Final report

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

Interim Evaluation: Functioning of the European chemical market after the introduction of REACH

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Interim Evaluation: Functioning of the European chemical market after the introduction of REACH
Final report

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# List of abbreviations

**List of common abbreviations used in the report**

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>CA</td>
<td>Competent Authorities</td>
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<tr>
<td>CEFIC</td>
<td>European Chemical Industry Council</td>
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<tr>
<td>DUs</td>
<td>Downstream Users</td>
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<tr>
<td>DUCC</td>
<td>Downstream Users of Chemicals Coordination</td>
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<tr>
<td>ECHA</td>
<td>European Chemicals Agency</td>
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<tr>
<td>eSDS</td>
<td>extended Safety Data Sheets</td>
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<tr>
<td>EU</td>
<td>European Union</td>
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<tr>
<td>Eurofer</td>
<td>European Steel Association</td>
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<tr>
<td>Eurometaux</td>
<td>European Association of Metals</td>
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<tr>
<td>LoA</td>
<td>Letters of Access</td>
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<tr>
<td>OR</td>
<td>Only Representatives</td>
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<tr>
<td>Orgalime</td>
<td>European Engineering Industries Association</td>
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<td>REACH</td>
<td>EU Regulation on the Registration, Evaluation and Authorisation of Chemical substances</td>
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<td>SDS</td>
<td>Safety Data Sheets</td>
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<tr>
<td>SIEF</td>
<td>Substance Information Exchange Forum</td>
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<tr>
<td>SME</td>
<td>Small and Medium Enterprises</td>
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<td>SVHCs</td>
<td>Substances of Very High Concern</td>
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Objectives of the study and methodology

The objective of the CSES study has been to evaluate the implementation of the REACH Regulation in relation to its impact on the operation of the single market and the competitiveness of the European chemicals industry. The study aimed to:

- Evaluate the relevance, coherence, efficiency, effectiveness, sustainability and impact of the REACH Regulation in relation to the operation of the market of chemical substances.
- Identify strengths and weaknesses of the REACH implementation with respect to the dynamics of the market, consumer choice and prosperity, costs of compliance and administrative procedures. The impact on SMEs was given particular focus given the presence of relevant provision in REACH Regulation and the expectation that any discrimination against them is avoided.
- Provide recommendations to remedy the weaknesses identified during the evaluation with a view to minimise possible adverse effects of the REACH implementation.

The methodology of the study was based on the analysis of the Regulation’s intervention logic and the identification of areas that are expected to have an impact on the competitiveness of industry and the operation of the single market. Collection of the relevant data relied on a combination of research tools including:

- A programme of more than 100 interviews including Commission and ECHA officials, European and national industry associations’ representatives, Member States authorities and other stakeholders such as representatives of trade unions and environmental groups.
- A pan-European online business survey. A total of 1601 responses were received from firms or business units with different roles in the chemicals supply chain (manufacturers or importers of chemicals, formulators of chemical preparations, producers or importers of articles, distributors and end users).
- Extensive desk research including professional and academic publications and statistical databases.
- A number of case studies focusing on specific aspects identified during the course of the study that considered in greater detail various aspects of implementation of the Regulation.

It should be noted that this study has taken place at a rather early stage of implementation of the Regulation, shortly after the first registration phase, and well before some of the procedures and processes have been fully developed. As a result, for certain aspects examined the available evidence was not sufficient to allow conclusive judgements of their efficiency, effectiveness and the long term impacts to the competitiveness of industry. Furthermore, they did not provide clear indications of what types of modifications would be required to the legal text or other aspects as actors are still getting acquainted with the various provisions.

Main findings and conclusions of the study

Relevance of the REACH Regulation

The analysis of the findings indicates that the REACH Regulation remains relevant in relation to both the maintenance and enhancement of the competitiveness of the EU chemical industry and in the

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1 More information on the structure of the sample is available in the report.
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Protection of the internal market. However, the analysis also indicates that important part of the potential benefits still remain to be seen as the implementation of the Regulation goes forward.

In relation to the competitiveness aspect there is recognition of the potential to stimulate innovation and development of new substance and of the presence of relevant mechanisms. But, so far, the contribution of those mechanisms is yet to be realised. At the same time, there are significant costs of implementation related to REACH and, at least in the short term, parts of industry considers that the Regulation can have a negative impact on the competitiveness of EU firms, primarily in relation to their access to non-EU markets. These impacts are expected to be reduced in the future as experience with the implementation builds up but also as third countries also introduce certain types of registration and authorisation requirements for chemical substances. Our analysis suggests that there is still scope for the reduction of costs without a detrimental effect on other objectives of the Regulation.

There is also agreement that REACH is integral to the harmonisation of the internal market, and of central importance in the development of a level playing field and free market competition. However, national practices and differences in interpretation - most notably discrepancies in the notification concerning requirements of SVHCs in articles - but also differences in the enforcement of the Regulation mean that the demands of this objective are not yet fully met.

Effectiveness of the REACH Regulation

Costs of compliance with the REACH regulation

Analysis of the provisions of the REACH Regulation pointed to a number of cost elements already incurred by firms with different roles in the supply chain to this point. These include:

- Human resources dedicated to the various REACH-related activities (concerns all firms);
- Costs of pre-registration and registration of chemical substances (concerning primarily manufacturers and importers of chemicals);
- Information exchange activities along the supply chain (applies to all firms in the supply chain);

There are also other relevant costs elements that have not materialised so far or for which available data are still rather limited. These include:

- Notification for articles (concerns manufacturers of articles);
- Downstream users chemical safety reports (concerns downstream users);
- Costs for changes in production and relevant R&D activity\(^2\), management of risk and other necessary investments (concerns all firms);
- Authorisation and restriction (concerns manufacturers and importers of chemicals as well as downstream users);

The study focused primarily on those cost elements for which data was available, including human resources, registration and supply chain communication.

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\(^2\) The impact of REACH on innovation is the subject of the second study conducted by CSES. While clearly relevant when considering issues of competitiveness, the impacts on costs related to R&D have not been covered in the context of the competitiveness study.
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Human resources

The survey results indicate that over 60% of manufacturers, importers of chemicals and formulators have established a dedicated REACH unit. Large firms have more typically followed such an approach (63% of total) in comparison to small or micro firms (35%). In the case of multinational firms, REACH centres have often been created with the intention of increasing efficiency through the centralised coordination of REACH related work. In the majority of the cases (55% of the total respondents of the business survey) REACH units occupy between 1 and 5 Full Time Equivalent (FTE) while among smaller firms 0.5-1 FTE are typically occupied in REACH related activities.

External consultants are also used to a significant extent by firms either as a replacement or in addition to in-house staff. There is limited information on the budget allocated to these services, as this varies depending on size of the firm, the substances involved, and the country. Small firms often outsource most of REACH related activities including the preparation of registration dossiers, the communication within SIEFs and the exchange of information with suppliers and customers limiting the internal resources dedicated. Large and small firms also use consultants for legal or technical support or for training in relation to specific aspects of REACH.

Pre-registration and registration costs

The main cost elements of the pre-registration process were the human resources associated with completing the procedure, not least because additional time was often needed for familiarisation with the legislation and analysis of the inventory of firms to decide which substances should be pre-registered. Typical costs stated by firms were around one working day per substance but there is great variability depending on the size of the firm and the number of substances but also important learning curves. However, the information available that a large share of the total of 2.7 million pre-registrations - although not clear what is the exact share - was submitted by firms that did not conduct a proper assessment but only registered a large list of substances without prior analysis with the objective to secure their business. The costs per registration for these firms were very limited and it is one of the reasons that led to a very large number of pre-registrations.

Concerning the costs for registration, the business survey suggests a rather wide range in terms of the average total costs per registration, with the most typical value falling within the range of €50,000-100,000. In the case of importers of chemicals the distribution was skewed towards lower cost ranges while among manufacturers of chemicals average costs of over €250,000 are not that uncommon. For the great majority of firms (close to 70%) registration costs did not exceed 1% of their annual sales in 2010, although for a small number (around 7%) they were above 5%.

The analysis of the main drivers of the registration costs suggests that ECHA fees often represent 50% or more of the total costs, especially in the case of more simple substances. For larger firms, or in the case of more complicated substances data collection, costs related to SIEFs and consortia - including management and other fees - are the main cost element often exceeding €100,000.

On the basis of the information available and the number of registrations for the period up to 2011 (around 25,000 by the end of 2010), we estimated that the total cost for all firms that have been pre-registered and registered is

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3 The time and cost of registration of substances with similar properties could be much lower following the pre-registration of the first substance.

4 Based on an average cost per pre-registration of €500, an estimation based on information provided during the course of the study.
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involved in the registration process has been around €2.1 billion\(^5\) with a broader range of €1.1 - €4.1 billion providing a more secure estimate. This estimate is close to the €2.3 billion (2003 values; around €2.8 billion in 2011 values) that was expected to be the cost for the whole 11 year period according to the 2003 Commission working paper but around two times higher than what was expected for the first registration period.\(^6\) However, the Commission estimates covered the additional costs arising from the Regulation and did not cover the financial costs related to the fees paid by many firms for access to already existing studies. Furthermore, the Commission estimates were based on rather ambitious assumptions of the use of QSAR method for the testing of chemicals that could have led to cost savings of up to €1.3 billion. So far the use of the QSAR method has been limited.

Communication in the supply chain

For the majority of the survey respondents (close to 70%) REACH appears to have led to an increase of the costs of managing information exchange along the supply chain. Human resources are currently dedicated by firms to the development, handling and extraction of the relevant information included in the SDSs or the extended safety data sheets (eSDS). The typical costs for the preparation of an SDS is around €200 and over €500 for an extended version, but can reach up to €2,500 in the case of translations in all European languages. IT systems are also often purchased by firms to support the handling of SDSs with costs ranging from a few thousand Euros to more than a million depending of the size of the firm and the extent that they are integrated in the firms’ resources management systems. An important part of these costs – investment in IT or initial development of SDSs – should be considered as one-off costs but there are still aspects that will incur on-going costs.

Evolution of costs in the future

Most respondents (75%) indicated that they expected REACH compliance costs to increase in the coming years. Despite the reduced data requirements and ECHA fees for the second registration period, more registrations are expected for substances for which data are not available. Furthermore, the involvement of more firms may also lead to increased communication costs in the context of SIEFs. However, as experience develops, SDSs become more standardised and more firms acquire the necessary experience, information exchange is expected to become more efficient and certain cost elements may gradually decrease.

Impact on financial situation of firms

Most firms and associations suggested that it is too early to identify long term impacts of REACH on their financial position. In the short term, REACH compliance costs had a certain impact on the financial situation of an important number of firms, including suppliers of chemicals and, less so, downstream users. The severity of this impact depends on the type of product traded. For firms in highly competitive markets, as is the case for basic chemicals and metals that are treated as commodities, already low profit margins appear to have been further squeezed as there is limited capacity to transfer these costs to consumers through price increases. In other markets, such as certain segments of the specialty chemicals, firms may have greater capacity to increase prices and maintain profit margins without seriously affecting their overall financial position.

\(^5\) Reliance on the arithmetic mean values would produce a total cost of around €3.4 billion. However, given the positive skewness of the distribution and the uneven and larger size of the higher cost ranges we do not consider that this represents the appropriate value to be used for this estimation.

\(^6\) Equal to around €2.8 billion in 2011 prices.
Access to chemical substances

The evidence made available indicates that REACH is associated with a certain level of withdrawal of chemical substances. Close to 35% of survey respondents indicated that they have experience of at least one substance being withdrawn from one or more of their suppliers. Among those, the vast majority (84%) indicated that this did not concern more than five substances. A common response of manufacturers or importers producing at levels close to 1000 tonnes per year has been to reduce production volumes below the threshold.

The costs of registration is the most common reason for the withdrawal of a substance or the decision to reduce production below the 1000 tonnes per year level as they are often expected to make the overall trading of the substance unprofitable. When applicable, the placement of substances in the candidate list for authorisation is also stated as an important factor. The information collected suggests increasing trends towards removal from final products of chemicals in the candidate list or even beyond that. This is very often driven by the request of the producers or retailers of the final products in sectors as diverse as electronics, furniture producers or general retailers.

Still, while it may differ in certain sectors, the general picture is that so far the withdrawal of substances is not a widespread phenomenon and that there are only limited cases where this has become problematic in terms of the access of firms to essential raw materials. Furthermore, some of these substances withdrawn were towards the end of their life cycle and firms were already preparing for their substitution. However, there are also firms – mainly in the coatings sector – that feel that substitution will require many years of research and may not always lead to substitutes of equal quality and desirable properties.

The most common response of downstream users to the withdrawal of a substance is the substitution of chemicals or a change to suppliers inside the EU. Very few firms decided to register the substance themselves in order to ensure continuous access to it.

Impact on prices of chemicals

Available data on the development of prices of chemical products does not permit an assessment of the impact of REACH on prices. On the basis of the information collected, the overall conclusion is that REACH has a certain impact on the price of chemicals, but that this is not sizeable.

According to the survey, the majority of firms (over 50%) have predominantly tried to absorb the costs resulting from REACH rather than pass the costs down to their customers. This depends also on the sector of the firm. In the case of commodity chemicals there is limited scope for passing down costs while this is more possible for specialty and consumer chemicals. Still, 61% of firms suggested that REACH has led to an increase in the relative prices of their products in comparison to non-EU firms. There seems to be a certain level of contradiction in the responses of firms. Even among those that state that they absorbed the costs more than one third reported to increase in relative prices. While there is no clear explanation for this apparent contradiction, we consider that these responses could also be seen as reflecting the general negative view of firms on the cost implications of REACH for firms.

Considering the prices of articles, any impacts is even more marginal as chemical substances costs represent only a small share in the total production costs of articles.

At the same time though, REACH has led to a reduction in the number of suppliers of some substances leading to an increase in level of concentration in some chemicals’ markets with potential medium term impact on the level of competition in the market and, in some cases, the prices of chemicals. The scale of this effect at this stage is rather marginal.
Impacts on trade
The study has not identified any particular impact of the REACH Regulation on levels of trade. The data on intra-EU trade over the last 10 years suggests that the volume of trade of chemicals has increased faster than the total level of trade of goods in the EU. At the same time, there has been an increase in the share of intra-EU trade in the total trade of chemicals inside and outside the EU since the introduction of the single market.

In terms of the role of REACH in the operation of the single market, the study suggests that, besides a broadly recognised positive role in avoiding the fragmentation of the market, the majority of firms (close to 60%) do not consider REACH as relevant in their decision to enter new EU markets and, at least so far, the Regulation is not associated with a reduction of administrative costs and ease of exporting. Existing differences among Member States concerning the requirements for notification of SVHCs in articles are quite often cited as an example of the lack of harmonisation of the market directly linked to REACH.

However, any comparison made by firms at this stage does not take into account the danger of multiple different regulations being developed across the EU in the absence of REACH. The comments made focus on existing implementation and enforcement problems and tend to ignore the benefits of the presence of a single regulation across the EU.

Benefits from REACH for the industry
The study results indicate a level of scepticism as to the potential of the Regulation to bring some of the initially expected benefits of REACH. More specifically:

- **REACH has not had, at least to this point, a sizable contribution to increasing consumer confidence for chemical products.** More than 55% of responding firms considered that there is no role or no impact of REACH on consumer confidence, while less than 20% thought that it has contributed to this at a moderate or greater degree. There has also been limited use of the information provisions of Article 33 by consumer organisations and the level of awareness of consumers appears to be rather low.

- **Firms are more positive in relation to the possible contribution of REACH to improving knowledge on the uses and properties of chemical substances.** However, there is still a certain level of scepticism as to the extent that this new knowledge will translate into business opportunities in the new future. One explanation often provided by industry representatives and experts is that, so far, REACH registration has mainly covered substances for which most of the relevant information was already available. The second and third registration period will possibly produce more useful information. However, it should be noted that the more recently published Eurostat baseline study indicates that significant additional knowledge in relation to the properties of chemicals has taken place during this first period.

- **There is still scepticism from the majority of firms of the potential of REACH in terms of the benefits from the information exchange requirements arising from REACH.** The Regulation has led important number of firms to increase level of communication with suppliers and customers and led some of

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7 More detailed analysis as regards the usefulness of such knowledge and the contribution on innovation is provided in the Innovation study conducted by CSES: Impact of the REACH regulation on the innovativeness of EU chemical industry to be made available from http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/review2012/innovation_en.htm

8 The CSES has been given access to a brief document summarizing the key findings of the study.
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them to the development of more advanced supply chain management practices – including the use of IT tools. There is thus a potential for important productivity results in the future. However, for the majority, these potential benefits are overshadowed by the costs and the challenges of supply chain communication that they experience at this stage.

• While there is some recognition of a contribution in improving risk management procedures, it is still too early to link REACH with specific cost reduction related to occupational health and safety.

The overall conclusion concerning most of the expected benefits is that, in most cases, it is too early to identify a material contribution to firms' operations and their competitiveness while the costs aspects are still significant.

Efficiency of REACH - Role of REACH structures and mechanisms

Operation of Substance Information Exchange Forums (SIEFs)

SIEFs are generally accepted as an effective mechanism to reduce registration costs - 65% of survey respondents agreed with this statement. However, there are various problematic aspects in their operation and the cost savings are smaller than expected. The key issues identified relate to communication and coordination problems that have been acute in a number of SIEFs especially in the case of SIEFs with a large number of "dormant" pre-registrants. Thus, close to 75% of firms suggest that SIEFs created important information exchange costs.

To a certain extent the problems with the operation of SIEFs are addressed when relevant consortia are in place. 80% of firms have a positive view of consortia while 30% of firms in consortia have a positive view of the operation of SIEFs, in comparison to only 13% among non-consortia members.

Another issue identified is the fear of loss of confidential information as a result of the participation in SIEFs. While there was no evidence found in the context of this study that would suggest a systematic breach of intellectual property or proprietary information, the fact that participation in a SIEF provides strong indications as to what substance a firm produces and at what volume could be considered important business intelligence.

A more crucial point concerns the cost of letters of access that often represent more than 50% of the total registration costs and are often portrayed as a tool used by large firms to push small competitors out of the market. The analysis suggests that the key issue at this stage is the absence of a transparent approach in presenting the various cost elements and how the price of letters of access is being set. Greater transparency can help make comparisons with other consortia in relation to management and other fees. It will also allow firms to conclude on the adequacy and proportionality of the costs and assess whether the REACH provisions on the opt-out from joint registration apply to them.

Use of Safety Data Sheets for supply chain communication

At this point, the exchange of communication along the supply chain is generally seen as a rather complicated process and it is an aspect that affects almost all firms. 44% of firms felt their experience so far was either 'negative' or 'very negative', with a further 44% seeing it as moderate.

The main problem that firms face in relation to the handling of SDSs is that there is no single standardised format and that extended SDSs can often be very long (often over 100 pages) making extraction of information from downstream users particularly time consuming. Furthermore, information along the supply chain often involves manufacturers inside and/or outside Europe with limited awareness of the requirements. This makes obtaining the necessary information a demanding process for all actors involved and adds further to the human resources costs indicated earlier.
Support mechanisms – ECHA and national helpdesks

The survey results indicate a generally positive view on the role of ECHA, national helpdesks and other support mechanisms. 92% of respondents stated that they have used ECHA support at least once and a similarly high share of firms (87%) has made use of national helpdesks. National association (87%) and European Trade association (69%) are also often used in assisting companies in the registration process. In relation to their usefulness, National and European Trade Associations were generally thought to be more useful, with 78% and 70% respectively finding them as at least “quite useful”, as opposed to 59% for the ECHA support tools and 49% for national helpdesks. Because of the relatively generic information provided by ECHA and the national helpdesks, companies put significant value to the role of their Trade Associations in translating the guidelines into more practical helps tailored to the specific needs of firms.

Smaller firms tend to make less use of most of European structures with greater focus on national helpdesks, associations and private consultants. 13% of small and micro firms have made no use of ECHA in comparison to only 4% among larger firms. There are also differences, although smaller, in terms of the perceived usefulness of the above structures. Small size firms tend to provide a less positive assessment.

Examining certain ECHA tools in more detail, the usefulness of guidance documents or IT tools is generally accepted (60% consider them as at least quite helpful) but there are complaints concerning the timing of changes or the fact that new interpretations in guidance documents have created some confusion and extra costs for firms. As regards national helpdesks, discrepancies are often connected to the limited resources allocated at the national level.

Role of only representatives

Only Representatives (ORs) have assumed a key role in the facilitating the access of non-EU firms in the EU chemicals market, including their involvement in 19% of the total registrations. Their role is particularly important for smaller size firms with limited capacity to follow the EU regulations.

Despite the generally positive view, the study identified a few areas of uncertainty with regard to the role and operation of ORs. The provisions of Article 8 of REACH are not clear enough in terms of setting minimum requirements for assuming the role of an OR and information on the capacity of existing ORs is still rather limited. This is reflected on the issues of reliability and trust raised by some non-EU firms. There are also certain grey zones concerning the responsibility of ORs in updating safety data sheets and the absence of provisions for involvement in the authorisation process. Both issues were recently addressed by the Commission9 clarifying that ORs should be considered responsible for the SDSs and also allowing ORs to apply for authorisation on behalf of their clients even for substances that were not registered by the specific OR.

Market surveillance

Market surveillance is paramount in ensuring the creation of a Single Market throughout the EU. Among those firms with experience in market surveillance, only 5-15% - depending on their role in the supply chain or the country - made a positive assessment of the existing level of market surveillance. Between 30% and 50% provided a negative assessment and 40-50% characterised it as “fair”. There is generally a perceived lack of capacity by enforcement authorities to adequately uphold the regulation with reference often made to the limited resources available. Further to that, existing work in the context of

9 http://chemicalwatch.com/9633/eu-commission-set-to-permit-or-authorisation-under-reach
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Enforcement Forum indicates substantial variation in the approach of inspections, requirements and imposing penalties across the EU.

Besides providing some indications, we consider that it is too early for conclusions on this aspect. A number of coordination and joint inspection projects have been set up by ECHA in order to improve consistency and the RIPE database will help exchange in information among enforcement authorities.

Overall acceptance of REACH Regulation

The responses of businesses suggest a moderate overall attitude towards the Regulation. Negative opinions are expressed by around 40% of respondents, 20% stated a positive opinion and 40% being neutral. There is limited deviation among firms and stakeholders of different roles in the supply chain and no significant difference depending on firm size. Given the stage in the implementation and the quite problematic experiences indicated concerning various administration and communication aspects, we consider that this could be seen as a rather positive message. Furthermore, the involvement of additional firms – and more SMEs - in the second and third registration period will be another testing point of the overall acceptance of the REACH Regulation.

