in particular.

Ways to make it easier and cheaper for firms to protect IP and CBI within REACH, especially small firms, should be considered. Such a project could have as starting point bringing together all the categories of data ECHA currently holds on firms and their substances through the REACH systems such as REACH IT, EUCLID, and CLP inventory) and how it is collected, and submitting this to a critical review to identify what is mandatory in terms of the regulation and what not, what is really critical in terms of HSE, and where, if possible data needs can be reduced or where and how additional protection to IP and CBI can be provided.

5.3.3 Outputs

The most important factors we can envisage as contributing to improved outputs at this stage are:

Improved predictability about timing and costs and reduced expected times for processing of new substance/use inquiries and registration by ECHA. This would reduce some uncertainties in the innovation process and encourage innovation. It is understood that ECHA has reservations about the completeness and quality of submissions, but ways to work through this should be developed and resources provided to ECHA as it seems there is currently a bottleneck at this stage of the process. ECHA should work towards a way to provide increased predictability about timing and costs and reduced expected times for registration for phase-in substances which could also encourage innovation using those substances.

A research project should be carried out into the feasibility of developing a new category in REACH, that of a “small chemical company”, in line with EU definitions of firm sizes, and with a chemical function/volume dimension, such as, for example, usage volumes of substances (e.g. if less than 100 tpa to register only by 2030). Such firms could, for example, be subject to reduced REACH registration obligations (when the substance and use are already registered), or be able to claim reduced costs for Letters of Access.

From the point of view of improving the overall understanding between the regulator and industry, it is suggested that all ECHA staff above a certain level spend one week a year in a chemical industry SME.