Recommendations

On the basis of the analysis, the key recommendations of the study are the following:

- **Avoid**, to the extent possible, changes to any of the key or provisions of the Regulation. The implementation of the Regulation is still at the early stages and there is significant learning for all stakeholders involved. Any changes will potentially nullify the significant experience and learning built by all categories of stakeholders but possibly lead to additional resources being dedicated. Stability and certainty are important at this early stage of the implementation. In addition, the key problematic aspects identified in this review - the operation of SIEFs and the exchange of information on the basis of SDSs - can be improved without changes to the text of the Regulation.

- **Aim to clarify any unclear requirements, increase predictability and improve tools and implementation structures to reduce or eliminate unnecessary costs.** We consider that priority should be given to improving the various implementation mechanisms to ensure effective and efficient compliance capitalising on existing experience gained and, whenever possible, to clarify, simplify or streamline aspects that can help minimise administrative and other related costs. More specifically the evaluation team proposes the following steps and actions:
  - Promote greater standardisation of extended Safety Data Sheets content and presentation and work with industry representative to identify possible simplifications to the information requirements provided or the way they are presented in the SDSs. The focus should be on making the introduction and the extraction of the relevant key information as easy as possible.
  - **Consider setting specific dates for the publication of the updates of guidance documents** or other important developments related to the implementation of the Regulation and the feasibility of reducing the frequency of the update of some of those documents. The objective should be to reduce the work required by firms for the revision or update and increase the predictability of the system.
Executive summary

− Consider setting specific dates during the year for the publication of the updates of the candidate list and the appropriateness of introducing a transition period between the time that a substance enters the candidate list and the time that information obligations may arise.

− Provide further guidance concerning communication practices and sharing of costs within SIEFs on the basis of the exchange of best practices.

− Propose minimum information provision requirements concerning the fees for letters of access with a breakdown of the costs in order to achieve higher levels of transparency.

− Clarify the role of ORs in relation to authorisation procedures and in terms of their responsibility in the exchange of information with importers. While changes to the text of the Regulation could also be considered it should also be possible to address this issue by providing clarifications concerning the practical requirements deriving from article 8.2 of REACH for a “background in the practical handling of chemicals”. In cooperation with industry and Only Representatives, the Commission should consider the feasibility of developing a quality standard in the form of a “code of conduct”, a certification scheme or the development of a publicly available database listing Only Representatives on the basis of a registration process.

− Utilise structures such as the Directors’ Contact group and ensure high level of coordination between the Commission, ECHA and industry. More generally, the approach adopted should be one of involvement of relevant stakeholders in the decisions and any development work to ensure predictability.

• Prepare for the following registration periods with focus on the needs of SMEs - The 2nd and 3rd registration periods are expected to be more challenging as they will most probably involve a larger number of firms, more SMEs with limited capacity and no prior experience on REACH. It is important that both ECHA and Member States have all the tools and necessary resources in place to support the second stage and minimize problems and associated costs. More specifically we recommend that:

− Additional support to firms should be made available through ECHA and national helpdesks in preparation of the 2nd and the 3rd registration periods in cooperation with the relevant industry associations.

− Priority should be given on the availability and effectiveness of the existing support tools and mechanisms and less on the development of new tools or guidance document that can possibly lead to confusing messages.

− While the majority of guidance documents are already available in all languages, gaps should be addressed whenever they exist.

− Ensure that ECHA is adequately supported with the resources and other relevant capacity necessary to ensure – to the extent possible – the quality and efficiency of the developed IT tools and all other services related to registration. A moratorium period for changes in guidance documents and IT tools should be adopted for a significant period prior to the registration deadline.
Executive summary

- **Expand the awareness raising and information provision tools.** There are a large number of firms, especially among downstream users, that are not aware of REACH and its implications for them. Limited awareness is very often the cause of delays and additional work for firms especially in relation to supply chain communication. More specifically we proposed:
  - All efforts should be made in close cooperation with industry associations to increase awareness through additional communication campaigns at EU and national level.
  - Given that SMEs are the main target audience, alternative networks with proven capacity to reach SMEs, such as the Enterprise Europe Network, could also be considered.

- **Strengthen and coordinate market surveillance and enforcement** – A key challenge for the coming period is to ensure effective and uniform market surveillance and enforcement across the EU. There is limited experience at this stage that could also lead to more specific recommendations, but the following points should be considered:
  - Member States should ensure that the necessary resources from the relevant authorities are in place.
  - Customs’ authorities should be brought more into the picture in those countries where they are not already properly involved.
  - At the European level the existing coordination and information exchange tools (enforcement forum, enforcement projects, RIPE) could be utilised in full aiming for consistency in monitoring and inspection practices.
  - The Commission and the Member States should seek to clarify as soon as possible the requirements in relation to the notification requirement for SVHCs, in articles aiming for a unified approach across the EU.

- **Continue monitoring of market and industry developments** – This study has come at an early stage and cannot reach final conclusions on a number of aspects related to the competitiveness of industry or the operation of the single market. It is necessary to continue monitoring of the developments in the chemicals markets in a systematic way. More specifically:
  - The Commission should consider an extension of the scope of the REACH baseline study conducted by Eurostat and include indicators covering key aspects of internal market operation and competitiveness. These indicators should primarily focus on those aspects most directly affected by the REACH Regulation (e.g. availability/withdrawal of substances, new substances and new uses development, costs of compliance). In case the extension of the baseline study is not considered appropriate a separate monitoring tool could be established.
  - Additional studies in the coming periods both during and after the second registration should aim to increasing the understanding of the operation and implementation or other practical aspects of the Regulation. Particular focus should be on the way SMEs or specific sectors are affected by the Regulation or of the substitution costs involved in compliance with the Regulation.
Executive summary

- Support industry in the use of knowledge - The Commission could use existing programmes (e.g. CIP, Framework programme for research, LIFE) to support research and development activities aiming on the development and use of alternative chemical substances to replace substances of very high concern. Member States should also initiate or continue similar support schemes.
This document contains the draft final report submitted by the Centre for Strategy & Evaluation Services (CSES) LLP in respect to the assignment: 'Interim Evaluation: Functioning of the European chemical market after the introduction of REACH'.

1.1 Aim of the study

The objective of the CSES study has been to evaluate the implementation of the REACH Regulation in relation to its impact on the operation of the single market and the competitiveness of the European chemicals industry. The study aimed to:

- Evaluate the relevance, coherence, efficiency, effectiveness, sustainability and impact of the REACH Regulation in relation to the operation of the market of chemical substances.

- Identify strengths and weaknesses of the REACH implementation with respect to the dynamics of the market, consumer choice and prosperity, costs of compliance and administrative procedures. The impact on SMEs was given particular focus given the presence of relevant provision in REACH Regulation and the expectation that any discrimination against them is avoided.

- Provide recommendations to remedy the weaknesses identified during the evaluation with a view to minimising possible adverse effects of the REACH implementation.

1.2 Structure of the report

The report is structured as follows:

Section 1: Introduction

Section 2: Presentation of the background of the REACH Regulation – Presents the background of the REACH Regulation and its main provisions and mechanisms and analyses the structure of the EU chemicals industry

Section 3: Methodological framework and presentation of research tools – Describes the methodological framework used in the study and the research tools used

Section 4: Analysis of findings - Provides an analysis of the information collected in relation to the all evaluation questions raised in the terms of references and a synthesis of the findings

Section 5: Conclusions and recommendations - Summarises the conclusions of the analysis and presents the recommendations

The appendices include:

Appendix A: presents the 11 case studies conducted

Appendix B: presents the list of articles and sources of information extracted through desk research

Appendix C: the interview programme
2.1 The European chemicals industry

2.1.1 Structure of the European chemicals industry

The chemicals industry is one of the largest European industrial sectors and an important source of direct and indirect employment in many regions of the European Union (EU). In 2009, the EU chemical industry comprised some 29,000 enterprises that employed around 1.2 million employees representing 4% of the total employment in the EU manufacturing sector. 96% of the companies in the sector are SMEs – 61% with less than 9 employees – and account for 28% of sales and 35% of employment of the sector.

With a total production value of €449 billion in 2010, the chemical industry’s contribution to the EU gross domestic product amounted to 1.1% representing about 7% of the total for the manufacturing sector. This is a substantial reduction from the €684 billion production value in 2007, primarily a result of the financial crisis. CEFIC predicts an increase in the sales for the coming period but this very much depends on the fragile economic climate in Europe.

According to CEFIC, in the 10-year period from 1999 to 2009 the chemical industry production experienced an average growth rate of 0.4%, slightly higher than the 0.3% average growth rate for total EU manufacturing. However, there has been a decrease in the total employment of the sector from 1.48 million in 1999 to 1.2 million in 2009 as a result of productivity gains due to cost-saving and restructuring steps taken over the last decade. In terms of productivity, the chemical industry is the second leading manufacturing sector in Europe. Productivity rates in the EU chemical industry during the period 1999 to 2009 increased at 2.2% per annum (higher than the average in the manufacturing sector in the EU) while labour costs per employee increased at a higher rate of 3.3%.

One of the key features of the chemicals sector is its important contribution to all branches of the economy. Around 30% of the combined output of the chemical and pharmaceutical industry is sold to end users while the rest is sold as intermediate inputs. Raw materials and feedstock are transformed into tailor-made solutions for customers in the chemicals industry but also most downstream industries in almost all manufacturing sectors, in construction services and in general services. Thus, the EU chemicals industry has a key position in the value chain.

The outputs of the EU chemicals industry are typically classified in five wide ranges of products: Petrochemicals, Basic Inorganics, Polymers, Specialities and Consumer Chemicals. These sectors have rather different characteristics.

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10 Eurostat Structural business statistics:
11 http://www.cefic.org/Documents/FactsAndFigures/FF%20One%20page%20per%20section/Growth_4_EU_Chemical_outlook.pdf
13 According to the input-output tables for the German economy for 2007, besides the chemicals and the rubber and plastics sector, the automotive, the textiles, wood processing, other machinery, basic metals are the sectors with the highest levels of use of chemicals. In addition, the agriculture sector and the health services sector make a high use of chemicals.
Basic chemicals (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% and 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.

Among the EU countries, Germany is the largest chemicals’ producer in Europe, followed by France, Italy and the United Kingdom (see table 2.1). Together, these four countries generated over 60% of the sales of chemicals by EU countries. The share rises to 88% when including the Netherlands, Spain, Belgium and Ireland. Poland has the largest share from “new” EU countries holding a 2.1% of total EU chemicals sales and occupying close to 6% of the total workforce in the sector. In contrast, the Baltic countries, Cyprus and Malta have particularly small chemical industry sectors representing no more than 0.02% of the total turnover of the industry.

Table 2.1 – Key data for the chemicals and chemical products manufacturing sector (excluding pharmaceuticals) by country (2008) – ranked by turnover size

<table>
<thead>
<tr>
<th>Country</th>
<th>Number of enterprises</th>
<th>Number of persons employed</th>
<th>Production value (million €)</th>
<th>Turnover (million €)</th>
<th>Cumulative share in total turnover</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU27</td>
<td>29,073</td>
<td>1,255,822</td>
<td>541,353</td>
<td>495,078</td>
<td></td>
</tr>
<tr>
<td>Germany</td>
<td>2,891</td>
<td>323,518</td>
<td>134,822</td>
<td>116,027</td>
<td>23.4%</td>
</tr>
<tr>
<td>France</td>
<td>3,288</td>
<td>163,973</td>
<td>78,549</td>
<td>69,303</td>
<td>37.4%</td>
</tr>
<tr>
<td>UK</td>
<td>3,113</td>
<td>132,201</td>
<td>68,801</td>
<td>64,305</td>
<td>50.4%</td>
</tr>
<tr>
<td>Italy</td>
<td>5,022</td>
<td>124,236</td>
<td>53,950</td>
<td>51,774</td>
<td>60.9%</td>
</tr>
<tr>
<td>Netherlands</td>
<td>760</td>
<td>44,042</td>
<td>49,752</td>
<td>46,394</td>
<td>70.3%</td>
</tr>
<tr>
<td>Spain</td>
<td>3,777</td>
<td>98,574</td>
<td>36,859</td>
<td>34,685</td>
<td>77.3%</td>
</tr>
<tr>
<td>Belgium</td>
<td>686</td>
<td>45,712</td>
<td>30,696</td>
<td>29,077</td>
<td>83.1%</td>
</tr>
<tr>
<td>Ireland</td>
<td>147</td>
<td>12,909</td>
<td>23,031</td>
<td>22,689</td>
<td>87.7%</td>
</tr>
<tr>
<td>Poland</td>
<td>2,110</td>
<td>81,839</td>
<td>12,172</td>
<td>11,534</td>
<td>90.0%</td>
</tr>
<tr>
<td>Sweden</td>
<td>792</td>
<td>22,927</td>
<td>8,489</td>
<td>7,812</td>
<td>91.6%</td>
</tr>
<tr>
<td>Austria</td>
<td>349</td>
<td>16,990</td>
<td>6,997</td>
<td>6,594</td>
<td>93.0%</td>
</tr>
<tr>
<td>Finland</td>
<td>297</td>
<td>13,827</td>
<td>6,425</td>
<td>5,899</td>
<td>94.1%</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>1,446</td>
<td>30,807</td>
<td>5,353</td>
<td>4,981</td>
<td>95.2%</td>
</tr>
<tr>
<td>Hungary</td>
<td>577</td>
<td>14,940</td>
<td>4,181</td>
<td>3,805</td>
<td>95.9%</td>
</tr>
<tr>
<td>Portugal</td>
<td>881</td>
<td>14,209</td>
<td>4,112</td>
<td>3,802</td>
<td>96.7%</td>
</tr>
<tr>
<td>Denmark</td>
<td>256</td>
<td>13,106</td>
<td>3,683</td>
<td>3,657</td>
<td>97.4%</td>
</tr>
<tr>
<td>Slovenia</td>
<td>164</td>
<td>13,887</td>
<td>2,905</td>
<td>2,648</td>
<td>98.0%</td>
</tr>
<tr>
<td>Romania</td>
<td>1,023</td>
<td>36,446</td>
<td>2,832</td>
<td>2,775</td>
<td>98.5%</td>
</tr>
<tr>
<td>Greece</td>
<td>363</td>
<td>12,021</td>
<td>2,510</td>
<td>2,316</td>
<td>99.0%</td>
</tr>
<tr>
<td>Slovakia</td>
<td>172</td>
<td>9,646</td>
<td>1,826</td>
<td>1,738</td>
<td>99.3%</td>
</tr>
<tr>
<td>Lithuania</td>
<td>93</td>
<td>5,654</td>
<td>1,479</td>
<td>1,491</td>
<td>99.6%</td>
</tr>
</tbody>
</table>
In relation to the trading of chemicals, the data on the chemicals wholesale sector indicate a similar dominant role of the same eight countries that represent 85% of the total turnover. In terms of employment or the number of enterprises a number of countries (Greece, Portugal, Bulgaria and Romania), have a rather disproportionately high number when compared against their low turnover shares.

Table 2.2 - Key data for the chemicals wholesale sector by country ranked by turnover (2008)
Background

In terms of specialisation, the analysis of Eurostat data reveals that certain member states focus on certain sectors. The Lithuanian, Irish, Dutch and Finish chemicals’ sectors have a very strong concentration in the basic chemicals subsector (petrochemical and other organic industries) representing over 60% of the total turnover of the chemicals industry. Austria has a particular, in relative terms, presence in man-made fibres. The main chemicals’ producing countries – Germany, France, Netherlands, Spain and the UK – have a significant presence in most sub-sectors.

Table 2.3 - Chemical industry specialisation of EU Member States (based on share of value added in manufacturing in comparison to EU average) – 2007 data

<table>
<thead>
<tr>
<th>Chemical industry subsector</th>
<th>Share in total EU manufacturing value-added</th>
<th>Top 5 producing countries (share in total EU)</th>
<th>MSs where sector is important 14 (% in the chemicals sectors turnover)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basic chemicals</td>
<td>3.72%</td>
<td>DE (25%), UK (13%), NL (12%), FR (12%), BE (6.8%)</td>
<td>LT (90%), IE (64%), FI (68%), NL (74%)</td>
</tr>
<tr>
<td>Pesticides and other agrochemical products</td>
<td>0.16%</td>
<td>DE (35%), FR (28%), UK (10%), IT (8%), ES (5.7%)</td>
<td>CY (5%), FR (3%)</td>
</tr>
<tr>
<td>Paints, varnishes, printing ink</td>
<td>0.69%</td>
<td>DE (26%), IT (16%), UK (12%), FR (10%), ES (9%)</td>
<td>EE (48%), CY (21%), GR (13%), PT (13%), SL (12%)</td>
</tr>
<tr>
<td>Soap, detergents</td>
<td>0.97%</td>
<td>FR (29%), DE (18%), IT (14%), UK (13%), ES (9%)</td>
<td>PL (23%), FR (17%), GR (18%), ES (14%), IT (14%), BG (14%)</td>
</tr>
<tr>
<td>Other chemical products</td>
<td>0.92%</td>
<td>DE (29%), FR (15%), IT (14%), UK (13%), ES (8%)</td>
<td>BG (13%), DK (12%), EE (11%), IT (10%), SL (10%), ES (10%)</td>
</tr>
<tr>
<td>Man-made fibres</td>
<td>0.15%</td>
<td>DE (36%), IT (14%), NL (10%), AT (8%), ES (7%)</td>
<td>AT (9%), SK (10%)</td>
</tr>
</tbody>
</table>

Source: Eurostat Structural Business Statistics, 2007

At the same time, the structure of the market for the EU chemical industry has changed significantly over the last 15 years. In 1995, sales to home markets represented around 55% of the total. This was down to 25% by 2009. By contrast, sales to other EU partner countries more than doubled between 1995 and 2009 15, from €98 to €222 billion. Intra-EU trade represents close to 50% of the total sales. The

14 Countries where the share of sector in manufacturing value added is higher than that of the EU27 in total.

accession of ten new EU member states in 2004 and 2007 created an additional intra-EU trade boost. In parallel, extra-EU sales have also increased significantly from €55 billion in 1995 to €117 in 2009.

2.1.2 Competitiveness of the European chemicals industry

There are a number of indicators suggesting that the European chemical sector is losing ground with regard to its competitiveness. Compared to 1999, the EU share of world chemical sales has declined by 8.1 percentage points (from 32.1% in 1999 to 24% in 2009). While still in a strong position, it has lost its top ranking in terms of sales to Asia, mainly due to the rise of China but also the Middle East. The Trade Competitiveness Indicator (TCI) of the overall EU chemicals industry declined from 21.6 % to 16.5 % in the period 2003 to 2007, indicating that imports are growing faster than exports.

Further analysis indicates variations among individual sub-sectors. According to CEFIC data for the period 1999 – 2007 the EU has increased its trade surplus in the speciality chemicals with most of its main trading partners (except with advanced chemical producing countries like US, Japan and China). The same applies to consumer chemicals and polymers. In contrast, the trade balance has been deteriorating during the last 5-10 years in the case of basic organics (petrochemicals, fermentation products) and even more so for basic inorganics (such as fertilisers) where EU has a trade deficit (mainly against Middle East countries).

Generally speaking, the European chemicals industry is doing better in innovation-driven sub-sectors than in more cost-orientated basic chemicals sub-sectors where investment in larger facilities, access to cheap raw material and energy costs provide a comparative advantage to facilities in China, Russia or the Middle East. Furthermore, as some important downstream industries (e.g. textiles) have moved out of Europe, manufacturing of products like dyes and fibres has also followed.

At this point, the competitiveness of the chemicals industry is very much dependent on the access to highly skilled labour and its innovative capacity. Employees with medium and high education account for 80% of the workforce with the share of the high education segment continuously increasing. However, discussions with CEFIC suggest that shortage of skilled workforce is a problem for the chemicals industry. Furthermore, the EU chemicals sectors account for 8% of total EU manufacturing spending in R&D (data 2003), and has high R&D intensity in relation to most other EU manufacturing sectors. However, compared to its counterparts, the EU chemicals industry has for some time (period 1991-2007) had a lower R&D intensity than that of the Japanese or the US chemicals sectors (2.3%) - 2.1% of sales in Europe in comparison to 5.2% in Japan and 2.3% in the US.

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17 An indicator that compares the trade balance to the total trade (exports plus imports) of a region
19 CEFIC, Facts and figures
2.2 Background to the REACH Regulation

Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) applies to all categories of chemical substances manufactured, imported, used as intermediates or placed on the market unless explicitly excluded by the Regulation. The Regulation was voted by the European Parliament and of the Council on 18 December 2006, and came into force on 1 June 2007. The Regulation was amended by Regulation 1272/2008 in relation to the classification, labelling and packaging of substances and mixtures. Furthermore, in the period 2008–2010 a number of amendments to the Annexes of REACH Regulation were introduced.

2.2.1 Reasons for introduction of Regulation – objectives

The introduction of the Regulation is the main output of a new chemicals policy put forward by the Commission as set out in White Paper 'Strategy for a future Chemicals Policy'.

The introduction of the new regulatory system for the safe use of Chemicals was considered necessary to address the increasing concern that the then existing regulatory framework did not provide sufficient protection for workers, consumers and citizens' health and the environment.

There had been an increasing incidence of diseases over the last decades in which certain chemicals appeared to play a causative role. However, there was in general a lack of knowledge about the impact of many chemicals and the existing legal framework did not ensure the provision of the necessary information that would allow taking the necessary precautionary measures. This could have had a negative effect on public health but also on the trust of the public concerning the use of and exposure to chemicals with possible significant negative impacts to the chemical industry.

The Commission conducted a review of the main legal instruments applicable at that time that regulated the testing, risk reduction measures and duties regarding safety information for a range of chemical substances. The review indicated the presence of a number of problems of the existing legal framework that had to be addressed:

- The legislative framework for chemical substances was a mixture of Directives and Regulations which had developed historically and set different rules for "existing" and "new" chemicals. Under Regulation (EC) 793/93 the distinction was based on the cut-off date of 1981. Chemicals that were reported as being on the European Community market between 1 January 1971 and 18 September 1981 were called "existing" chemicals. In 1981, these numbered more than 100,000 different substances. Chemicals introduced to the market after 1981 were termed "new" chemicals. While these new chemicals (more than 3800) had to be tested before being placed on the market, there were no such provisions for "existing" chemicals. Thus, there was general lack of knowledge regarding almost 99% of the chemicals that had been placed in the market before 1981.
- According to Directive 67/548 "new chemicals" had to be notified and tested even in the case of volumes of production or use as low as 10 kg per year. This created a barrier to innovation for the EU chemicals industry by discouraging research and invention of new substances and favoured the use of existing substances over new ones.

21 CEFIC (2010), Facts and figures.
The allocation of responsibilities was considered inappropriate as public authorities were responsible for undertaking comprehensive, rather than targeted and use-specific, risk assessments of substances. Enterprises that manufactured, imported or used the substances did not have any responsibility. Since 1993 only 141 chemicals marketed in volumes of over one tonne per year (out of more than 30,000) had been identified as priority substances for risk assessment. Recommendations for risk reduction were only available for a limited number of those chemicals. In general the risk assessment process and the subsequent introduction of risk management measures were slow and resource-intensive and did not allow the system to work efficiently and effectively.

The legislation required the manufacturers and importers of chemicals to provide information, but did not impose any obligations on the downstream users (industrial users and formulators) unless the substance was supplied further down the supply chain. Information on uses of substances was difficult to obtain and information about the exposure arising from downstream uses was generally scarce.

There were important problems in establishing liability in relation to the marketing and use of dangerous substances, and ensuring that producers assume responsibility for their products. Causal connections between substance and resulting damage could not be made in the absence of adequate test data on the effects of substances.

### 2.2.2 Objectives of REACH

Taking into account these conclusions and following a broad stakeholder consultation, the 2001 White Paper "Strategy for a future Chemicals policy" formulated a set of political objectives and the key principles of a new system to achieve them. According to the White Paper, the overriding goal of the Commission intervention was to achieve a sustainable development in the chemicals industry within the framework of the Single Market. In order for this goal to be achieved, a new a system for the Registration, Evaluation and Authorisation of Chemicals (REACH) needed to be introduced that could serve the following objectives in a balanced way:

1. **Ensure protection of human health and the environment** by the registration and testing of all – existing and new – chemical substances placed in the market and by imposing authorisation requirements and restrictions to substances that give rise to high concern. The new system was intended to transfer the burden of proof of the safety of chemicals and the generation and dissemination of the necessary information to industry and also include downstream users of chemical substances. In addition, the system was intended to promote the substitution of hazardous chemical substances by less dangerous ones.

2. **Maintain and enhance the competitiveness of the EU chemical industry** by stimulating innovation and minimising, to the extent possible, the resource implications of the implementation of the Regulation for industry.

3. **Prevent the fragmentation of the internal market** on the basis of full harmonisation of the market.

4. **Increase transparency** by enhancing access to information on chemicals for consumers in order to make informed decisions about the substances they use and for enterprises to understand the regulatory process.

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5. **Ensure integration with international efforts** in view of the global nature of the chemicals industry and the trans-boundary impact of certain chemical substances and in order to avoid the duplication of test efforts. This also had to include the obligation on importers to test their chemicals, in order to avoid the competitiveness of the EU chemical industry being compromised.

6. **Promote non-animal testing** and minimising test programmes balancing the protection of human health and the environment against protection of the welfare of laboratory animals.

7. **Conform with EU international obligations under the WTO** ensuring that no unnecessary barriers to trade could be created and that would be no discrimination against imported substances and products.

Furthermore, the Regulation states that 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.

A fundamental principle adopted for the development of the system was the Precautionary Principle. According to the Precautionary Principle, if there is reliable scientific evidence that a substance may have an adverse impact on human health and the environment but there is scientific uncertainty about the nature or the magnitude of the potential damage, decision-making must be based on precaution in order to prevent damage to human health and the environment. However, according to the relevant Commission Communication, when action is taken on the basis of the precautionary principle, it should be proportional, non-discriminatory, consistent with measures already taken, balancing costs and benefits, and subject to review.  

On the basis of impact assessment studies conducted during the preparation phase of the REACH Regulation, the Commission took the view that the overall cost of the legislation was estimated at €2.8 to 5.2 billion over the first eleven years period, with about 90% of the costs relating to the testing and the registration requirements. The total of €2.8 to 5.2 billion also includes the costs to downstream users of switching their technologies to alternatives after a number of substances would be removed from the market following a decision not to register them.

The costs were considered justified and proportionate as REACH is expected to have occupational and public health and environmental benefits. In an illustrative scenario analysed by the Commission, the potential scale of the health benefits of REACH was estimated to approach €50 billion over a 30 year period. REACH is also expected to contribute to reduced pollution of air, water and soil and reduced pressure on biodiversity.

In parallel, REACH requirements are expected to unlock innovation, as new substances will require similar testing to that for existing ones. The new chemicals management system should also generate a vast amount of information on the properties of the substances and their uses down in the supply chain.

This information, otherwise unavailable to the actors in the supply chain, will allow them to address the needs of the market with a greater precision, thereby stimulating innovation and creating new jobs.

The position for SME manufacturers and importers is also expected to be improved by the rise in the tonnage threshold for the registration of substances from the previous level of 10 kg per year for new chemicals to 1 tonne per year under REACH. SMEs should benefit from the exemption from in vivo toxicity testing for phase-in substances manufactured/imported at 1 to 10 tonnes per year.

Another expected benefit for the industry comes from the fact that testing for higher tonnage substances is tailored to risk, and the time for product and process oriented research and development is extended from one to five years by giving an exemption from registration for pre-commercial substances.

Finally, by identifying and restricting chemicals of high concern, REACH was intended to increase consumer and investor confidence, as well as employee and community trust therefore potentially leading to a more positive business environment and a more competitive, innovative, and economically sustainable chemical industry.

2.3 Provisions of the REACH Regulation

The key characteristic of the REACH Regulation (1907/2006) is the requirement for producers and importers of chemicals to prove that their substances are safe before they can be placed on the market. Manufacturers and importers of chemicals need to identify and manage risks linked to the substances they produce and market.

REACH applies to the manufacture, placing on the market or use of substances on their own, in mixtures or in articles. The obligations do not directly apply to the preparations or articles but to the substances contained in them. All substances are covered by the REACH Regulation unless they are explicitly exempted. Exemptions introduced include radioactive substances, non-isolated intermediates (substances which are not intentionally removed from the equipment in which the chemical processing takes place), wastes, substances under customs supervision and, if Member States choose, substances necessary for the interests of defence. Furthermore, other substances (e.g. polymers or substances used for research and development) are excluded from certain requirements of REACH such as the registration procedure.

The REACH Regulation requires the registration of about 30,000 substances for which new data will have to be produced. For those marketed at 1 to 10 tonnes per year only a limited number of tests are required. However, for those marketed at over 10 tonnes per year a more comprehensive testing is required. This system does not apply to many of the existing substances in EINECS which are site-limited intermediates and therefore are not ‘placed on the market’ in the meaning of the Regulation.

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27 Two or more substances mixed together forming a mixture or a solution.

28 An object that has been given a specific shape, surface or design so that it can be used for a specific purpose such as cars, textiles, electronic chips.
Another key change introduced by REACH is the departure from the previous system for general industrial chemicals based on the distinction between "existing substances" i.e. all chemicals declared to be on the market in September 1981 (about 100,000 listed on the EINECS \(^{29}\)), and "new chemicals" i.e. those placed on the market since that date (about 3,800 listed on the ELINCS \(^{30}\)). Indeed, with the adoption of REACH, the chemical legislation is now based on a single, tonnage -tiered, system applicable to all commercial chemicals.

However, the Regulation distinguishes between **Phase-in** and **non-Phase-in** substances. Non-phase-in substances are those substances that were not produced or marketed prior to the entry into force of the Regulation. Phase-in substances are the substances listed in the EINECS, \(^{31}\) those that had been manufactured in the Community but not placed on the Community market in the last 15 years and those that had been notified in accordance with Directive 67/548/EEC, but that do not meet the definition of a polymer as set out in REACH Regulation. For these two groups there are certain differences in the registration procedures as described below.

### 2.3.1 Key procedures

The implementation of the Regulation is based on some key procedures that set requirements and tasks for the manufacturers, importers and downstream users of chemical substances and require the development of the necessary infrastructure and a number of actions on behalf of the Agency, Member States’ authorities and the Commission.

**Pre-registration**

In the case of phase-in substances a manufacturer or importer can continue manufacturing and importing them for several years until the registration deadline is reached. However, in order to benefit from this transition period, they were required to pre-register them during the period between 1 June 2008 and 1 December 2008. The objective of pre-registration was also to facilitate sharing of data between registrants, reduce the costs to industry, and, where possible, to reduce unnecessary testing, especially on vertebrate animals. According to the ECHA database, a total of 2.7 million registrations for 143,000 substances were submitted in the pre-registration period by around 65,000 companies. \(^{32}\)

A late pre-registration process was also provided in cases where phase-in substances or articles containing these substances were manufactured or imported for the first time in more than one tonne per year by a company after December 2008.

**Registration**

For substances produced or imported in quantities of one tonne or more per year, per company, manufacturers and importers need to demonstrate that they have obtained information on the substances they manufacture or import, and use this information to assess the risks arising from the substances.

\(^{29}\) European Inventory of Existing Commercial chemical Substances .

\(^{30}\) European list of notified chemical substances .


\(^{32}\) http://apps.echa.europa.eu/preregistered/pre-registered-sub.aspx
uses and to ensure that the risks which the substances may present are properly managed. This should be done by means of a registration dossier, to be submitted to the Agency.

The registration requires submission of a technical dossier, for substances in quantities of 1 tonne per year (tpy) or more, and a chemical safety report, for substances in quantities of 10 tpy or more. The dossier must contain information on the properties, uses and on the classification of a substance plus guidance on safe use. Information requirements are set out in the annexes of the Regulation and vary depending on the tonnage in which the substance is manufactured or imported, and the needs of the chemical safety assessment. General rules are set out for the use of existing information, for use of various techniques (e.g. (Quantitative) Structure Activity Relationship) and for waiving of tests in order to minimize the use of animal tests. The Chemical Safety Report documents the hazards and classification of the substance and the assessment as to whether the substance is persistent, bio-accumulative and toxic (PBT) or very persistent and very bio-accumulative (vPvB). The contents of the report and how Chemical Safety Assessment is to be conducted are determined in Annex I of the Regulation and are supplemented by a technical guidance document.

For the non-phase in substances registration is required before placing them or an article containing them in the market. Prior to registration, potential registrants need to submit to inquire from ECHA whether a registration has previously been submitted for the same substance. An inquiry dossier needs to be submitted. Registration can not be initiated before the Agency responds with an inquiry number and a possible indication of the need for a joint registration. The inquiry process applies also to registrants of or phase-in substances that were not pre-registered.

For phase-in substances the time limits for the registration vary depending on two broad criteria, volume of production or imports per year and level of risk. For chemicals produced at an annual volume of more than 1000 tonnes the registration deadline was initially set at three years and subsequently extended to 3.5 years (30 November 2010). For chemicals produced or imported at 100 - 1000 tonnes per year the deadline for registration was set at 6 years (May 2013) and for those produced at 1 - 100 tonnes the registration deadline is set for May 2018 (11 years). Highly hazardous substances produced at more than one tpy also had to be registered by 30 November 2010. These include carcinogenic, mutagenic or toxic to reproduction substance (CMR), persistent, bio-accumulative and toxic substances (PBTs), and those that are very persistent and very bio-accumulative (vPvBs). Furthermore, substances classified as dangerous for the aquatic environment with R50/53 manufactured or imported at more than 100 tpy also needed to be registered by that deadline.

Certain categories of chemicals manufactured or imported in volumes of more than one tonne/year are exempted from the Registration process. These are defined in Annexes IV and V of the Regulation. It includes substances exempted from the previous Existing Substances Regulation (Reg. 793/93), with the addition of cellulose pulp and those that meet criteria taken from experience in the operation of the New Substances Directive 67/548. Certain classes of substance are also exempt unless they are chemically modified. They include minerals, ores, ore concentrates, cement clinker, natural gas, liquefied petroleum gas, natural gas condensate, process gases and components, crude oil, coal and coke. Basic elemental substances (hydrogen, oxygen, several noble gases and nitrogen) are also exempt. Substances that had been notified in accordance with Directive 67/548/EEC are regarded as registered although the registration shall be updated if production or import is increased to a higher tonnage levels, or if new information becomes available. Finally, substances used as on-site isolated intermediates or transported isolated intermediates have less demanding registration requirements.
According to the data provided by the ECHA, 26,337 dossiers had been submitted by the end of the first quarter of 2011 covering around 4,300 distinct chemical substances. The great majority of registrations (23,678) were submitted in 2010, the year of the first registration deadline. 80% of the registrations dossiers submitted were full registrations while the remaining concerned isolated intermediates. 3,400 of the total 4,300 substances were phase-in substances and the remaining 900 were non-phase in substances.\(^{33}\)\(^{34}\)

A third new element of the Regulation is the bringing of Downstream Users (DU) into the system. DUs may be industrial users of chemicals, formulators of preparations (e.g. paint producers) or users of chemicals such as oils and lubricants in other industrial processes or producers of articles that contain chemical substances (e.g. cars, chips). DUs generally do not have registration obligations but they cannot use or place on the market substances unless there have been registered by their suppliers. Furthermore, they are required to consider the safety of their uses of substances, based primarily on information received from their suppliers in the form of Safety Data Sheets (see below) and to apply the appropriate risk management measures. They are also required to communicate information on dangerous substances and preparations further down the supply chain including the provision of the necessary Safety Data Sheets.

DUs may want to keep their use confidential or decide to use a substance outside the conditions described in the exposure scenario(s) in the SDS. In such cases they may provide to suppliers a general condition of use to be included in the safety data sheets or perform themselves the necessary chemical safety assessment (CSA) and develop the exposure scenarios for the intended uses.

**Evaluation**

REACH includes three different evaluation processes. The ECHA is responsible for two of those evaluations:

- A Dossier evaluation to be done early on by the Agency to check the quality of the registration dossiers submitted. It shall check the compliance with the requirements laid down for registration in the Regulation. The Dossier evaluation is expected to cover around 5% of all dossiers submitted.
- Evaluation of testing proposals submitted as part of the registration dossier for substances over 100 tonnes annually. In order to prevent unnecessary animal testing the Agency is expected to check the testing proposals submitted as part of the registrations before such tests are performed. Currently, the Agency is working on evaluating the approximately 500 proposals for tests submitted during the first registration process. The deadline for responding to the testing proposal submitted by the first deadline is December 1\(^{35}\) 2012 while for non-phase in substances it is 180 days from the date of the receipt of the dossier.

The decisions of ECHA in relation to the above evaluation may lead to the conclusion that no further action is required, that additional information is required or to the rejection of the testing proposal.

A third type of evaluation – the substance evaluation - is expected to take place over time and is mainly responsibility of the Member States Competent Authorities. The objective is to clarify suspicions of risks.
to human health or the environment on a basis of a priority list of substances developed jointly by ECHA and the Member States Committee. The Agency also identifies the Member State who shall carry out the evaluation of those priority substances.

The results of the evaluation may lead authorities to the conclusion that additional action needs to be taken under the restrictions or authorisation procedures in REACH, or that information needs to be passed on to other authorities responsible for relevant legislation.

**Authorisation**

For substances of very high concern (CMR, PBTs, vPvBs and others defined on a case by case basis such as endocrine disruptors) an authorisation is required for their use and their placing on the market. Substances of very high concern (SVHC) are expected to be identified by the Agency or the Member States on the basis of a dossier in accordance with Annex XV. A candidate list of substances for authorisation has been developed taking into consideration comments from interested parties. So far 53 substances have been included in the list, although a roadmap agreed by the Commission and the Agency is expected to bring the number of chemicals on the list of SVHCs to 135 by 2012. The candidate list is followed by a prioritisation process involving ECHA and the Member State that includes a decision as to which substances on the initial candidate list are to be covered (included in a priority list), which uses may be exempted from the authorisation and which deadlines have to be met.

For those substances that require authorisation, manufacturers, importers or downstream users need to apply for an authorisation for each use of the substance including an analysis of possible substitutes and including information on relevant research and development activities. If the analysis shows that suitable alternatives are available then a substitution plan shall also be described. Authorisation shall be granted if the applicant can demonstrate that the risk from the use of the substance is adequately controlled. It may also be granted if the socio-economic benefits outweigh the risks and there are no suitable alternative substances or processes.

All authorisations will be reviewed after a certain time. If suitable substitutes have become available by the time of the review, the Commission may amend or withdraw the authorisation.

The introduction of a substance in the candidate list means also that manufacturers or importers of articles have to submit a notification to ECHA if these substances are present in the articles in concentration of 0.1% weight per weight and in total quantities of over 1 tpy. The does not apply in case exposure of humans and the environment can be excluded under normal conditions of use.


37 A broader list of 356 substances has been identified by NGOs and public interest groups and has been included in a REACH SIN list, [http://www.chemsec.org/list/about-sin](http://www.chemsec.org/list/about-sin)
Restriction

In the case of certain substances where there is an unacceptable risk to health or the environment restrictions at a Community level concerning the manufacture, placing on the market or use of or prohibition of any of these activities may be imposed.

Proposals for restrictions may be prepared by a Member State or by the Agency on behalf of the Commission in the form of a structured Dossier that shall demonstrate that there is a risk to human health or the environment that needs to be addressed at Community level and to identify the most appropriate set of risk reduction measures.

Classification and Labelling requirements

Besides registration, REACH requires manufacturers and importers to classify and label all substances subject to registration and/or authorisation, and to submit this information to the Agency to be included in an inventory of chemical substances. Annex VI of the Regulation sets specific rules and requirements related to this.

The inventory of hazard classification is expected to be developed in 2011 on the basis of the notifications submitted by industry and the information provided in the registration dossiers. The objective is to eliminate any divergences between classifications of the same substance over time. Member States or the Agency can propose – on the basis of dossiers following the requirements of Annex XV of the Regulation - the harmonised classification and labelling of substances as of very high concern.

The criteria and obligations relating to classification and labelling had been carried from the Directive 67/548/EEC concerning dangerous substances and the dangerous preparations Directive 1999/45/EC. However, Regulation 1272/2008 (CLP Regulation) amended these two Directives and complements the REACH Regulation. It incorporates the classification criteria and labelling rules of the Globally Harmonised System of classification and labelling of chemicals (GHS) agreed at UN level.

Substance Information Exchange Forums (SIEFs)

In order to make the registration process less bureaucratic, and to reduce the costs to individual companies, group applications are required for registering similar substances. According to Article 29 of the Regulation all registrants (or potential registrants), downstream users and third parties who submitted information during the pre-registration process for the same phase-in substance, are expected to participate in a substance information exchange forum (SIEF). By September 5 2011 a total of 3,455 SIEFs had been formed. 38

The purpose of SIEFs is to help share information about each substance, to avoid duplication of testing, and agree on classification and labelling where there are differences. In the case that a SIEF participant has conducted a relevant study, it shall share the results and be compensated by the other members of the SIEF. Where an appropriate study does not exist, one of the members of SIEF shall conduct the

necessary tests and, upon payment, share the results with the other SIEF participant. A key role in each SIEF is that of the Lead Registrant that is responsible for the submission to the Agency of the joint dossier for the registration of the specific substance. The other members are only required to submit company-specific information.

Opt-outs from this mandatory principle can be granted to companies if they prove that disclosure would harm their commercial interests or violate their intellectual property rights.

SIEFs do not have any specific legal form and represent an informal way of exchanging information. The Agency does not participate in the operation of SIEFs but operates as a facilitator of their operation. It has established procedures for resolving disputes concerning data sharing among the members of the SIEF. In order to facilitate the creation of the SIEFs, the Agency places companies who pre-registered substances with the same name in the same pre-SIEF as a mechanism to facilitate the formation of the SIEF. In addition, the role of a SIEF formation facilitator was created for companies that wanted to take the initiative for the formation of a SIEF and to coordinate discussions.

Furthermore, according to article 26 of the Regulation an inquiry process is required for all firms that want to register a non-phase in substance or a phase in substance that has not been pre-registered. The aim is for ECHA to assess if this substance has already been registered and to point to already existing studies.

While SIEFs include all firms that have registered a single similar substance, some firms may also organise themselves in consortia to structure how they can work together in order to comply with the requirement of the Regulation, including the collection of relevant data and the development of the joint registration dossiers. Consortia may not include all members of the SIEF and may also work for the preparation of more than one registration dossiers. Members of SIEF that are not members of consortia have the right to access the data required for the submission of the application on the basis of a fee paid to reimburse part of the costs incurred by the consortium members. According to Chemical Watch consortia database a total of 257 consortia have been formed to this point.

2.3.2 Communication in the supply chain – Safety Data Sheets

Communication among firms in the supply chain is another key element of the Regulation. Manufacturers and importers of substances and downstream users are expected to communicate information on the properties of substances and their use in order to ensure their safe use. The primary tool for information transfer from manufacturers and importers to Downstream Users and distributors is the Safety Data Sheet (SDS) that is typically prepared by manufacturer s or importers for all dangerous substances or preparations. The content of the SDSs is described in Annex II of the Regulation. In general, SDSs follow the same principles as before REACH but, for certain categories of substances, they must also include exposure scenarios specifying the conditions under which the substance or preparation can be used safely, for uses that have been identified. On the basis of this information, Downstream Users should ensure that they use a substance within the conditions described in the SDS, and to apply these conditions. In case that a use is not included they need to inform their supplier in order to update their registration or to submit their own chemical safety report.

39 Chemical watch, http://chemicalwatch.com/REACH_consortia
Cooperation and exchange of information between Downstream Users and suppliers is considered necessary to help identify the various uses to be described in the Safety Data Sheets and for the development of relevant exposure scenarios as part of the registration process.

In addition to the requirements for information sharing between different actors in the supply chain, Article 35 of the Regulation provides for the right for workers and their representatives to access the information provided in the SDS, and the other relevant documents described in the Regulation, in relation to substances or preparations that they use or may be exposed to in the course of their work. Similarly, the Regulation provides for the right for the general public to access information held by the Agency concerning the chemical substances registered, their properties and the total volumes produced. Certain information of commercial interest should not be disclosed unless it is necessary to protect human health, safety or the environment.

2.3.3 Support tools

To ensure support to all REACH processes, Information Technology tools have been developed to store and exchange information and data on chemicals. They include REACH IT, IUCLID5, CHESAR all run by the ECHA.

The objective of REACH-IT is to enable interested parties to submit, retrieve, exchange, evaluate, treat and view information on chemical substances. It consists of three main parts:

- An industry-focused website addressed to manufacturers, importers, and downstream users where a company can pre-register or make inquiries on substances, submit registrations, download invoices and view the status of submitted registrations and payments. In addition, it will allow online preparation of certain types of dossier.
- An Authorities-focused website addressed to the Agency and Member States’ Competent Authorities staff to support communication and enable them to fulfill their various tasks.
- A dissemination-focused website addressed to the general public where non-confidential data on chemicals and information on the status of those chemicals are provided.

IUCLID5 (International Uniform Chemical Information Database) is the database that enables firms to prepare a registration dossier as well as to prepare other types of dossiers. IUCLID5 uses internationally harmonized formats for reporting data on chemicals. A company can use IUCLID5 to collect, store and maintain relevant data on its substances in order to prepare a dossier that can then be submitted through REACH-IT.

CHESAR tool has been designed to help companies carry out their Chemical Safety Assessments (CSA) and prepare their Chemical Safety Reports (CSR). The tool was developed by ECHA as a plug-in to IUCLID 5.

The Agency is responsible for the development, operation and maintenance of the above tools and the possible development of new tools or updated versions to respond to the procedural demands of the regulation to ensure the safe and secure access to the information provided. Furthermore, additional navigation, guidance documents and other information provided through the ECHA website is expected to support the implementation of the Regulation.
2.3.4 **REACH requirements for firms in the supply chain**

The REACH Regulation sets requirements for almost all actors that are directly or indirectly involved with the chemical industry. In order to assess the impact of the Regulation it is necessary to identify the various actors along the supply chain, understand their responsibilities and how they are expected to interact.

Manufacturers and importers of basic chemicals and preparations represent the constituents of the chemical industry with most obligations at all stages of REACH. Similar roles apply to both producers and importers of articles that contain chemical substances intended to be released. The Regulation has however also brought the downstream users of chemicals into the system by introducing a number of obligations. A number of sub-sectors inside the chemical industry have a role which is first and foremost one of a downstream user role. Their activities tend to include the mixing of chemical substances in formulations (e.g. manufacturers of dyes, detergents, perfumes, aerosols). Outside the chemical sector, a large number of manufacturing activities and processes require the use of chemicals either as intermediate inputs for the production of the final products or lead to the production of articles that contain chemicals that are not expected to be released under normal conditions of use. These are all considered downstream users for the purposes of the regulation, and the same categorisation applies to the importers of such articles.

In addition, distributors and retailers of chemicals substances or of articles that contain chemical substances have certain obligations under REACH related to delivering information along the supply chain and passing information on to consumers.

Finally, the role of Only Representatives (ORs) has been introduced under Article 8 of the Regulation to allow manufacturers not based in the EU to register their substances instead of relying on importers.

The following table provides a summary of the responsibilities and obligations of the different types of actors along the supply chain.

**Table 2.3 - Categories of actors in the supply chain and their responsibilities and obligations under REACH**

<table>
<thead>
<tr>
<th>Actors across the supply chain</th>
<th>Type of sectors involved</th>
<th>Responsibilities/roles under REACH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturers of chemical substances (on their own or in preparations)</td>
<td>NACE 241, 247 (Basic organics and inorganics, plastics, gases, man-made fibres)</td>
<td>Pre-registration if phase-in substance Registration for phase-in and non-phase in substances Enquiries for new uses of non-phase in phase in substances and non-phase in substances Authorisation if substance in Annex XIV Compliance with restriction requirements if substance in Annex XVII Provision of necessary information to customers (downstream users and distributors) using SDS if substance is dangerous or in the candidate list.</td>
</tr>
<tr>
<td>Importers of chemicals substances (on their own or in preparations)</td>
<td>Wholesale and retail</td>
<td>As above</td>
</tr>
</tbody>
</table>
### Background

#### 2.1 Actors across the supply chain

<table>
<thead>
<tr>
<th>Actors across the supply chain</th>
<th>Type of sectors involved</th>
<th>Responsibilities/roles under REACH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Producers of articles with chemicals intended to be released</td>
<td>All manufacturing sectors (e.g. Dying of textiles, Lacquering of steel, Production of electrical and electronic equipment, Packaging material, Batteries, Plastic products, Processed paper, Toys, Automotive tyres)</td>
<td>Registration of substance in article if not already registered, Authorisation requirement if substance included in Annex XIV, Comply with restriction requirements, Comply with SDS requirements and exposure scenarios, Report uses not covered by SDS and communicate to suppliers other relevant information, Communicate information (SDS or other way) to customers</td>
</tr>
<tr>
<td>Importers of articles including chemicals intended to be released</td>
<td>Wholesale and retail</td>
<td>Same as above</td>
</tr>
<tr>
<td>Formulators of chemicals substances (downstream users)</td>
<td>NACE 242, 243, 245, 246, 247 (e.g. Dyes, Pigments, Aerosols, Detergents, Adhesives, Cleaning products, Fuels, Polishes, Perfumes, Coatings, Inks)</td>
<td>No registration requirement but may chose/have to submit own Chemical Safety report if use not described by supplier, No authorisation requirement unless uses not covered by authorisation of supplier, Comply with any restriction requirements, Comply with SDS requirements and exposure scenarios, Report uses not covered by SDS, Provide SDS to downstream users and end-users</td>
</tr>
<tr>
<td>Re-fillers (i.e. transfer substances or preparations from one container to another) (downstream users)</td>
<td></td>
<td>As above</td>
</tr>
<tr>
<td>Industrial users of chemicals substances/preparations that do not remain in the product (used as processing aid) (downstream users)</td>
<td>Manufacturing and Construction sectors</td>
<td>No registration requirement but may chose/have to submit own Chemical Safety report if use not described by supplier, No authorisation requirement if substance not in Annex XIV or authorisation, Comply with restriction requirements, Comply with SDS requirements and exposure scenarios, Report uses not covered by SDS and communicate to suppliers other relevant information, Communicate information (SDS or other way) to customers</td>
</tr>
<tr>
<td>Professional users of chemicals (downstream users)</td>
<td>Support service activities (e.g. cleaning services), Manufacturing</td>
<td>As above</td>
</tr>
<tr>
<td>Distributors/wholesalers/retailers of chemicals substances, preparations or articles</td>
<td>Wholesale - Retail sector</td>
<td>Pass on information related to the goods distributed (uses, SDS, authorisation, restriction) from one actor in the supply chain to another, Possibly develop own extended SDS</td>
</tr>
</tbody>
</table>
2.3.5 Main actors involved in the implementation of the Regulation

European Chemicals Agency

The European Chemicals Agency (ECHA) was established in 2007 and is located in Helsinki, Finland. It is the main entity responsible for managing the technical, scientific and administrative aspects of the REACH system at Community level, aiming to ensure that the legislation can be properly implemented. It is responsible for managing the registration, evaluation, authorisation and restriction processes for chemical substances in order to ensure consistency across the European Union. The Agency is required to check the registration dossier submitted by manufacturers and importers and to ensure compliance with the Regulation. It also evaluates the testing proposals to ensure that the assessment of the chemical substances does not result in unnecessary testing, especially on animals, and also that adequate information is provided.

In its operation, the Agency is expected to make use of the best available scientific and technical data and socio-economic information, and to provide scientific advice to Member States and the Commission on questions related to safety and socio-economic impacts from the use of chemicals. By assessing and approving testing proposals, the Agency minimizes animal testing.

Furthermore, ECHA is the main entity responsible for supporting industry and other stakeholders in the implementation of the Regulation through the development of guidance documents, the organisation of information days for stakeholders, the operation of a helpdesk (ECHA Helpdesk), and through ensuring the effective and efficient operation of REACH-IT, IUCLID and other IT tools.

In 2010, the Agency had a budget of € 75 million (€ 2.5 million coming from fees) and 426 employees. In 2011 the budget was expected to reach €100 million with a total of 456 staff. Its management structure comprises of a Management Board of 35 members (representatives of the Member States, Commission and Parliament), an Executive Director, and a Secretariat. Furthermore three Committees, with permanent and alternate members appointed by the Member States, support the operation of ECHA in three key areas:

- A Member State Committee resolving differences of opinion on draft decisions related to the evaluation process that are proposed by the Agency or Member States and making proposals for identification of substances of very high concern.

- A Risk Assessment Committee preparing opinions on evaluation, on applications for authorisation, on proposals for restrictions and on classification and labelling.

- A Committee for Socio-economic Analysis preparing opinions on applications for authorisation, on proposals for restrictions, and on questions relating to the socio-economic impact of proposed legislative action.

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- A Board of Appeal has also been set to decide on appeals against decisions taken by the Agency concerning registrations, sharing of data, exemptions et c.

ECHA is also responsible for supporting the operation of the **Forum for Exchange of Information on Enforcement** (more information in the following section).

**The European Commission**

The European Commission played a key role in the preparatory stages of the Regulation and maintains a supervisory and policy making role. Besides the various consultations with Member States, stakeholders and the Parliament on the provisions of the Regulation and the conduct of an impact assessment study, the Commission undertook a number of preparatory actions in the period before the implementation of the Regulation. Two trials runs were embarked on in the period 2004 -2005 to establish the workability of REACH in cooperation with Member States’ authorities and industry representatives (SPORT and PRODUCE projects). Another project (SHERPER) was carried out to identify the best strategy for the development of national helpdesks. In addition, the Commission conducted a study to establish a baseline concerning the impact of chemicals on human health and the environment, and develop a monitoring system to identify the changes that take place was conducted, and a study for the development of the IT tools to help industry in the implementation of the Regulation.

Since the creation of the Agency a large number of responsibilities concerning the implementation of the Regulation have been transferred to it. Still, the Commission maintains the key role of **updating and completing the Regulation** and in taking decisions concerning authorisation and restrictions of chemical substances. A number of reviews of the various Annexes of the Regulation have already taken place. The Commission also participates in updating REACH guidance documents and supports the European Chemicals Agency in a number of tasks.

In addition, the Commission is responsible for any additional implementing legislation necessary to put the provisions of REACH into effect. These include:

- Regulation 340/2008: setting the fees and charges for registration and applications for authorisation and establishing possible waivers or reductions in the case of joint application and for SMEs.

**Member States**

Member States are primarily responsible for the enforcement of REACH through the establishment of the necessary enforcement structures, the conduct of inspections and, if necessary, by imposing penalties in cases of non-compliance. Enforcement structures and the relevant responsible authorities

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and inspection bodies vary among the Member States even though the implementation of REACH is intended in all cases to provide an effective mechanism for monitoring and control. Variance in the implementation of REACH may well interfere with achieving uniformity of approach in the single market.

Concerning the penalties for non-compliance, under the Regulation each Member State is required to set the level of penalties that apply in the case of infringement, which should be “effective, proportionate and dissuasive”. A study carried out on behalf of the Commission in 2010 provided information on the penalties set in the different Member States indicating significant variation.

Furthermore, in order to facilitate exchange of information, cooperation and to develop common enforcement strategies, a Forum for the exchange of information on enforcement (the Forum) has been set in the context of the ECHA. It brings together representatives of the enforcement authorities and it is responsible for implementing a range of tasks (described in Article 77(4) of the Regulation) to ensure the best possible enforcement of the Regulation. The role of the Forum is also to ensure effective coordination and exchange of information between the authorities in the Member States, the European Chemicals Agency and the Commission. The Forum has already met eight times since 2007 and in 2009, has developed a work programme, and has already run a coordinated enforcement project to test the level of compliance with the registration, pre-registration and Safety Data Sheets requirements.

Besides enforcement, as required by Article 117(1), Member States are expected to submit reports on the operation of REACH.

Finally, Member States are responsible for the operation of national help desks that should serve as a first point of reference providing advice to companies and other stakeholders on the obligations they may have under REACH. In most cases these helpdesks are located in national Competent Authorities.

**CARACAL**

Besides the Forum, the European Commission and ECHA receives advice on questions related to REACH by the CARACAL expert group (Competent Authorities for REACH and CLP). It is composed of representatives of Member States and EEA -EFTA countries’ competent authorities for REACH but also observers from non-EU countries, international organisations and stakeholders.

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46 Information on enforcement structures and authorities in 22 Member States is available from: [http://echa.europa.eu/reach_enforcement/enforcement_t_in_ms_en.asp](http://echa.europa.eu/reach_enforcement/enforcement_t_in_ms_en.asp)


Other support structures

Beyond the support structures provided by the Agency and the Member States, the industry itself - through the European and national industry associations - has also developed support structures aiming to inform and support companies in complying with the Regulation. The Chemical Industry Bureau (CEFIC) as the main umbrella organisation for the Chemical industry has created dedicated units and a structure working almost exclusively in supporting industry through the development of guidelines, IT tools, operation of helpdesk, organisation of conferences etc. Individual associations inside the sector have also developed tools focusing on the needs of the specific sectors and have assumed the role of consortia and/or SIEFs formation facilitator and helped in the preparation of common parts of registration Dossier (e.g. CONCAWE, ERTMA). The Downstream Users Chemicals Coordination group focuses on supporting firms in the sectors of the chemicals industry that operate as downstream users (chemicals formulators such as cosmetics, detergents, paints, adhesives) and distributors. The aerospace and automotive industry association has created a joint task force aiming at supporting the member of the industry in their compliance with the Regulation. Other associations have also created working groups or other mechanism aiming to support their members in fulfilling the requirements of the Regulation.

From the consumer and workers side the focus of activity is primarily on the promotion of information and awareness concerning access to information, and the inclusion of substances in the candidate and authorisation list of substances of very high concern.

Finally, a number of consulting firms are active in the provision of various services to firms - especially SMEs. They offer technical and legal support towards fulfilling the obligations under REACH, manage the SIEFs and consortia created or act as representatives on behalf of firms (only representative or third party representative).

52 http://www.duccplatform.org/home.html
This section presents the methodological framework and the research tools used in the study.

3.1 Methodology

The terms of reference specified in detail the evaluation questions to be addressed concerning the relevance, effectiveness, efficiency, utility and sustainability of the Regulation in relation to the issues of competitiveness of the EU industry and the operation of the internal market. In addition, questions concerning the consistency of the Regulation, the distribution of benefits and costs and the level of acceptance of the Regulation were also included.

While the questions already provided a basis for the evaluation, additional analysis was conducted to develop a coherent evaluation framework for the study. The first task was the development of an intervention logic establishing the logical linkages between the overall objectives of the Regulation and the various operational elements. The second was the identification of the mechanisms through which the Regulation should be expected to impact the competitiveness of the European chemicals industry and the operation of the single market.

The intervention logic of REACH Regulation

The intervention logic of the Regulation is depicted in the diagram on the following page. At the highest level the needs, problems and issues identified in the White Paper ‘Strategy for a future Chemicals Policy’ are depicted along with the broader policy framework related to the Lisbon Agenda for the promotion of innovation but also the Lisbon Treaty provision for the operation of the Single market. This general framework is linked with the generic goals stated in that White Paper, including the issues of competitiveness and avoiding the fragmentation of the internal market. The specific goals and the principles of the regulation have been identified on the introduction of the Regulation text and include the basic principles related to the transfer of burden to industry, the improvement of information on chemicals and promotion of substitution but also the need for a fair share of costs and avoidance of discrimination towards SMEs. At the operational level the Regulation has set out in detail the procedures, mechanisms and tools for implementation and the described the role of the European Chemical Agency, the Member States and the Commission. The actions on the ground refer to the implementation at the European and national level by the Commission, the Agency, Member States and industry to support the implementation of the Regulation. It includes the actions of individual firms as well as of associations and other actors. The inputs include the human, financial and other resources (costs for industry and authorities) that are necessary 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 the longer-term impacts of the Regulation.
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Framework for assessing impact on competitiveness

A key consideration of the study has been that, in many respects, it is too early for a full assessment of the impacts of the Regulation on the competitiveness of the European chemicals industry. The Regulation will only fully enter into force in 2018, and a number of mechanisms – such as authorisation or restriction – are only in the early stages of their implementation. Furthermore, while short term compliance costs were expected to be incurred early on, possible benefits from acquisition of knowledge or new product development require substantial time to materialise. Those considerations were confirmed during the initial interviews with industry representatives and other REACH experts in the initial stages of the study. As a result, it was generally expected that it would not be possible to identify changes to standard competitiveness indicators such as trade balance, export growth, level of productivity that could be directly attributable to the REACH regulation. In order to be able to identify a connection between REACH and competitiveness it would be necessary to focus on the potential impact on the inputs and processes that determine the competitiveness of the chemicals’ industry and to develop hypotheses as to the different ways that the Regulation may have an impact on them.
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For the purposes of the analysis, the competitiveness framework used for a number of sector competitiveness studies was adopted.\(^{53}\) It is based on a consideration of the internal characteristics and strengths of a sector as well as the external framework conditions. The analysis of the REACH Regulation, a review of the studies conducted prior to its implementation and the discussions with industry and other stakeholders helped identify the various parameters where the Regulation is expected to have an impact. These are summarised below:

1. **Impact on key inputs**

   - **Factors of production** – The main aspect related to factors of production concerns the possible impact on raw materials in the case that REACH leads to the withdrawal of critical substances or to an increase in their prices. Substitution costs may have an important negative impact, at least in the short term for certain sectors. In addition, increased labour costs may also arise as additional human resources will have to be dedicated to the implementation of the Regulation.

   - **Innovation**: REACH is expected to create incentives for firms to develop new less dangerous substances or identify new uses of existing chemical substances both due to the substitution requirements but also as a result of the new knowledge acquired of the properties of substances and their uses downstream. Firms are expected to take advantage of these incentives and use the knowledge created to develop more ecological and less harmful substances in Europe, and these can provide a competitive advantage for certain sectors. On the other hand, according to parts of the industry, the tests and studies required may lead to a diversion of investment and human resources away from more productive R&D and innovation activities. In addition, issues of confidentiality and protection of business intelligence may arise because of REACH’s disclosure requirements, and may affect the innovative capacity of the industry.

2. **Impact on industry structure:**

   - **Level of concentration and specialisation**: REACH related costs may lead certain firms to the decision to rationalise their product portfolio and withdraw from certain market segments. While there may also be new entrants to the market, greater level of concentration of the overall market may be a result of this. To the extent that firms in different Member States or regions have different capacity to respond to these additional costs, there may also be an impact on the geographical concentration of the industry. In addition, since certain sectors or sub-sectors of the EU chemicals industry or downstream users have different capacity to respond to the costs posed by the regulation or to utilise the knowledge created the level of specialisation of the industry will be affected. Finally, while there REACH may create opportunity for new market entries – existing or new firms - on the basis of new less hazardous chemicals, the registration costs introduce a certain market barrier the importance of which depends on the extent of the relevant market opportunities.

   - **Role of SMEs**: The REACH regulation imposes requirements on firms of all sizes. There are provisions – fees, requirements in the case of smaller volumes of production – aiming to reduce the costs to SMEs and avoid excessive burdens that could put them in an unfavourable position against large

\(^{53}\) [http://sectorcompetitiveness.com/](http://sectorcompetitiveness.com/)
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firms. Still, the resources that need to be dedicated to REACH and the possible impact on profit margins may have adverse effect on SMEs.

3. Impact on industry processes

- **Inter-industry relations:** REACH introduces demands for an advanced level of communication between actors in the supply chain. This can be expected to cause increased costs during the initial period but may also lead to the development of co-operation and more efficient supply chain linkages in the medium to long term. The existing level of cooperation inside the chemicals industry and with downstream sectors varies greatly. As a result certain sectors should be expected to be affected or benefit more than others.

- **Business strategy:** Time-to-market is an important consideration in the business strategy of firms. It is possible that the implementation of the Regulation may lead to delays in the introduction of products as a result of the authorisation or evaluation procedures. On the other hand the products that emerge as a result of the process may be safer and more cost-effective.

4. Impact on outcomes

- **Profit margins:** The costs of compliance with the Regulation should be expected to have an impact, at least in the short term, on the profit margins for producers of chemicals and downstream users. Market actors may be affected in different ways depending on their capacity to transfer these additional costs further down the supply chain through increased prices. On the other hand the potential of development of new substances or identifying new uses for substances provides the opportunity for entering markets with limited competition and potential for greater profits margins.

- **Trade/exports:** To the extent that REACH compliance does affects costs and leads to possible increases in the prices of chemicals or products that include or use chemicals, EU firms may be at a less competitive disadvantage that can affect the level of exports, especially in sectors where competition is price driven. On the other hand, to the extent that it promotes innovation and the development of new chemical products, it can support an increase in the level exports.

5. Impact on framework conditions

- **Impact on demand:** REACH may have an impact on the demand for intermediate and final products promoting the use by industry and final consumers of less hazardous substances that have a more ecological profile. The extent of the shift in demand depends on the implementation and impact of REACH related procedures such as the authorisation and restriction procedures and the candidate list of substance of very high concern. The capacity of the industry to respond to such changes – if applicable - will be important in determining the extent of the impact.

- **Customer and investor confidence and access to finance:** The implementation of the Regulation can operate as a boost to the image of the industry which, under certain circumstances can lead to increased demand for its products. Increased demand for chemical products and reduced damages or liabilities incurred relating to environmental and occupational health issues may also lead to increased investor confidence and improve access to finance.
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*Impact on the single market*

The framework conditions stated above also concern the operation of the internal market. REACH is intended to help create a single market for chemicals and avoid fragmentation. Prior to REACH, the conclusion of most studies as regards the impact on the operation of the internal market was that REACH ought to be beneficial. The existence of Directives on hazardous substances meant a certain level of harmonisation but Member States could still introduce different requirements and obligations that posed significant costs for firms that traded in multiple countries. Companies had to be familiar with the different regulations in each Member State. At the same time, for a large number of substances there was no specific regulation – besides the general provisions for occupational health and safety and consumer safety.

By creating a common legal framework, REACH was expected to facilitate intra-EU trade and lead to increased competition in certain market segments. In the short term this can provide an advantage to manufacturers already active in a number of countries and those used to more extensive Regulation. For some producers of chemicals, a level playing field EU may be more costly than complying with the legislation in their own country before joining the EU. At the same time though, differences in the enforcement of the regulation by Member States authorities may lead to problems in the operation of the market, offsetting some of the benefits described above.

However, caution is required when considering the contribution by the Regulation to the development of the internal market, the increase of intra-EU trade and any impact on prices. Even before REACH came into force, there was a substantial increase in the share of intra-EU trade. The removal of a number of other trade barriers led to an almost threefold increase of the intra-EU trade between 1995 and 2008.54 As mentioned, the EU market currently represents close to 50% of the total sales of the chemicals industry, while national markets are gradually losing share. Investments in new production facilities in the new member states by multinationals since 2004 have led to an additional increase in the level of intra-EU trade. Certain shifts in the balance of trade between Member States in certain subsectors in the chemicals industry or further down the supply chain may occur due to increased competition and the different productivity level of firms across the EU, but it may be rather difficult to discern on the basis of available data.

*3.2 Research tools*

The reference framework described serves as the basis for the development of research tools used in the collection of the necessary information for testing the presence and extent of the expected effects of the REACH regulation. A combination of research methods – bringing together quantitative and qualitative approaches – has been used:

- An interview programme covering European and national industry associations, Member States authorities and other stakeholders (representatives of trade union and environmental groups).

- A pan-European survey of firms with different roles in relation to the REACH Regulation.

54 From €98 billion in 1995 to €268 billion in 2008
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- Case studies focusing on specific issues aiming to complement the general analysis. The topics of the case studies were identified during the course of the fieldwork period and were approved by the Commission services.

- Extensive desk research to collect data and other relevant information.

These tools are presented in more detail in the following section.

### 3.2.1 Interview programme

A total of 108 interviews were conducted covering all types of actors involved in the Regulation (see table below). Furthermore, within the context of the case studies on more specific issues (see below) several interviews and informal discussions with individual firms were completed.

Table 3.1 - Interview programme

<table>
<thead>
<tr>
<th>Type of stakeholder</th>
<th>Number of interviews</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EU level</strong></td>
<td></td>
</tr>
<tr>
<td>Commission Services</td>
<td>3</td>
</tr>
<tr>
<td>European Chemicals Agency</td>
<td>5</td>
</tr>
<tr>
<td>Industry/trade associations/firms</td>
<td>25</td>
</tr>
<tr>
<td>Consumer and environmental groups</td>
<td>2</td>
</tr>
<tr>
<td>Trade union associations</td>
<td>1</td>
</tr>
<tr>
<td><strong>National level</strong></td>
<td></td>
</tr>
<tr>
<td>Member states enforcement authorities/national helpdesks</td>
<td>26</td>
</tr>
<tr>
<td>EU National industry/trade associations</td>
<td>26</td>
</tr>
<tr>
<td>Non-EU industry associations</td>
<td>2</td>
</tr>
<tr>
<td>Interviews with individual firms</td>
<td>20</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>108</strong></td>
</tr>
</tbody>
</table>

Appendix A provides a detailed account of the interview programme.

### 3.2.2 Business survey

An online business survey was organised by CSES targeting firms falling under the following categories of actors affected by the REACH regulation:

1. Manufacturer of chemical substances or preparations
2. Importers of chemical substances or preparations
3. Producers 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
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7. Distributor/retailer of chemical substances, preparations or articles that contain chemical substances intended to be released

8. Only representatives

9. Other roles

For each category a tailored made questionnaire was developed and translated into all 22 official languages. Participants had access to the online questionnaire while an electronic version of all questionnaires was also made available. The survey was launched on the 1st of June and remained open for a period of 2 months. Since CSES did not have access to the contact details of individual firms we sought the support of European and national industry associations. They were asked to forward the survey to their individual members. Furthermore, the European Chemical Agency sent an email to all firms that registered a chemical substance during the first registration process. The Commission services also promoted the survey by adding a news item in the news section of DG Enterprise and Industry.

A total of 1601 responses had been received by August 6 although only not all respondents answered all questions in the questionnaires. Manufacturers of chemicals represented the main group of respondents with a total of 530 questionnaires submitted while formulators and importers of chemicals provided a large number of responses. Smaller number of responses was received from importers of articles and distributors and others that included consultants, third party representatives and some associations.

Chart 3.1 – Number of respondents to the survey by main type of function stated

In relation to the size of the firms responding, the analysis of responses suggests that large firms (>250 employees) represent the larger group of respondents (over 33%) with significant presence of medium
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(28%) and small size (24%). However this varies in the case of manufacturers of chemicals or articles but not in the other categories. This picture is probably a reflection of the fact that large size manufacturers were the main category of firms that registered substances during the first period and received the invitation by ECHA. In the other REACH related functions that are involved in the chemicals’ supply chain there is no similar bias.

Table 3.3 – Distribution of survey respondents by firm size and role (number of employees)

<table>
<thead>
<tr>
<th></th>
<th>Total</th>
<th>Micro (&lt;10)</th>
<th>Small (10-49)</th>
<th>Medium (50-249)</th>
<th>Large (&gt;250)</th>
<th>Not stated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manufacturers of chemicals</td>
<td>530</td>
<td>3.2%</td>
<td>12.8%</td>
<td>27.4%</td>
<td>44.3%</td>
<td>12.3%</td>
</tr>
<tr>
<td>Formulators</td>
<td>291</td>
<td>5.8%</td>
<td>33.7%</td>
<td>37.8%</td>
<td>22.7%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Importers of chemicals</td>
<td>237</td>
<td>27.4%</td>
<td>32.5%</td>
<td>22.4%</td>
<td>16.5%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Manufacturers of articles</td>
<td>182</td>
<td>2.7%</td>
<td>20.9%</td>
<td>24.7%</td>
<td>45.6%</td>
<td>6.0%</td>
</tr>
<tr>
<td>End users</td>
<td>168</td>
<td>2.4%</td>
<td>32.7%</td>
<td>35.1%</td>
<td>29.2%</td>
<td>0.6%</td>
</tr>
<tr>
<td>Distributors</td>
<td>74</td>
<td>9.5%</td>
<td>36.5%</td>
<td>28.4%</td>
<td>25.7%</td>
<td>0.0%</td>
</tr>
<tr>
<td>Others</td>
<td>61</td>
<td>39.3%</td>
<td>14.8%</td>
<td>18.0%</td>
<td>19.7%</td>
<td>8.2%</td>
</tr>
<tr>
<td>Importers of articles</td>
<td>58</td>
<td>13.8%</td>
<td>22.4%</td>
<td>17.2%</td>
<td>44.8%</td>
<td>1.7%</td>
</tr>
<tr>
<td><strong>Number</strong></td>
<td><strong>1601</strong></td>
<td><strong>147</strong></td>
<td><strong>385</strong></td>
<td><strong>454</strong></td>
<td><strong>529</strong></td>
<td><strong>86</strong></td>
</tr>
<tr>
<td><strong>Share in total</strong></td>
<td>9.2%</td>
<td>24.0%</td>
<td>28.4%</td>
<td>33.0%</td>
<td>5.4%</td>
<td></td>
</tr>
</tbody>
</table>

Source: CSES survey

In terms of country coverage (i.e. respondents operating in firms or units located in these countries), most responses came from Italian firms (312) followed by German firms (291), UK-based (220) and French (112) firms. There were also an important number of respondents representing multinational firms with headquarters inside and outside the EU. In contrast, in some countries the responses were particularly low. There were very few responses from a number of countries - Austria, Bulgaria, Estonia, Denmark, Greece, Hungary, Ireland, Latvia, Poland, Portugal, Romania, Slovenia and Sweden.

Table 3.2 – Distribution of survey respondents by country of operation

<table>
<thead>
<tr>
<th>Country</th>
<th>Total responses</th>
<th>Country</th>
<th>Total responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>EU-based multinationals</td>
<td>86</td>
<td>Latvia</td>
<td>6</td>
</tr>
<tr>
<td>Non-EU based multinationals</td>
<td>89</td>
<td>Lithuania</td>
<td>34</td>
</tr>
<tr>
<td>Austria</td>
<td>18</td>
<td>Luxembourg</td>
<td>12</td>
</tr>
<tr>
<td>Belgium</td>
<td>32</td>
<td>Malta</td>
<td>6</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>8</td>
<td>Netherlands</td>
<td>52</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>31</td>
<td>Poland</td>
<td>26</td>
</tr>
<tr>
<td>Cyprus</td>
<td>1</td>
<td>Portugal</td>
<td>17</td>
</tr>
<tr>
<td>Denmark</td>
<td>7</td>
<td>Romania</td>
<td>3</td>
</tr>
<tr>
<td>Estonia</td>
<td>3</td>
<td>Slovakia</td>
<td>22</td>
</tr>
<tr>
<td>Finland</td>
<td>17</td>
<td>Slovenia</td>
<td>5</td>
</tr>
<tr>
<td>France</td>
<td>112</td>
<td>Spain</td>
<td>70</td>
</tr>
<tr>
<td>Germany</td>
<td>291</td>
<td>Sweden</td>
<td>14</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Country</th>
<th>Total responses</th>
<th>Country</th>
<th>Total responses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Greece</td>
<td>6</td>
<td>UK</td>
<td>220</td>
</tr>
<tr>
<td>Hungary</td>
<td>15</td>
<td>Norway</td>
<td>7</td>
</tr>
<tr>
<td>Ireland</td>
<td>13</td>
<td>Croatia</td>
<td>3</td>
</tr>
<tr>
<td>Italy</td>
<td>312</td>
<td>Switzerland</td>
<td>14</td>
</tr>
<tr>
<td>USA</td>
<td></td>
<td></td>
<td>8</td>
</tr>
<tr>
<td>Japan</td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Other</td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Total</td>
<td>1563</td>
<td>Total</td>
<td>1601</td>
</tr>
</tbody>
</table>

Source: REACH survey

The initial minimum sample size target for each country was 96 responses. It would have allowed for an analysis with a 95% confidence level with 10% margin of error for target populations of over 10,000 firms. In that respect, only the answers from the four countries stated above allow for comparisons with the same minimum level of confidence at the national level. Still, for the whole of the EU the responses fulfil the minimum requirements for most of the key roles in the supply chain. Despite consistent efforts to reach these broader audiences through national and European associations it was to be expected that firms in the chemicals sector – manufacturers, importers or distributors – or those directly linked to the chemicals sectors were much more willing to respond to the survey.

In relation to the ownership structure of the firms in the sample, single site independent firms represent close to 47% of responses followed by responses from units that are part of a broader enterprise group operating in one or in more European member States (26.2% in total). REACH units of EU27-based firms represent for 10% of the sample while around 7% of responses are from non-EU based firms. Further analysis indicates, as expected, that micro and small firms are mainly single-site independent firms while REACH units are primarily among large firms and more often represent manufacturers of articles.

Table 3.4 – Distribution of survey respondents by ownership type

<table>
<thead>
<tr>
<th>Row Labels</th>
<th>Number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>A single-site independent firm</td>
<td>750</td>
<td>46.8%</td>
</tr>
<tr>
<td>Unit of a multi-site firm operating in only one country in the EU27</td>
<td>252</td>
<td>15.7%</td>
</tr>
<tr>
<td>Dedicated REACH unit of an EU27 based enterprise group/company</td>
<td>201</td>
<td>12.6%</td>
</tr>
<tr>
<td>Other unit of an EU-based enterprise group/company</td>
<td>168</td>
<td>10.5%</td>
</tr>
<tr>
<td>Unit of a non-EU27 based enterprise group/company</td>
<td>92</td>
<td>5.7%</td>
</tr>
<tr>
<td>Dedicated REACH unit of a non-EU27 based enterprise group/company</td>
<td>34</td>
<td>2.1%</td>
</tr>
<tr>
<td>Other</td>
<td>5</td>
<td>0.3%</td>
</tr>
<tr>
<td>Not indicated</td>
<td>99</td>
<td>6.2%</td>
</tr>
<tr>
<td>Total</td>
<td>1601</td>
<td>100%</td>
</tr>
</tbody>
</table>

In relation to the distribution by legal form, the great majority of respondents are private or public limited companies (84% of respondents).
Table 3.5 – Distribution of survey respondents by legal form

<table>
<thead>
<tr>
<th>Legal Form</th>
<th>Number</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Private limited company</td>
<td>830</td>
<td>51.8%</td>
</tr>
<tr>
<td>Public limited company</td>
<td>532</td>
<td>33.2%</td>
</tr>
<tr>
<td>Limited liability partnership</td>
<td>48</td>
<td>3.0%</td>
</tr>
<tr>
<td>Sole proprietorship / trader</td>
<td>34</td>
<td>2.1%</td>
</tr>
<tr>
<td>Unlimited liability partnership</td>
<td>28</td>
<td>1.7%</td>
</tr>
<tr>
<td>No answer</td>
<td>129</td>
<td>8.1%</td>
</tr>
<tr>
<td>Total</td>
<td>1601</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

Finally, we need to note that, on average, around 70% of respondents submitted fully completed questionnaires. Some respondents preferred not to answer some questions rather than indicate the “do not know” or “not applicable” options. In the analysis of the results we have included not fully completed questionnaires aiming to make use of all answers provided.

Overall, despite certain limitations, we consider that the survey provides an sound source of data for understanding the issues and experiences of the chemicals industry and downstream users in relation to the implementation of REACH Regulation.

### 3.2.3 Desk research

Desk research focused on the analysis of certain key sources of data and other complementary information related to the REACH Regulation. They include databases, studies and professional publications that were identified through extensive web search or following recommendations during the interview programme.

The main sources of data used include:

1. ECHA website and annual reports providing data on registrations and other REACH procedures, the use of REACH structures (e.g. ECHA helpdesk) and other efficiency related questions.

2. Eurostat: The Eurostat database provides data on the structure of the chemicals' industry, the level of trade (volume and value of imports and exports) and the evolution of consumer and producer price indexes.

3. Member States progress reports on the evaluation and enforcement of REACH, maintained by ClientEarth ([http://www.clientearth.org/progress-reports-reach](http://www.clientearth.org/progress-reports-reach)).

4. Professional publications providing up-to-date information on the developments in the chemicals' market and including a number of articles referring to the practical experience from the implementation of the regulation by firms and other experts. The main sources used included:
   - Chemical watch ([www.chemicalwatch.com](http://www.chemicalwatch.com))
Methodology and research tools

- REACH-news.Net (www.reach-news.net/)
- Journal of Business Chemistry (http://www.businesschemistry.org/issues/issue/)

A detailed list of the sources used is provided Appendix C.

3.2.4 Case studies

CSES completed 11 in depth case studies focusing on specific topics of the implementation of the REACH regulation. The topics were identified throughout the course of the fieldwork and approved by the Commission services. The objective was to shed further light to specific aspects of the implementation of REACH identifying additional data or providing an analysis of issues or implications for industry. They have been based on a more detailed analysis of business survey along with additional desk research and interviews with firms and experts. The topics covered by the eleven case studies are:

1. Analysis of the costs of compliance with REACH: Provide a break-down of the costs for businesses with the different actors in the chemicals market and differentiating between small and large firms.

2. Use of information exchanged along the supply chain: Examine how firms make use of the information exchange requirement along the supply chain.

3. Impacts and responses to substance withdrawal: Assesses the immediate and longer terms impacts related to the possible withdrawal of critical substances for different categories of downstream users and the respective responses.

4. Cooperation in consortia and SIEFs: Assessment of the operation of SIEFs and consortia and the cooperation and exchange of information within their context.

5. Overlap of the REACH Regulation on other regulations: Synergies, overlaps or conflicts of REACH with other EU legislation focusing on the real-life experience of firms.

6. Impact of REACH on Member States with low levels of production of chemicals (absolute and relative): Identify relevant information indicating market changes/shift resulting from REACH in the case of Member States with low shares in the EU chemicals market.

7. Role of only representatives: Assess their role of Only Representatives in the implementation of the regulation and identify the areas where problems may exist in their communication with other market actors.

8. Impacts on companies from third countries: Assessment of what REACH means for firms from non-EU countries that trade with and/or invest in the EU and undertake a wide range of value-adding activities.

9. Bulgaria and Romania case study: Due to the very limited number of responses in the business survey the case study attempted, through interviews with industry and a few firms, to obtain qualitative feedback on developments in the two Member States as regards the implementation of the REACH and the effects on Competitiveness and the Single Market.
Methodology and research tools

10. Toll manufacturing and the REACH regulation: Analyse the issues resulting from the introduction of the REACH Regulation on the practice of toll manufacturing in the chemicals industry and possible impacts on industry.

11. Analysis of the practical implications of the use of alternative interpretations for determining the concentration of SVHCs in articles concerning the requirement of suppliers of articles for notification – The case study provides an analysis of the practical implications for the automotive and the electronics sector of applying the approach proposed in the relevant ECHA guidance document – calculation of concentration for the whole article – in comparison to that proposed by six Member States based on individual components.

The case studies are presented in detail in Appendix B of the report although, when appropriate, findings have also been used in the report as illustrations to support the analysis and conclusions.
In this section we provide an analysis of the information and data collected during the course of the study in relation to the evaluation questions set in the terms of reference. The presentation of the findings follows the sequence of the evaluation questions as set in the terms of reference of the study.

4.1 Relevance of REACH against needs identified in the white paper

Among the seven "political objectives" set out in the white paper 'Strategy for a future Chemicals Policy'55 two inform the subject matter of this study: the "maintenance and enhancement of the competitiveness of the EU chemical industry" and, the prevention of the "fragmentation of the internal market".

The preservation and enhancement of competitiveness in the chemicals sector was identified by the White Paper as a central objective, and one that must be counterbalanced against the need for the development of safer chemicals. In this respect, the introduction of REACH Regulation was seen as a major factor in shaping the behaviour of firms towards their processes of innovation, whilst at the same time suggesting that it was essential that the costs to enterprises resulting from the Regulation should be limited to the absolute minimum necessary.

In relation to question of the relevance of REACH on innovation, there is substantial theoretical and empirical evidence56 supporting the view that, if properly designed, environmental regulation can have a positive role in the process of innovation, either focusing on environmental/social innovation but, more generally, on the development of new products and processes that bring direct benefits to firms. Provisions of the REACH Regulation, procedures like the authorisation and restriction are designed to push industry towards the development of new products. In addition, provisions such as those set out in the PPORD, and REACH's equal burden on old and new substances, are, according to CEFIC and other industry association, important in promoting innovation. However, at this stage it is still too early to assess the actual results in this area. There is more evidence, albeit still anecdotal, that the candidate lists for authorisation provide a market signal that creates incentives for substitution of chemicals and, in some cases, investment in R&D and the development of innovation. The evidence presented in the following sections supports the view that it often operates in a positive way, even if the substitution of substances does not by itself constitute innovation and does not necessarily lead to better products.

57 In relation to the questions of the impact of innovation and the role of the different mechanisms a separate study is being conducted by CSES on behalf of the Commission services. As a result, this report did not consider the specific issue in detail. Nonetheless, given the close relationship with the question of competitiveness some key aspects were examined.
However, so far the role of REACH remains less evident when it comes to the creation and, to an even lesser extent, the utilisation of new knowledge. The data generated in the first registration period concerned substances that were already quite well known while, but whilst relevant, the industry had not been able to translate them in product innovation. It should be expected – and this is generally supported by the survey feedback – that after 2018, when the regulation is fully in place and the regulatory framework is established, the industry may be able to utilise more of this new knowledge, and identify new pathways to product development and approach the innovation process with different product properties in mind. The role and contributions of the various information and knowledge creation and sharing tools – such as the SIEFs and Safety Data Sheets – is also unclear at this stage. There are still practical aspects that hinder the exchange of information and knowledge creation.

Overall, we would say that REACH Regulation and its mechanisms are relevant for the development of innovation, a key aspect in maintaining the competitiveness of the chemicals sector. However, in real terms their contribution remains to be seen, but may well be positive.

In relation to the costs of REACH, it is quite clear from the feedback from industry that REACH has introduced significant additional workloads and administrative costs for almost all firms in the sectors considered. Based on this, and at least in the short term, the majority of industry representatives claim that the Regulation has had a negative impact on the competitiveness in comparison to non-EU firms. From the evaluators point of view the evidence at this stage is inconclusive as to the extent to which these costs have a strong and long-term negative impact on the competitiveness of the chemicals industry or downstream users’ sectors and the financial crisis since 2007 has made any assessment even more difficult. Certain categories or types of firms (e.g. SMEs) and certain sectors (e.g. coatings, textiles) appear to be more affected than others. Furthermore, there are developments in other regions with introduction of REACH-type legislation (e.g. China, Korea, and Turkey) that may reduce the negative impact of REACH costs, even though these legislations are less demanding than REACH. Overall, our analysis suggests that there is scope for a positive-sum reduction of the actual compliance costs through improvement of procedures and clarification of requirements, and without having a detrimental effect on the main objectives of the Regulation.

The second objective of the harmonisation of the internal market is equally critical. The introduction of REACH as an EU legislation – against the possibility of national action – was justified on the grounds that it can help avoid fragmentation of the chemicals market and contribute to enjoy the benefits of the single market. Indeed, at least at the general level, the general view of industry is that the introduction of a single EU-wide legislation for chemicals and avoidance of fragmentation of the market are both important and relevant objectives that are served by REACH. For commodity chemicals this appears to be less of an issue given that the market is rather global, but it is more relevant for the specialty or the consumer chemicals. The introduction of REACH is indeed a very relevant tool in the promotion of a level playing field. However, as it pointed out, a number of national authorities can, and often do, deviate on certain aspects, or introduce additional requirements and permit procedures for certain chemicals. Irrespective of the justification of such measures, the harmonisation of the internal market is not served. Inconsistencies and overlaps with other EU legislations such as the Cosmetics Directive, the Construction products regulation or RoHS also create problems in ensuring a harmonised implementation across Europe. Within the context of REACH, different interpretations are also possible in a number of implementation and market surveillance aspects. Deviation from notification
requirements for articles is a commonly stated example. In addition, the limited resources and capacity dedicated to Market Surveillance mean that the internal market is, in practice, not harmonised.

Overall, there is agreement that REACH is relevant to the harmonisation of the internal market and central to the development of a level playing field and market competition. However, practical aspects and varying national practices mean that in practice this objective is still not fully realised.

### 4.2 Effectiveness in relation to the competitiveness of the chemicals industry and the operation of the Single Market

In this section we examine a number of aspects related to the implementation of the REACH Regulation and its effectiveness in terms of maintaining, if not enhancing, the competitiveness of the European chemicals’ industry and the downstream user sectors as well as the operation of the chemicals market more specifically.

The specific areas considered include:

- The costs of compliance incurred by firms so far focusing on those elements where significant experience exists
- The impact of REACH on the financial situation of firms and their profitability
- The impact of the Regulation on the prices of chemical substances used by downstream users and of the final consumer products
- The impact on the availability of chemical substances
- The impact of the Regulation on downstream users
- The impacts on the level of trade inside and outside the EU
- The existing and expected business gains for firms as a result of REACH
- The possible impact on job creation
- The operation of the single market on chemicals and the impact of the REACH regulation

#### 4.2.1 Costs of compliance with REACH

Compliance with the REACH regulation incurs a range of direct and indirect costs for firms. The discussions with industry and the review of the REACH regulation indicated a number of possible costs “elements” that include:

- Human resources dedicated to the various REACH-related activities (concerns all firms);
- Costs of pre-registration and registration of substances (concerns, primarily, manufacturers and importers of chemicals);
- Authorisation application (concerns manufacturers and importers of chemicals as well as downstream users);
- Notification of articles and submission of chemical safety reports by importers of articles and, in some cases, downstream users;
- Information exchange activities along the supply chain (applies to all firms in the supply chain);
- Costs for changes in production, substitution of substances, management of risk and other necessary investments (concerns all firms).
Not all of the above cost elements have materialised to the same extent at this point and for some experience and relevant data are still very limited. Registration has only been completed for non-phase in substances and phase in substances produced in over 1,000 tonnes per year. Thus, for a large number of firms, registration costs are expected to take place in the coming period – prior to the 2013 or the 2018 deadlines. In the case of authorisation there is still very limited data on the relevant costs for firms, as there have thus far been no such applications. The same difficulty applies to the notification requirements for articles. In relation to investments for production changes and adoption of risk management practices the survey responses indicated that it is still too early for the great majority of firms to comment. The following paragraphs present the information available and the relevant estimates on the costs for firms and for the whole industry for each of the costs elements.

**Human resources**

The implementation of REACH requires the dedication of a minimum level of human resources for almost all firms directly or indirectly affected by the Regulation. So far, pre-registration and registration related activities have been the main task for the staff involved. Registration is expected to continue to occupy substantial resources through the possible updates and reviews of dossiers, and the subsequent second and third round of registrations. In parallel, the development and handling of SDS and more general information exchange requirements along the supply chain are already occupying firms, including both manufacturers and importers, and also downstream users and distributors of chemicals.

The response of many firms – primarily the large ones – has been the creation of dedicated REACH units to bring together all the necessary expertise. The business survey results indicate that among large manufacturers, importers of chemicals as well as downstream users, over 60% have established a REACH unit. In the case of multinational firms, centralised REACH centres have often been created with the intention to minimise work required at the level of the single entity in different locations. Still, at least one REACH officer is appointed in the separate production units. Discussions with industry associations indicated that in some cases REACH units may occupy up to 100 staff. However, according to the survey responses, in most cases – around 55% – REACH units typically occupy between 1 and 5 staff (Full Time Equivalent). The survey responses suggest that, as expected, manufacturers of chemicals tend to have more sizable REACH units than downstream users and distributors. Even when no REACH unit has been created – which is usually the case for smaller sized firms – most survey respondents indicated that less than one FTE staff member is typically occupied in REACH related activities, and often as part of other health and safety related responsibilities.

Based on an average EU27 cost of €50,000/FTE for the EU chemicals industry, annual human resource costs for the typical large firms is in the range of €100,000-€250,000 per annum, and €25,000-50,000 for smaller size firms. For the total chemicals sector (NACE 20), approximately 28,000 micro and small sized firms and around 1,160 medium and large sized firms, the above average costs indicate total annual human resources costs in the range of €0.8-1 billion, around 1.5% of the total personnel costs of the sector in 2008 (Eurostat data). However, as these calculations are based on a number of assumptions concerning the type of staff involved they should be treated with caution.
In addition to in-house staff, or often instead of them, firms sometimes employ external consultants for the provision of legal and technical support. A large number of small firms outsource most, if not all, of the registration and other REACH related activities. The consultants often take charge of the preparation of the firm’s own part of the registration dossier, the communication with SIEFs and consortia. Thus, for many firms the small number of FTEs dedicated to REACH is replaced by fees to consultants. Precise data on such fees has not been made available and can vary depending on the activities outsourced. In relation to registration activities, close to 50% of the CSES survey respondents who have made use of consultants suggested that their fees did not exceed 10% of the total registration costs, while 32% suggested that this was in the range of 10-25%. A possible downside of the extensive use of consultants, although not often stated by firms, is that it inhibits learning and creates a long term dependency. It is often a strategic decision made by firms as to whether the development of REACH-related internal capacity is necessary or not.

In relation to the evolution of human resources costs, the survey data indicates that the number of staff occupied with REACH related work has been gradually increasing over the 2008-2010 period. The responses received suggest that the majority of respondents expect the total workload to increase further in the coming period as the second and third registration periods add to the supply-chain information exchange requirements. A survey for Chemical Watch of large manufacturers indicated that firms expect an increase in both in-house staff and the use of external consultants.

Table box 4.1 – Examples of human resources costs incurred by firms

<table>
<thead>
<tr>
<th>Case Study</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A large multinational</td>
<td>A single REACH unit occupying close to 5 FTE.</td>
</tr>
<tr>
<td>A small size manufacturer</td>
<td>A REACH unit but occupying only one staff on a part time basis.</td>
</tr>
<tr>
<td>A large producer</td>
<td>A central REACH unit in 2010 occupying a team of 7 FTE. At the same time there are 23 people occupied part time across other units and departments of the company – including marketing, procurement, sales. They are expected to increase to a total of 45 in the coming period.</td>
</tr>
<tr>
<td>A small size producer</td>
<td>A technical person dedicated full time along with support for communication along the supply chain. The total annual cost is estimated at around €50,000. On top of that they spent a round €13,000 for consulting support.</td>
</tr>
<tr>
<td>A large size producer</td>
<td>A dedicated person with half time on REACH, mainly related to communication with suppliers and customers.</td>
</tr>
<tr>
<td>A major oil and petroleum refiner</td>
<td>Stated that a team of 60 FTEs was working solely on registration during the period before the 2010 deadline.</td>
</tr>
</tbody>
</table>

Source: CSES survey and interviews

59 Service providers guide 2011
Pre-registration

The main costs for firms in relation to the pre-registration process were the human resources dedicated to the process. The input from the survey indicates that the experience of firms and the time dedicated varied. Given that this was the first experience with the implementation of REACH and its implications concerning the future registration of substances, many firms invested time to understand the regulation obligations, assess the possible implications and collect the relevant data. A number of them had to hire consultants although this was not typically the case. The discussion with various firms and experts indicate that the typical costs were not greater than around one working day per individual substance pre-registered with some additional resources sometimes spent for familiarisation with the legislation and the analysis of the substance inventory to decide which substances to register. In the case of firms with multiple substances of similar properties or in the same family, the pre-registration of each substance was often a matter of a few hours.

Table box 4.2 – Examples of pre-registration costs incurred by firms

<table>
<thead>
<tr>
<th>Description</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large manufacturer of basic metals spent around €70,000 to prepare the pre-registration of around 50 substances.</td>
<td></td>
</tr>
<tr>
<td>Medium size producers of paints and varnishes – formulator – stated that they had pre-registration costs.</td>
<td></td>
</tr>
<tr>
<td>Large multinational firm producing power systems and engines and using over 1000 alloys and coatings – producer of articles – stated that it spent more than €100,000 during pre-registration. This also included time invested with legal experts to understand REACH legislation and its implications, develop business strategy and analyse existing inventory to decide substances to pre-register.</td>
<td></td>
</tr>
</tbody>
</table>

Source: CSES survey and interviews

Registration costs

Registration costs have been, so far, the most important cost element of the regulation affecting manufacturers and importers of chemicals. Formulators and other downstream users may also need to register under certain circumstances, although the survey responses indicate that so far this has been rather limited. Less than 10% of formulators in the survey indicated that they registered at least one substance. Registration costs include the costs of the preparation of dossiers, collection of data from available studies, conducting of new tests (if necessary), development of the Chemical Safety Reports, and the registration fees to ECHA.

The business survey asked respondents to provide information on the average total costs incurred by their firms for the registration of one substance. The results vary greatly but the most common average value stated (mode) falls in the range of €50,000-100,000. The broader range of €25,000-€250,000 represents over 70% of the total responses. In the case of importers of chemicals the distribution is skewed towards lower cost bands, with an important part referring to total costs of €10,000-€25,000. In
contrast, among manufacturers of chemicals average registration costs of over €250,000 were not that uncommon (more than 10%), with a few exceptional cases indicating more than €1,000,000.

Table 4.1 indicates also the mode, the median and the arithmetic mean of the answers provided. Due to the uneven size of the upper value ranges the mean is expectedly higher than the median value. However, as the distribution of values in all cases is positive skewed, we consider that the median represents a most appropriate central value estimate.

Table 4.1 - Distribution of total costs of registration of one substance

<table>
<thead>
<tr>
<th>Costs (€)</th>
<th>Importers of chemicals</th>
<th></th>
<th>Man of chemicals</th>
<th></th>
<th>Total</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>%</td>
<td>No</td>
<td>%</td>
<td>No</td>
<td>%</td>
</tr>
<tr>
<td>0-10,000</td>
<td>7</td>
<td>7.6%</td>
<td>11</td>
<td>4.3%</td>
<td>21</td>
<td>5.6%</td>
</tr>
<tr>
<td>10,001-25,000</td>
<td>18</td>
<td>19.6%</td>
<td>20</td>
<td>7.9%</td>
<td>41</td>
<td>11.0%</td>
</tr>
<tr>
<td>25,001-50,000</td>
<td>22</td>
<td>23.9%</td>
<td>51</td>
<td>20.2%</td>
<td>80</td>
<td>21.4%</td>
</tr>
<tr>
<td>50,001-100,000</td>
<td>24</td>
<td>26.1%</td>
<td>74</td>
<td>29.2%</td>
<td>106</td>
<td>28.4%</td>
</tr>
<tr>
<td>100,001-250,000</td>
<td>19</td>
<td>20.7%</td>
<td>57</td>
<td>22.5%</td>
<td>80</td>
<td>21.4%</td>
</tr>
<tr>
<td>250,001-500,000</td>
<td>2</td>
<td>2.2%</td>
<td>24</td>
<td>9.5%</td>
<td>28</td>
<td>7.5%</td>
</tr>
<tr>
<td>500,001-1,000,000</td>
<td>0.0%</td>
<td>0.0%</td>
<td>7</td>
<td>2.8%</td>
<td>8</td>
<td>2.1%</td>
</tr>
<tr>
<td>&gt;1,000,000</td>
<td>0.0%</td>
<td>0.0%</td>
<td>9</td>
<td>3.6%</td>
<td>9</td>
<td>2.4%</td>
</tr>
<tr>
<td>Total</td>
<td>92</td>
<td>100%</td>
<td>253</td>
<td>100%</td>
<td>373</td>
<td>100%</td>
</tr>
<tr>
<td>Median</td>
<td>48,863</td>
<td>86,824</td>
<td>70,900</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lower quartile</td>
<td>23,333</td>
<td>46,200</td>
<td>41,328</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upper quartile</td>
<td>102,083</td>
<td>188,816</td>
<td>159,532</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean</td>
<td>76,630</td>
<td>162,420</td>
<td>149,500</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Source: CSES survey

The survey responses also provide information on the costs of registration by firm size. The responses show that, on average, the costs for large firms have been higher and skewed towards higher values. In all size groups the distribution is more or less positively skewed towards lower values.

Table 4.2 - Total registration costs per substance - Average values provided by respondents with different firm size

<table>
<thead>
<tr>
<th>Costs (€)</th>
<th>Micro</th>
<th></th>
<th>Small</th>
<th></th>
<th>Medium</th>
<th></th>
<th>Large</th>
<th></th>
<th>Total</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No</td>
<td>%</td>
<td>No</td>
<td>%</td>
<td>No</td>
<td>%</td>
<td>No</td>
<td>%</td>
<td>No</td>
<td>%</td>
</tr>
<tr>
<td>0-10,000</td>
<td>3</td>
<td>10.3%</td>
<td>6</td>
<td>12.0%</td>
<td>7</td>
<td>6.4%</td>
<td>5</td>
<td>2.7%</td>
<td>21</td>
<td>5.6%</td>
</tr>
<tr>
<td>10,001-25,000</td>
<td>8</td>
<td>27.6%</td>
<td>5</td>
<td>10.0%</td>
<td>14</td>
<td>12.8%</td>
<td>14</td>
<td>7.6%</td>
<td>41</td>
<td>11.0%</td>
</tr>
<tr>
<td>25,000-50,000</td>
<td>9</td>
<td>31.0%</td>
<td>9</td>
<td>18.0%</td>
<td>30</td>
<td>27.5%</td>
<td>31</td>
<td>16.8%</td>
<td>80</td>
<td>21.4%</td>
</tr>
<tr>
<td>50,001-100,000</td>
<td>4</td>
<td>13.8%</td>
<td>17</td>
<td>34.0%</td>
<td>28</td>
<td>25.7%</td>
<td>57</td>
<td>31.0%</td>
<td>106</td>
<td>28.4%</td>
</tr>
<tr>
<td>100,001-250,000</td>
<td>5</td>
<td>17.2%</td>
<td>11</td>
<td>22.0%</td>
<td>21</td>
<td>19.3%</td>
<td>43</td>
<td>23.4%</td>
<td>80</td>
<td>21.4%</td>
</tr>
<tr>
<td>250,001-500,000</td>
<td>0.0</td>
<td>0.0%</td>
<td>2</td>
<td>4.0%</td>
<td>7</td>
<td>6.4%</td>
<td>19</td>
<td>10.3%</td>
<td>28</td>
<td>7.5%</td>
</tr>
<tr>
<td>500,001-1,000,000</td>
<td>0.0</td>
<td>0.0%</td>
<td>2</td>
<td>1.8%</td>
<td>6</td>
<td>3.3%</td>
<td>8</td>
<td>2.1%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;1,000,000</td>
<td>0.0</td>
<td>0.0%</td>
<td>0</td>
<td>0.0%</td>
<td>9</td>
<td>4.9%</td>
<td>9</td>
<td>2.4%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Analysis of findings

<table>
<thead>
<tr>
<th></th>
<th>Micro</th>
<th>Small</th>
<th>Medium</th>
<th>Large</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>29</td>
<td>100</td>
<td>50</td>
<td>100</td>
<td>373</td>
</tr>
<tr>
<td>Mode</td>
<td>29,167</td>
<td>78,572</td>
<td>29,546</td>
<td>82,501</td>
<td>75,001</td>
</tr>
<tr>
<td>Median value</td>
<td>34,722</td>
<td>57,353</td>
<td>56,251</td>
<td>86,843</td>
<td>70,900</td>
</tr>
<tr>
<td>Lower quartile</td>
<td>17,969</td>
<td>29,167</td>
<td>30,209</td>
<td>46,775</td>
<td>41,328</td>
</tr>
<tr>
<td>Upper quartile</td>
<td>71,876</td>
<td>106,819</td>
<td>119,643</td>
<td>208,140</td>
<td>159,532</td>
</tr>
<tr>
<td>Arithmetic mean</td>
<td>57,500</td>
<td>88,100</td>
<td>103,716</td>
<td>184,008</td>
<td>149,500</td>
</tr>
</tbody>
</table>

Source: CSES survey

Considering the main drivers of these costs, the survey responses indicate that registration fees and data access – in the form of studies or letters of access are the main cost drivers. Registration fees can represent up to 50% or more of the total costs, especially in the case of rather simple substances when the second important cost element, costs of data or letters of access, are in the low range of €5,000-10,000. The costs for access to data or the relevant studies are often the critical cost driver (>50% of total) for very small firms (<less than 10 employees) that typically buy letters of access but, according to the responses to the survey, not for other categories. For larger firms or in the case of substances that require more complicated studies and data, data collections and SIEF and consortia related costs – including management and other fees – are the main cost element and often exceed €100,000 for each firm. Costs for additional tests are often not included in the estimates provided as they need to be approved by ECHA first. Depending on the substance and the size of the SIEFs they can contribute significantly to the total cost of registration. Human resources costs and/or fees for external consultants for registration are another important cost driver representing, in most cases, between 10-25% of the total. In-house staff is important mainly for large firms while consultants are more often important for smaller size firms. The survey responses indicate no difference between small and large firms in relation to ECHA fees.

Table 4.3 - Main drivers of registration costs - Share of the total costs of different cost elements related to registration (number and share of total respondents indicating)

<table>
<thead>
<tr>
<th></th>
<th>ECHA fees</th>
<th>Data and studies</th>
<th>SIEFs admin. costs</th>
<th>In-house staff</th>
<th>Consultant fees</th>
<th>Additional test costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Not applicable</td>
<td>5</td>
<td>1.6</td>
<td>34</td>
<td>12.2</td>
<td>55</td>
<td>20.6</td>
</tr>
<tr>
<td>1-10%</td>
<td>78</td>
<td>24.6</td>
<td>77</td>
<td>27.7</td>
<td>112</td>
<td>41.9</td>
</tr>
<tr>
<td>11-25%</td>
<td>102</td>
<td>32.2</td>
<td>84</td>
<td>30.2</td>
<td>51</td>
<td>19.1</td>
</tr>
<tr>
<td>26-50%</td>
<td>90</td>
<td>28.4</td>
<td>59</td>
<td>21.2</td>
<td>31</td>
<td>11.6</td>
</tr>
<tr>
<td>51-75%</td>
<td>32</td>
<td>10.1</td>
<td>18</td>
<td>6.5</td>
<td>13</td>
<td>4.9</td>
</tr>
<tr>
<td>76-100%</td>
<td>10</td>
<td>3.2</td>
<td>6</td>
<td>2.2</td>
<td>5</td>
<td>1.9</td>
</tr>
<tr>
<td>Total</td>
<td>317</td>
<td>100.0</td>
<td>278</td>
<td>100.0</td>
<td>267</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Source: CSES survey

More detailed analysis of the cost drivers is provided in Case study 1 in the Appendices.
On the basis of the data available we also made a rough estimation of the total costs incurred by industry for the registration process. According to ECHA data the total number of registration dossiers submitted by the end of the first registration deadline 2011 was around 25,000. The great majority of them (86%) were submitted by large firms, 9% from medium sized, 4% from small and 1% from micro. Thus, on the basis of median value for each of the above categories the central estimate of the cost incurred by all firms that have been involved so far in the registration – manufacturers, importers and, less so, downstream users – is around **€2.1 billion**. The broader range of €1.1 billion to €4.1 billion represents a more certain estimate.

There are some caveats in relation to these numbers. The survey did not differentiate between full registrations and registration of intermediates that, according to ECHA, represent close to 20% of the total. Costs for the registration of intermediates are typically less than €10,000. This would imply a reduction of the above estimate to around €1.65 billion. However, as large number of dossiers (86% according to ECHA) did not successfully demonstrate that these substances were intermediates, additional costs may also apply as part of their update work.

Furthermore, the values provided here do not include the costs for the additional tests that may be necessary for some of the substances. According to ECHA, 574 dossiers containing testing proposals, representing around 2.5% of the total number of registrations, for a total of 1175 tests, including 711 vertebrate animal tests although there is no information as to the types of tests proposed. Industry input suggests that the costs of the various tests may range between hundreds of thousands or in some cases over one million Euros per substance but no specific cost data were made available. According to an earlier study that collected data from a large number of public and private labs in 2004, costs for all testing in the case of substances over 1000tpy were estimated at around €1.5-2 million per substance. The impact assessment study conducted by RPA had indicated testing costs ranging from €80,000 to €450,000 for phase-in substances over 1000tpy on the basis that for a large number required data would be already available or that in-vitro and QSAR methodologies may be used. Using a mid-range value of €250,000 per substance the additional costs for the first registration period it can be estimated that the total additional costs may be around €150 million.

Finally, it should be noted that there are additional updates taking place to most registration dossiers on the basis of comments by ECHA, which introduce additional costs for firms.

**Table box 4.3 – Examples of registration costs incurred by firms**

| Large manufacturer of basic and specialty chemicals with sales across the EU indicated costs of around €15 million for the registration of around 100 substances, representing 0.1% -0.5% of the total annual turnover. |

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61 ECHA data
62 Reliance on the arithmetic mean values would produce a total cost of around €3.4 billion. However, given the positive skewness of the distribution and the uneven and larger size of the higher bands we do not consider that this represents the appropriate value to be used for this estimation.
A Medium size manufacturer of activated carbon registered 20 substances in total indicating costs of close to €10 million, representing around 0.5 -1% of the total annual turnover.

A small size producer of 2 gasoline additives, subsidiary of a large multinational, referred to registration costs of around €50,000, less than 0.1% of the total annual turnover.

A large size importer of metals and other alloys referred to costs of close to €2.5 million for the registration of 20 substances, a little less than half of the total substances they import.

A large unit of a multinational firm producing glues, adhesives and coatings (formulations) referred to average costs per registration of a few critical substances used in their products of around €250,000 with a total share of less than 0.1% of annual turnover. The reason for deciding to register was that suppliers were unclear as to whether they were planning to register the specific substance themselves.

A small size importer of dyes for textiles and paper products has not registered any substance so far but expects significant costs in the coming period for registration related to close to 500 substances.

Source: CSES survey and interviews

Attempting to identify the registration costs incurred at firm level is rather difficult given the great variation in the number and the type of substances registered. The survey data indicates that the majority of firms, close to 50% of respondents, registered between 2 and 10 substances in the first registration period. Thus, on the basis of the cost estimates provided earlier, for the majority of firms that submitted a registration in the first registration period, the total registration costs were within the range of €100,000 to €1,000,000. For the fewer large firms with more than 100 registrations, total registration costs have sometimes exceeded the total of €10 million. In relation to the firms’ turnover, for the great majority of firms (close to 70%) registration costs did not exceed 1% of their annual sales in 2010, although for a small number (around 7%) they were above 5%. There were no marked differences between small and large size firms in this respect.

Communication in the supply chain

Communication in the supply chain includes in most cases significant human resources that are dedicated to the development, handling and extraction of the relevant information to be included in the SDSs or the extended SDSs. IT applications are also often purchased by firms to help them in the development and handling of SDSs and eSDSs and the large number of questions and emails from suppliers or customers. External consultants are also often used to help in the development and, if necessary, the translation of the eSDS to the relevant language of their customers. For firms that decide to outsource the development of SDSs, one source indicates fees around €200 for each SDS and €500 for eSDSs. Translation costs can add between €100 -300 per language.

66 A number of firms suggested that the share in total sales is not an appropriate indicator and that the share in the total profits should have been considered.
67 Data for these cost is currently only provided by one source and need to examined further.
The human resources costs related to the exchange of information in the supply chain are largely included in the staff costs analysed in the previous section. In the case of IT systems the CSES survey did not provide information on such costs. However, individual discussion indicates costs for medium size firms of €30,000 or more and reaching a few hundred for large firms. An analysis by Accenture Consultants of IT systems which support a greater range of REACH activities indicates that the costs for such systems can range from €1 million for a small size company with a single entity, to up to €16 million for a medium to large company with multiple units.

In summary, it is rather difficult at this stage to provide overall estimates of the costs from these activities. According to the majority of the survey respondents (close to 70%) REACH has increased the costs of managing information exchange and this applies more or less equally for firms with different roles in the supply chain. The individual comments provided by all types of firms; large or small, manufacturers, importers, downstream users and distributors, and corroborated by most industry associations, is that at this stage the whole information exchange is adding to administrative costs as a result of the non-standardised and often very long eSDSs (often over 100 pages and in some cases up to 1,000), and a large number of information requests that absorb time and resources. Disclosing information along the supply chain often involves manufacturers inside, and/or outside Europe with limited awareness of the requirements which makes obtaining the necessary information a demanding process for all actors involved and possibly add further to the human resources indicated earlier.

http://www.accenture.com/SiteCollectionDocuments/PDF/Accenture_Chemicals_P_OV_REACH.pdf
The handling of SDSs clearly has a role in the experience and the costs for firms. The business survey suggests that the main problematic aspects of the safety data sheets include the time and resources necessary to prepare them (91%), their length and complexity (90%), the difficulty in fulfilling the information requirements (81%), the short time allowed to develop them (79%) and the lack of standardised format. (see more information on SDSs in Case study 2)

However, a number of survey respondents proposed that as experience develops and eSDSs become more standardised, information exchange should improve and become much more efficient. However, for the time being it is still a very demanding and resource-intensive exercise. SME producers or importers dealing with downstream users with very limited understanding of the Regulation consider this a very demanding and resource intensive exercise. Arguably, in sectors with already integrated supply chains (e.g. automotive or medical equipment) the adjustment appears to be smoother than in others (e.g. electronic devices or machinery) with more arms length relationships among many small and medium size firms and limited experience of communication. As described in more detail in case study 2 some sectors (automotive, aerospace, plastics) have developed tools to help extract and communicate the necessary information.

Furthermore, we should note that important part of these costs (IT system, initial work for the preparation of the SDSs) are one-off costs and that once in place the handling of SDSs will require less time and resources.

### Table box 4.4 – Examples of supply chain communication costs incurred by firms

A medium sized manufacturer of activated carbon selling in six EU countries referred to a total expenditure of around €6,000 for the preparation of five SDSs and one extended SDS.
A large sized producer of power engines and other equipment for the aeronautic and defence industry (producer of articles) has invested in a number of IT tools for the management of REACH related information internally and externally and to integrate with other resources and operations systems. The total cost so far has been over €750k and an additional €1-1.5 million has already been budgeted for the coming period. The costs of handling SDS so far could not be estimated as there is limited information on the number of SDSs that they may have to prepare themselves as they are still waiting to receive the new SDSs by their suppliers of chemicals (formulators).

A small sized producer of paints and varnishes (formulator) has had to handle close to 3,000 SDSs, and no more than 20 eSDS. They acquired specialised software to help handle information in SDSs and also had to make modifications to existing systems and to train staff. The total costs so far have been around €11,000.

A small sized producer of specialised coatings for defence related equipment has spent close to €55,000 for a new IT system to help develop SDSs related to most of the 100 products they produce and the 500 chemical substances used. They suggested that they have spent a lot of time in communication with suppliers and customers.

A medium sized producer of coating used in the automotive sector with over 1,000 different products referred to a budgeted investment to a dedicated IT system to help handling SDSs. The total costs were expected to be in the range of €250,000 with additional €25,000 maintenance costs annually.

A large sized distributor of over 100 chemicals selling in five countries in the EU referred to the significant problems from the length of some SDS documents and the frequency of communication for their update. They exchanged over 50,000 emails for only one product when this entered the candidate list and spent significant amount of spent explaining to suppliers the various information requirements.

Source: CSES survey and interviews

Authorisation application

So far the costs incurred by industry for the authorisation process have been rather limited. The first six substances were introduced in the authorisation list on February 2011, and no authorisation application has been submitted so far. ECHA indicates that around 100 authorisation applications are expected annually after 2014.

The costs of authorisation applications is expected to include the fees to ECHA that can start from €7,500 for micro enterprises applying for the authorisation of one substance and only one use but can exceed a total of €100,000 for large firms applying for multiple uses or multiple substances. These fees are however expected to be a minor part of the total costs, which will include the development of chemical safety reports, studies and data collection for the assessment of alternatives (that can also include R&D activities), and the socio-economic impact analyses. There is no available evidence so far to allow for the creation of meaningful estimates. On the basis of the costs for the registration procedure, the fact that additional data is needed, and that there will be a much smaller number of firms applying –
very often only one – the costs for each authorisation may well exceed the total of €500,000 or even €1,000,000 per substance.

Notification of articles

Producers or importers of articles may also need to submit a notification to the Agency in the case of articles containing more than 0.1% w/w of substances of very high concern (SVHCs). The first deadline was on the 1st of June 2011 but the Agency indicated that there have been only a handful of notifications so far. Information from one source indicated that the cost for a notification is usually in the range of €800-1000. This cost element is expected to affect only a small share of firms since it only concerns firms using SVHCs and only when the use of the substance is not already described in the registration.

Investments in risk management processes

At this stage, there has been limited evidence in relation to the possible investments in risk management processes resulting from the additional information acquired. Firms still have 12 months to react to any relevant information included in the SDSs, and not all SDSs have been sent yet. Around 10% of the survey respondents indicated that there was a change in risk management processes but most suggest that it is still too early to assess the impacts of such changes as the focus is on registration and development of SDSs. If any, these costs – as well as the relevant benefits from improved health and safety - are expected to come in the coming years.

Other costs

A number of firms refer to the necessary training activities for their employees (seminars etc.). Costs of training events may vary depending on the country, although they are typically in the range of several hundred Euros per participant. However, many of the training activities are organised by national or European industry associations or even Member states authorities with low fees for their participants. These costs cannot be seen as representing a substantial part of the total costs incurred, although this may not be the case for downstream users that are not involved in registration or other activities.

Finally, a few industry associations made reference to the important opportunity costs resulting from REACH, particularly in relation to R&D involved in the development of registration dossiers instead of new products development. There is no data available to estimate these costs for firms. However, as indicated in greater detail later in the report, only a small share of firms consider that the registration process leads to the creation of new useful knowledge for the firm.

Evolution of costs in the future

In relation to the evolution of the costs over time, most firms (75%) in the survey indicated that they expect them to increase in the coming years and only around 10% considered that they should decrease. Individual comments suggest that, despite the reduced data requirements and fees for the second

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70 In the case of industry associations’ activities there are still indirect costs through membership fees.
71 The REACH Innovation report might throw more light on this matter.
registration period, most firms expect that there will be more registrations in the coming period and for substances for which data are not available. However, this seems to be in conflict to the estimates provided by ECHA in relation to expected registrations for the coming years that were expected not to exceed a total of 15,000 in 2013 including updates of earlier dossiers. During our discussions with ECHA it was explained that the existing estimates are under revision awaiting the results of the feedback from industry. In our estimations of future costs we have used ECHA numbers but, based on the information available, a greater number of registrations should be expected.

Based on ECHA estimates, with an average registration cost for the second period at 50% of the estimate for first registration period (€37,500-50,000) and costs for updates around €10,000, the total registration costs for industry for the coming three years are estimated within the range of €0.6-0.8 billion.

Table 4.4 - Estimated registration costs for industry for the period 2012 -2014

<table>
<thead>
<tr>
<th></th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total registrations</td>
<td>5100</td>
<td>13300</td>
<td>6500</td>
</tr>
<tr>
<td>Number of updates</td>
<td>3825</td>
<td>4655</td>
<td>4875</td>
</tr>
<tr>
<td>Number of initial registrations</td>
<td>1275</td>
<td>8645</td>
<td>1625</td>
</tr>
<tr>
<td>Average cost for update</td>
<td>10,000</td>
<td>10,000</td>
<td>10,000</td>
</tr>
<tr>
<td>Total costs for updates</td>
<td>€38 million</td>
<td>47 million</td>
<td>49 million</td>
</tr>
<tr>
<td>Average cost for initial registration</td>
<td>70,000</td>
<td>35,000</td>
<td>35,000</td>
</tr>
<tr>
<td>Total cost for registrations</td>
<td>€90 million</td>
<td>€300 million</td>
<td>€57 million</td>
</tr>
<tr>
<td>Total cost estimate</td>
<td>€ 128 million</td>
<td>€ 347 million</td>
<td>€ 108 million</td>
</tr>
</tbody>
</table>

Source: ECHA and own estimations

However, as more firms become involved in the registration and exchange of information the communication activities in the supply chain may become even more demanding. Individual firms’ costs will vary greatly depending on the type of substances involved and number of supplier and customers but, overall, most industry representatives expect that the costs for each firm should increase in the coming period. On the other hand, as greater experience is gained and SDSs become more standardised the process should become more efficient.

Comparison with initial estimates accepted by the Commission

The cost estimate for registration, testing and ECHA fees of €2.1 billion provided in this study deviate from the estimates provided in the impact assessment presented by the Commission in 2003 which were based on an study conducted by RPA Ltd but were subsequently adopted following changes to certain cost elements as well as simplifications to the Regulation. The total estimate provided in the impact assessment for the whole 11 year period of the implementation of the Regulation was close to €2.3 billion (2003 values - around €2.6 billion in 2011 values). The impact assessment report does not


73 RPA (2003), Revised business impact assessment for the consultation document , Working Paper 4 - Assessment of the Business Impacts of New Regulations in the Chemicals Sector - Phase 2
provide specific figures for the first registration period but, on the basis of additional data made available from the Commission services, the costs for registration of the first registration period (including registration, testing and ECHA fees) was expected to be around €950 million in 2003 values (€1.1 billion in 2011 values). Thus, the cost estimate of the Commission in 2003 was close to 55% of the mid-range estimation of €2.1 billion on the basis of the information collected.

CSES attempted to identify the key parameters that led to this quite significant deviation by examining both the RPA study results and the subsequent changes made by the Commission services. The analysis indicates two main issues:

= Differences in comparison to the approach followed by RPA and the type of costs considered that should be expected to lead to higher costs in CSES study

- Assumptions in the calculation made by the Commission services that were based on the RPA study that further reduced the costs estimated

A key difference between this study and that of RPA study is that the latter considered only the additional, new, costs arising for industry from the REACH Regulation. The fees paid by firms for getting access to existing studies were not considered in their calculations. CSES average cost estimates include fees paid by firms to other SIEF members to get access to studies or for the letters of access. In that respect, these are financial costs for firms resulting from REACH even if they are not additional costs for the industry. It is not possible to provide an estimate of the difference arising, but clearly CSES estimates should be expected to be higher than those of the RPA study as well as the subsequent Commission estimates based on them.

The initial estimates of the RPA study were very close to the results of this study, when the costs related to the registration of polymers are excluded. According to the RPA report, the registration and testing costs for the first registration period were expected to be in the range of €1.8-1.9 billion in 2003 values (€2.1-2.2 billion in 2011 values). However, had RPA taken into consideration the fees paid for access to existing data the total cost estimate would have been higher.

On the other hand, the RPA study assumed a large number of individual registrations expected (close to 70% of total) and a smaller size of SIEFs/consortia – 3-5 in comparison to the actual average of around 7. This meant that the costs per registration and per firm were overstated.

At the same time, the final estimates presented by the Commission that followed the consultation process made some additional rather ambitious assumptions concerning the use of QSARs in testing that led to significant reduction of the expected total costs. The assumptions were based on a study of the Joint Research Centre and were expected to lead to savings in testing costs of up to €1.3 billion in comparison to the initial estimates of the RPA study. This amount exceeds the difference between the estimates resulting from the CSES study and the initial Commission estimates (around €1 billion in 2011 values).

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74 The initial draft Regulation provided for the registration of polymers which were included in the RPA calculations. Eventually the registration of chemicals was removed. We have deducted from the final number all costs related to polymers.

75 We are not suggesting that RPA made a mistake in their approach. We simply indicate that our study has produced a different type of cost estimate.
values). However, according to the recent ECHA report, QSARs have, so far, represented no more than 4.1% of any type of tests included in the registration dossiers in comparison to the average value of 30–60% assumed in the JRC study. Thus, most, if not all, of the €1.3 billion savings assumed have not materialised.

These two elements should be seen as explaining the important differences in the two estimates. On the one hand, there is a financial cost element added in this study that was not considered in the initial calculations. On the other, there were significant assumptions made on the savings from QSARs that have not materialised to this point.

Table 4.6 - Comparison of cost estimations for CSES study in comparison to RPA revised impact assessment and Commission estimates - 1st registration period

<table>
<thead>
<tr>
<th>Key figures</th>
<th>Commission estimates (&gt;1000 tonnes)</th>
<th>CSES study estimates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of phase-in and non phase in registrations</td>
<td>21,000</td>
<td>20,000</td>
</tr>
<tr>
<td>Intermediates’ registrations</td>
<td>4,575</td>
<td>5,000</td>
</tr>
<tr>
<td>Total registrations</td>
<td>25,575</td>
<td>25,000</td>
</tr>
<tr>
<td>Costs of registration (not including fees paid for access to existing studies)</td>
<td>€20 – 60k/registration/firm</td>
<td>€70,000/registration/firm (median value)</td>
</tr>
<tr>
<td>Costs of testing</td>
<td>€84k-440k/substance</td>
<td></td>
</tr>
<tr>
<td>Cost of intermediates registration</td>
<td>€8.8-27.8k/registration/firm</td>
<td>10,000</td>
</tr>
<tr>
<td>Average size of consortia/SIEFs</td>
<td>3-5</td>
<td>7</td>
</tr>
<tr>
<td>Cost estimates</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total registration costs (excluding polymers)</td>
<td>€284 million (2003 values)</td>
<td></td>
</tr>
<tr>
<td>Total testing costs (excluding polymers)</td>
<td>€1,540-1,580 million (2003 values)</td>
<td></td>
</tr>
<tr>
<td>Total cost of registration and testing (RPA study)</td>
<td>€1,824-1,886 million (2003 values)</td>
<td>€2,079-2,150 million (2011 values)</td>
</tr>
<tr>
<td>ECHA Fees for first registration period</td>
<td>€267 million (2003 values)</td>
<td>€350 million (2011 values)</td>
</tr>
<tr>
<td>Expected reductions from RPA estimates assuming high use of QSARs (Commission study)</td>
<td>Up to €1,300 million (2003 values)</td>
<td>€1,480 million (2011 values)</td>
</tr>
</tbody>
</table>

76 Excludes estimate for polymers
77 ECHA general report 2010
### Analysis of findings

<table>
<thead>
<tr>
<th></th>
<th>Commission estimates (&gt;1000 tonnes)</th>
<th>CSES study estimates</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total estimated cost of registration, testing and ECHA fees</strong></td>
<td>€955 millions (2003 values)</td>
<td>€2,100 million (2011 values)</td>
</tr>
<tr>
<td></td>
<td>€1,088 million (2011 values)</td>
<td></td>
</tr>
</tbody>
</table>

#### 4.2.2 Impact on the financial situation of companies

While many firms and associations suggested that it is still too early to properly assess the impacts of REACH on their financial position, comments from many upstream firms and industry representatives state that, in the short term, their financial situation has been negatively affected.

The severity of this impact depends on the type of product traded and the profit margins. For firms in highly price competitive markets (such as basic metals that are treated as commodities), low profit margins have been squeezed as there is limited capacity to transfer these costs to consumers through price increases. In other markets – such as certain segments of the fine chemicals industry – a number of respondents appeared confident of their capacity to increase prices and maintain profit margins, without seriously affecting their overall financial position. Overall however, it is usually the case that firms have tried to absorb the costs – thus possibly shrinking profit margins in the short term – rather than passing down the costs to their customers (see also analysis in section below).
Chart 4.2 - Response of firms to the increase of costs resulting from the REACH regulation (Percentage of responding firms indicating that they absorbed the costs or increased the price of their products/services frequently or always)

Source: CSES survey

This said, it is important to look at the impact of REACH in context. Irrespective of the sector, in all almost all cases the financial crisis and the increase in energy prices have proved rather inconvenient in their timing for the implementation of REACH and have often squeezed pressed further the financial position of firms.

The table below presents comments made by industry associations and individual firms that reflect the broad range of positions in relation to the impact on the costs for firms and their financial position.

Table box 4.5 – Representative comments from industry associations and firms on the impact on REACH costs on prices of products and financial position of firms

<table>
<thead>
<tr>
<th>Source</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Representative of construction chemicals' industry</td>
<td>There has been an increase in prices of products but it is very difficult to assess to what extent this was due to REACH or other costs (e.g. energy costs).</td>
</tr>
<tr>
<td>Representatives of ICT equipment manufacturers</td>
<td>For electronics it is still early on as the impact on the supply chain is related to information requirements. There are no changes in the market share of firms and prices are also not expected to be materially affected.</td>
</tr>
<tr>
<td>Cross-sectoral industry representative</td>
<td>It is hard to motivate firms to invest [especially] in products on the candidate list. Generally, compliance has drained financial resources by having to employ/contract more people. It is harder for smaller firms without substantial financial</td>
</tr>
</tbody>
</table>
## Analysis of findings

<table>
<thead>
<tr>
<th>Source</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>National association of Chemicals’ industries</td>
<td>Greek firms that face significant pressures and limited access to finance due to contraction of the domestic market. REACH is an additional cost at a time where many firms are facing survival issues.</td>
</tr>
<tr>
<td>Medium size manufacturer of metals</td>
<td>Administration costs have increased significantly for our substances. Upon registration [these costs] became dangerous [i.e. prohibitive].</td>
</tr>
<tr>
<td>Small sized manufacturer of articles in medical applications</td>
<td>We expect an increase in costs which we will not be able to translate to an increase in price due to heavy competition.</td>
</tr>
<tr>
<td>Large sized manufacturer of construction chemicals</td>
<td>REACH led to rise in costs that we were unable to pass to the market, thereby leading to reduced profits.</td>
</tr>
<tr>
<td>Medium sized firm producing formulations used for cleaning various types surfaces (formulator)</td>
<td>Difficult to evaluate. Higher prices for raw materials have so far been justified on higher manufacturing costs [by our suppliers], but no direct relation to REACH has been made.</td>
</tr>
<tr>
<td>Small firm using chemicals for surface coating in the aerospace industry (end-user)</td>
<td>We have not as yet been able to pass on the extra costs but know that they will increase in years to come.</td>
</tr>
</tbody>
</table>

Source: CSES survey and interviews

### 4.2.3 Impact of REACH on prices of chemical substances and final products

As already indicated, most firms have not, or very rarely, increased the price of their products to incorporate costs associated with REACH. 63% of companies claimed that they ‘never’ or ‘seldom’ increased the price of their products in order to incorporate costs. There is no notable difference between the answers depending on the position of companies in the supply chain. At the opposite end of the scale, only 16% of companies have indicated that they increased their price “frequently” or “always”. The survey results also allowed for a finer analysis of a few sub-sectors for which there are statistically significant answers (industrial gases, other inorganic basic chemicals and pesticides and other agrochemicals). All provided a similar response pattern, with between 15% and 18% claiming to have increased their prices ‘frequently’ or ‘always.”
However, when asked to state the impact of the Regulation, more than 55% of EU firms suggested that REACH has led to an increase in the prices of their products in comparison to their non-EU competitors affecting their competitiveness in non-EU markets. Comparing this data with the responses from the previous questions concerning the absorption or increase of prices, 45% of the firms which stated that they have not increased the price of their products seemed to contradict themselves by also stating that the prices of their products have increased in comparison to non-EU competitors. In particular this is the case among formulators, and to a lesser extent among manufacturers of chemicals. However, besides the possibility of an incorrect interpretation of the questions, we consider that firm’s responses reflect a more general negative view of REACH compliance costs to the competitiveness of firms. Despite the apparent lack of a clear picture on the impact on prices and relative competitiveness of EU firms, it is possible to establish a basic typology of the effect of REACH on prices. Market leaders or firms in niche markets – such as specialty chemicals – can more often increase their prices, unless they are competing in international markets. According to the feedback from industry associations, the prices of niche specialty substances have increased, although the extent of this price hike is a factor of disagreement. One national chemical association claimed that the price of fine chemicals increased by as much as 25%, while another referred to an increase in the range of 3%-5%. Furthermore, according to a trade association representing downstream users, the price of chemicals increased sharply before the registration deadline, because of users stocking certain substances before the entry of REACH into force. As suggested, prices of some chemicals have remained high due to the low number of registrants and this has allowed them to benefit with increases in prices of up to 50%.

In contrast, producers of commodity chemicals, such as basic chemicals, monomers for plastics, and basic metals will most often absorb the costs. According to the relevant associations, the price of high volume and low margin products, such as metals or the chlor-alkali, have not significantly increased as a
result of REACH. Despite the costs linked to registration, it has not been possible to pass on price increases to downstream users. In general, they absorb REACH related costs.

Considering the impact on the prices for final consumers, and on the basis of the answers presented above, it should be expected that certain categories of consumer chemicals should be affected by REACH compliance costs. Existing EU-wide or national data on the development of consumer prices for chemical products does not allow for any direct assessment of the impact of REACH. Price indices for chemicals depict trends that are affected by a large number of parameters such as energy prices, changes in demand, and levels of stocks and do not allow for meaningful conclusions in relation to the impact REACH.

Considering the prices of articles that include chemical substances, the answers of manufacturers of articles again indicate that price increases concern only a small share of products. The costs of chemical substances most often represent only a small share in the total production costs of articles. Thus, as far as articles are concerned, REACH contribution to price increases will most probably be marginal. At the same time, competition forces most often do not allow for an increase in prices. For example, according to the textile manufacturers associations, the high level of competition from non-EU countries does not allow them to pass on their costs to users further down the supply chain.

Concluding, whilst there may be several categories of chemicals and consumer products where prices may have been negatively affected there is, at least so far, no evidence that this has been a widespread phenomenon. The general trend across the supply chain has been towards the absorption of those costs in view of the competition with products outside the EU. In addition, in certain markets the stockpiling of chemicals or articles with chemicals that did take place prior to the entry of REACH into force may also play a role in the development of final consumer prices.

4.2.4 Access to chemical substances

An important issue concerning the overall impact of REACH is its affect on the availability of substances in the EU market. The survey results suggest that an important number of firms (37% of total) have experienced a withdrawal of substances as a result of REACH, either as suppliers or as users of substances. Furthermore, around 30% of the total respondents expect that this will happen in the future. Among suppliers, manufacturers and importers of chemicals around 25% stated that they decided to remove one or more substances from the market, most often usually representing a small share of their portfolio. On the other hand, among formulators there seems to be a much more frequent experience of withdrawal of substances they use. As indicated in some interviews another approach, even though less common, has been the sharing of the costs on the basis of agreements between manufacturers and downstream users.
The analysis of individual comments concerning downstream users suggests that ‘the experience of withdrawal’ most often does not mean complete loss of access to the specific substance, but rather the decision of the specific supplier to discontinue trading the substance. Furthermore, according to the survey responses, a sizable proportion of downstream users that have experience the withdrawal of at least one substance have switched to another supplier. (63% within the EU and around 40% to a non-EU supplier).

This picture of a limited degree of withdrawal of chemicals is confirmed by the input of industry associations. A number of them referred to expected or actual withdrawals of certain substances. The basic metals industry suggested that consortia for metals identified 11 substances that are expected to be withdrawn, the aerospace and defence industry referred to the possible withdrawal of chromium trioxide (commonly used as surface coating), while the representatives of distributors stated that according to a survey conducted among their members, 300 substances have not been registered and some are expected to disappear. These factors considered, they concluded that thus far substance withdrawal is not a widespread phenomenon.

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**Chart 4.4 - Experience of withdrawal of chemical substances from the market as a result of REACH**

(Manufacturers or importers of chemicals indicate their own activity in relation to chemicals they produce/import. Remaining categories referred to their experience in relation to the withdrawal of substances they use)

<table>
<thead>
<tr>
<th>Category</th>
<th>YES</th>
<th>NO, but expect in the future</th>
<th>NO and do not expect to happen</th>
<th>No experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Distributors</td>
<td>37%</td>
<td>31%</td>
<td>20%</td>
<td>11%</td>
</tr>
<tr>
<td>End users</td>
<td>27%</td>
<td>40%</td>
<td>22%</td>
<td>11%</td>
</tr>
<tr>
<td>Importers of articles</td>
<td>26%</td>
<td>21%</td>
<td>53%</td>
<td></td>
</tr>
<tr>
<td>Manuf. of articles</td>
<td>46%</td>
<td>28%</td>
<td>67%</td>
<td></td>
</tr>
<tr>
<td>Formulators</td>
<td>59%</td>
<td>26%</td>
<td>8%</td>
<td>6%</td>
</tr>
<tr>
<td>Importers of chemicals</td>
<td>28%</td>
<td>70%</td>
<td>2%</td>
<td></td>
</tr>
<tr>
<td>Manuf. of chemicals</td>
<td>25%</td>
<td>46%</td>
<td>42%</td>
<td>9%</td>
</tr>
</tbody>
</table>

Source: CSES survey
This is also supported by the responses of the survey concerning the actual number of substances withdrawn. Among companies with experience of withdrawals – either suppliers or downstream users – the great majority of them – 84% of the total – stated this did not apply to more than five substances.

Chart 4.5 - How many substances have been withdrawn so far?

Source: CSES survey

While the problem of access to substances does not seem to be critical at this stage, one can still conclude that the current developments indicate a trend towards higher market concentration in some chemicals’ markets. This is the combination of the withdrawal of some firms from certain markets, the reduction in the level of production by some others and, at the same time, the fact that a number of firms switch to existing producers. Put together this suggests that for certain chemicals – particularly those that offer low profit margins such as chromium or potassium-related ones – there has been a certain reduction in the number of suppliers leading to reduced choice and competition in these markets. During the fieldwork we were also told of decision of importers closing down or selling their businesses to larger firms due to the REACH costs. In the medium to long term this can possibly lead to increase in prices, a concern raised by the base metal and steel sectors.

Considering the reasons for the withdrawal of substances, by far the most common reason – according to the survey results – appears to be the registration costs that make the overall trading of the substance
unprofitable. This is in line with the initial expectation that REACH would lead some suppliers to decide to rationalise their portfolio by focussing on specific substances, or stopping production of lower margin products. An alternative approach followed by some firms producing at levels close to 1000tpy was to reduce production in order to avoid the first registration period costs.

Besides registration costs, the placement of a substance in the candidate list for authorisation is also stated by industry associations as a driver of chemical withdrawal, although it applies to only a relatively small share of the total number of substances. The majority of trade associations - both at national and at European level - referred to increased pressure from producers of articles and retailers in relation to the presence of such chemicals in products. There were specific examples of manufacturers in the electronics equipment sector, as well as of a number of retailers asking suppliers to stop using substances included in the candidate list even before they have been evaluated and placed on the authorisation list. Our own interviews with two large retailers supported this conclusion. However, as has been argued, this is far from a general rule.

Referring to the role of the candidate list, one global business association (the IPC – Association of Connecting Electronics) has also expressed concern about the business case for investing in developing substitutes as there is no certainty as to what might appear on the candidate list and when. From their point of view there is no discernible scientific rationale behind the inclusion of substances in the candidate list, including those that could make the process clearer and more predictable, and allow them to avoid developing substitutes that may also end up in the candidate list shortly after. From their point of view the candidate list is seen as creating high levels of uncertainty in the industry, discourages investment, and works against the overall competitiveness of the industry versus non-EU firms. While such strong views were not expressed by other industry representatives, there were still some concerns raised concerning the signal often sent once a substance is included in the list.

Overall, it could be said that the information available at this stage does indicate that a certain level of substance withdrawal has indeed taken place. However, with the exception of certain specific market segments, such as substances used in the metal coatings (e.g. aerospace, automotive, nuclear and building industries) does not seem thus far to have created problems in the supply of chemicals to consumers. Despite early fears from the industry, there is no evidence of "orphan" articles (i.e. articles containing substances that have not been registered). However, industry associations are still concerned that this may happen in the following two deadlines.

Table box 4.6 - Representative comments from industry associations and firms on the impact of the withdrawals of substances

<table>
<thead>
<tr>
<th>Source</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Representative of the mining industry</td>
<td>A number of niche chemicals that could have disappeared did not thanks to producers and downstream users agreeing to share the costs of registration.</td>
</tr>
<tr>
<td>Representatives of the aerospace and Defence industry</td>
<td>Concerned about possible withdrawals, or from people who decide not to register. Have acquired some firms to ensure security of supply from producers of small quantity chemicals</td>
</tr>
</tbody>
</table>

78 A total of 95 manufacturers or importers of chemicals stated this as the main reason. Because of the relatively low number of companies responding to this question, we prefer not to translate those figures into percentages.
Representative of a national textiles’ association | For the time being, we cannot estimate the possible withdrawal of chemical substances from the market. It is more the low volume substances which will have to be registered in 2013/2018 which might be at risk.

Representative of the steel industry | For some of our members this has already occurred whilst for others is something that is likely to happen in the near future specially with the substances subjected to Authorisation.

Medium Italian importer of chemicals | We have commenced buying from a European importer that has invested by registering the substance to the hilt, knowing that they would be the only ones and that everyone would have thus referred to them.

Large British formulator | Moved manufacture outside EU to sister companies in Singapore, China, India where legislation is not so restrictive.

Small formulator in the printing sector | The properties of our finished products are not as good as they used to be as no substitutes exist.

Medium UK-based coater | Built up stock prior to registration deadline. Substance affected was fully registered at a later date. Searching for an alternative to some formulations that have been withdrawn with little or no notice.

Source: CSES survey and interviews

4.2.5 Impact on downstream users

The main expected impact of the REACH regulation on downstream users is related to the loss of access to substances used in the production processes and the potential issues related to their substitution.

As already indicated, a certain degree of substance withdrawal has already taken place. A total of 36% of downstream users have seen substances being withdrawn from the market as a result of REACH, and a further 25% expect this to happen in the near future. However, according to a number of downstream users’ representatives, an important number of these substances had been in the last stages of the product life cycle, and they were expected to be withdrawn regardless of REACH. For those substances, the regulation has only accelerated a natural trend. Having said that, more, and more important, withdrawals are expected in the coming period. According to textile manufacturers some of the substances widely used for textile goods such as flame retardants or certain types of dye will be withdrawn because of non-registration.

So far, the most common response of firms was to identify substitutes (53% suggested it as the most common response). Only a small share of downstream users (close to 12%) stated that they have decided to register the relevant substance themselves on at least one occasion.

Table 4.7 – Response of downstream users to the withdrawal of critical substances as a result of REACH (% among firms that have experience the withdrawal of at least one substance).

<table>
<thead>
<tr>
<th>Options</th>
<th>Substituted with other substances with less hazardous properties</th>
<th>Switched to another supplier based inside the EU</th>
<th>Switched to another supplier based outside the EU</th>
<th>The firm registered the relevant substance</th>
</tr>
</thead>
</table>

Source: CSES survey and interviews
Interim Evaluation: Functioning of the European chemical market after the introduction of REACH
Final report

Analysis of findings

<table>
<thead>
<tr>
<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>Never</td>
<td>9</td>
<td>6%</td>
<td>44</td>
<td>37%</td>
<td>76</td>
<td>67%</td>
<td>94</td>
<td>88%</td>
</tr>
<tr>
<td>Seldom</td>
<td>20</td>
<td>13%</td>
<td>18</td>
<td>15%</td>
<td>11</td>
<td>10%</td>
<td>3</td>
<td>3%</td>
</tr>
<tr>
<td>Sometimes</td>
<td>42</td>
<td>28%</td>
<td>35</td>
<td>29%</td>
<td>23</td>
<td>20%</td>
<td>7</td>
<td>7%</td>
</tr>
<tr>
<td>Frequently</td>
<td>37</td>
<td>25%</td>
<td>15</td>
<td>13%</td>
<td>4</td>
<td>4%</td>
<td>0</td>
<td>0%</td>
</tr>
<tr>
<td>Always</td>
<td>41</td>
<td>28%</td>
<td>8</td>
<td>7%</td>
<td>0</td>
<td>0%</td>
<td>3</td>
<td>3%</td>
</tr>
<tr>
<td>Total</td>
<td>149</td>
<td>100%</td>
<td>120</td>
<td>100%</td>
<td>114</td>
<td>100%</td>
<td>107</td>
<td>100%</td>
</tr>
</tbody>
</table>

Source: CSES survey

The substitution of chemicals is not always possible or easy, especially when the properties of the substances to be replaced are rather critical. A number of manufacturers that have switched substances consider that the performance of their substitutes is poorer than what was the case with the original product. Referring to the example of chromium related to the RoHS Directive, the engineering industry association (Orgalime) indicated that finding a substitute in switches took close to seven years. In another example, in the case of aluminium silicates and chromium oxides used in coating aircraft, the known substitute has a far shorter lifespan (5 years instead of 30), and there is a loss in the time the aircraft needs to be off the commercial circuit for re-coating. When necessary, large firms in the automotive or defence sector decided to register a substance themselves in order to maintain access to it. In one case the firm supported their supplier financially and guaranteed a minimum level of sales in order to convince them to register the specific substance. In another, a firm in the aerospace sector decided to acquire an SME supplying a critical substance to ensure continuity of supply. Such strategic decisions are possible for large firms but in the majority of the cases not viable options for smaller size users of chemicals.

Switching to other suppliers can also be a difficult exercise. Firms referred to substantial resources dedicated to identifying alternative suppliers of substances and to confirm continuing supply in the future. It has often been hard to obtain such commitments that are legally binding.

Table box 4.7 - Representative comments from industry associations and firms on the impact of substitution on downstream users

<table>
<thead>
<tr>
<th>Source</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Representative of the aerospace industry</td>
<td>We spent two years trying to prove the capacity of certain substances for product needing high reliability. This leads to increased costs to the business.</td>
</tr>
<tr>
<td>Firm using zinc electroplated processes</td>
<td>We have had to try to sort another passivate substance from a different supplier but this is proving difficult as other suppliers are taking the same stance, that if a substance will be entered onto the SVHC list then ultimately they will discontinue supplying products containing this substance.</td>
</tr>
<tr>
<td>End user</td>
<td>Substitution could be done quite smoothly because we know a suitable alternative. However it was not easy and it cost to examine/compare the reliability of the products with the alternat ive.</td>
</tr>
<tr>
<td>Consumer electronics industry association</td>
<td>With complex supply chains, it is not always possible to ask suppliers outside the EU to substitute one or more of their substances.</td>
</tr>
<tr>
<td>Retailer</td>
<td>REACH can help with substitution – mainly linked with authorisation.</td>
</tr>
</tbody>
</table>
Analysis of findings

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(expect that it will help in substitution) – already changes in certain product groups – there is currently focus on substitutions for SVHCs.

Representative of the steel industry

For some substances, no substitute exists, for example coal tar pitch, borax in powder, strontium chromate. Substituting for these substances is very slow in comparison to the deadline for not using a certain substance. Therefore the company needs to adapt its processes and find technical solutions before, which in turn means high costs.

Source: CSES survey and interviews

Besides the issues related to the withdrawal of substances, the requirement to communicate along the supply chain is another key challenge stakeholders face with REACH. The experience of most downstream users with the handling of SDSs seems rather negative. The survey responses of DUs (formulators, manufacturers of articles and end-users aggregated) show that the safety data sheets pose problems to firms due to the time and resources necessary to prepare them (90%), their length and complexity (86%), the difficulty in fulfilling the information requirements (80%), the short time allowed to develop them (79%) and the absence of a standardised format (79%) (see also Case study 2).

4.2.6 Impact on imports and exports, competition from outside the EU and business relocation

One of the key concerns of industry towards the implementation of the REACH is related to the impacts that the compliance and information exchange costs may have to the capacity to compete against non-EU manufacturers.

In its most alarming form, a few industry representatives and firms referred to the danger of relocation of activities outside the EU in order to take advantage of reduced requirements in relation to the manufacturing of articles with chemicals. There were examples provided from the steel, medical devices industries, and the business survey also uncovered a few cases of firms indicating an intention to move all or part of their activities outside Europe. A director of a leading chemicals firm suggested that REACH confirms the image of the EU as a region with a very high regulatory burden that makes it less attractive for future new investment. However, most industry representatives considered that REACH related costs represent only a minor consideration in a longer list of variables that include access and costs of raw materials, labour or energy costs.

The majority of firms consider that REACH erodes their competitive advantage, at least in the short term. Almost half of EU based survey respondents see REACH as having led to an increase in the prices of their products in comparison to non-EU competitors and primarily in relation to non-EU markets. This appears to be the case for manufacturers of chemicals and to most types of downstream users. Importers of articles indicated that the impact of the Regulation on them was weaker, but given the small number of responses from this group there is a large margin of error. The analysis of the responses on the basis of firm size or legal form did not suggest any notable deviations from the general picture.

As suggested earlier, this general picture appears somehow in contrast to the statement that firms have tried to absorb costs. As a result, it should be treated with a certain level of caution. Either in the form of
increased prices or in the form of reduced profit margin, it is most probably the case that REACH compliance has had negative implications to the competitiveness of the majority of firms in the short term.

Table 4.8 – Impact of REACH on the relative prices of products

<table>
<thead>
<tr>
<th>Category</th>
<th>Strongly disagree - Disagree</th>
<th>Neither agree - nor disagree</th>
<th>Agree - strongly agree</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manuf. of chemicals</td>
<td>51 21.07%</td>
<td>46 19.01%</td>
<td>145 59.92%</td>
<td>242 100.00%</td>
</tr>
<tr>
<td>Importers of chemicals</td>
<td>23 19.17%</td>
<td>29 18.33%</td>
<td>75 62.50%</td>
<td>120 100.00%</td>
</tr>
<tr>
<td>Formulators</td>
<td>11 7.48%</td>
<td>18 25.00%</td>
<td>39 54.17%</td>
<td>72 100.00%</td>
</tr>
<tr>
<td>End users</td>
<td>15 20.83%</td>
<td>29 19.73%</td>
<td>75 72.79%</td>
<td>147 100.00%</td>
</tr>
<tr>
<td>Importers of articles</td>
<td>10 34.48%</td>
<td>8 27.59%</td>
<td>11 37.93%</td>
<td>29 100.00%</td>
</tr>
<tr>
<td>Manuf. of articles</td>
<td>21 23.86%</td>
<td>16 18.18%</td>
<td>51 57.95%</td>
<td>88 100.00%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>131 18.77%</td>
<td>139 19.91%</td>
<td>428 61.32%</td>
<td>698 100.00%</td>
</tr>
</tbody>
</table>

Source: CSES survey

The picture is less clear in relation to the impact on the market share. Between 15% and 25% of respondents linked REACH costs with a reduction of their market shares and this was close to 35% in the case of formulators of chemical mixtures.

Table 4.9 - Impact of the implementation of REACH on firms’ EU market share by supply chain role

<table>
<thead>
<tr>
<th>Category</th>
<th>Do not know/ not applicable</th>
<th>Strongly disagree - Disagree</th>
<th>Neither agree - nor disagree</th>
<th>Agree - strongly agree</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manuf. of chemicals</td>
<td>38 39.2%</td>
<td>22 22.7%</td>
<td>20 20.6%</td>
<td>17 17.5%</td>
<td>97 100.00%</td>
</tr>
<tr>
<td>Importers of chemicals</td>
<td>45 24.9%</td>
<td>32 17.7%</td>
<td>58 32.0%</td>
<td>46 25.4%</td>
<td>181 100.00%</td>
</tr>
<tr>
<td>Formulators</td>
<td>33 20.9%</td>
<td>28 17.7%</td>
<td>41 25.9%</td>
<td>56 35.4%</td>
<td>158 100.00%</td>
</tr>
<tr>
<td>End users</td>
<td>9 24.3%</td>
<td>12 32.4%</td>
<td>10 27.0%</td>
<td>6 16.2%</td>
<td>37 100.00%</td>
</tr>
<tr>
<td>Importers of articles</td>
<td>71 23.8%</td>
<td>90 30.2%</td>
<td>78 26.2%</td>
<td>59 19.8%</td>
<td>298 100.00%</td>
</tr>
<tr>
<td>Manuf. of articles</td>
<td>29 26.1%</td>
<td>35 31.5%</td>
<td>27 24.3%</td>
<td>20 18.0%</td>
<td>111 100.00%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>225 25.5%</td>
<td>219 24.8%</td>
<td>234 26.5%</td>
<td>204 23.1%</td>
<td>882 100.00%</td>
</tr>
</tbody>
</table>

Source: CSES survey

79 Distributors of chemicals were not included in this question.
80 Belonging primarily to the specialty chemicals, consumer chemicals and other types of chemical products subsectors.
The individual comments and the survey analysis suggest that this is possibly linked with the decision of a greater share of micro and small firms to remove certain products from the EU market. While less than 4% of large and medium sized firms indicated that they have decided to remove some of their products from the EU or the non-EU markets as a result of REACH implementation costs, and no more than 10% of micro and small firms did so. Even among those that did not withdraw from the EU market a large number reduced their production and sales volume below 1000tpy in order to reduce registration requirements and costs.

Chart 4.6 - Impact of the implementation of REACH on EU-based firms’ EU market share by firm size 81 (% of respondents indicating a loss of EU market share)

<table>
<thead>
<tr>
<th>Firm Size</th>
<th>Strongly disagree/disagree</th>
<th>Neith agree nor disagree</th>
<th>Agree/strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large (&gt;250 employees)</td>
<td>28.3%</td>
<td>27.4%</td>
<td>28.6%</td>
</tr>
<tr>
<td>Medium (50-249 employees)</td>
<td>22.1%</td>
<td>30.5%</td>
<td>28.3%</td>
</tr>
<tr>
<td>Small (10-49 employees)</td>
<td>28.4%</td>
<td>15.6%</td>
<td>24.9%</td>
</tr>
<tr>
<td>Micro (&lt;10 employees)</td>
<td>23.8%</td>
<td>16.7%</td>
<td>19.0%</td>
</tr>
</tbody>
</table>

Source: CSES survey

Furthermore, in relation to the production of articles, a large number of industry associations – ranging from the textiles to the aeronautics sectors – make reference to the advantage that non-EU manufacturers have acquired when it comes to the production of articles that contain hazardous substances. The fact that requirements for notification and authorisation only apply to EU production activities means that non-EU firms can continue to use such substances without restrictions and with lower production costs, thus obtaining a relative advantage. Of course, importers of such products would still have to assume certain costs that may be passed back to the respective manufacturers.

This rather negative view of EU manufacturers possibly overstates the advantages of their non-EU competitors. The information provided from discussions with Only Representatives, non-EU industry

---

81 Distributors of chemicals were not included in this question.
associations and from several publications indicates that non-EU manufacturers also face problems with compliance and some have decided not to enter the EU market for certain products (see also Case study 8). As it is argued, for some manufacturers in China or India the EU market is gradually becoming less critical while the additional costs for exporting to the EU as a result of registration obligations and supply chain communication - calculated to be between €60,000-€72,000 for Indian companies - is leading a number of them to withdraw from the EU market. At the same time, a number of sources (Only Representatives and associations) suggested that some EU based importers of chemicals or articles have already switched to EU manufacturers in order to avoid the burden of registration in case an Only Representative has not been appointed by their non-EU suppliers. Furthermore, the survey responses suggest that there are also concerns that REACH will in fact discriminate against non-EU companies that often do not understand the processes put in place. In that respect, and despite problems identified in their operation (see also Case study 7), Only Representatives represent the key mechanism to facilitate access to the EU market for non-EU manufacturers (see more information in case study 7).

To the extent that this proves to be a general trend in the coming years, it can also be seen as reducing the choice of suppliers and competition, and concentrating market power in the hands of fewer EU based suppliers.

Despite the negative views expressed concerning the impact of REACH on the level of EU trade in both directions, this is not reflected on the available trade data. According to the data on the volume of imports and exports to the EU for the period 2001-2010, there is no apparent trend for a drop in the level of trade that in 2010 exceeded the 2007 levels after the impact of the global financial crisis. Still, this should not be seen as conclusive proof of the impact of REACH on exports. It is possible that any such impact will need some time to be reflected on trade activity data due to stockpiling.

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In conclusion, on the basis of the data collected there appear to be multiple aspects related to the REACH regulation that both favour and work against the different trade flows for chemicals and articles with chemicals (exports, imports and intra-EU trade). The following table summarizes the relevant mechanisms and trends identified, although there is no information on the actual outcomes thus far.

Table 4.10 – REACH related mechanisms affecting trade flows inside and outside the EU27 – existing mechanisms

<table>
<thead>
<tr>
<th>Trade flows</th>
<th>Elements in favour</th>
<th>Elements against</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exports from the EU</td>
<td>Enhanced product innovation capacity of EU firms (although no apparent impact of REACH at this stage)</td>
<td>EU Manufacturers of chemicals and articles have to assume/absorb REACH related costs when trading in third countries</td>
</tr>
<tr>
<td>Imports to the EU</td>
<td>No notification or authorisation requirements for articles with chemicals produced outside the EU Single registration costs for non-EU firms with multiple entities (different from EU firms)</td>
<td>Low level of awareness of REACH requirements and costs of appointing ORs as intermediaries No/limited support structures available (labs etc.)</td>
</tr>
<tr>
<td>Intra-EU trade</td>
<td>Importers can select EU-based manufacturers to avoid registration</td>
<td>Increased costs for EU-manufacturers due to REACH may lead to higher prices</td>
</tr>
</tbody>
</table>
obligations (Downstream users role) if no OR appointed
Easier communication in the supply chain
in comparison to non-EU firms

4.2.7 Business gains as a result of compliance with REACH

The Regulation was expected to bring a number of possible benefits for firms. Among those identified early on was the potential for increasing consumer confidence and strengthening cooperation in the supply chain.

The information collected during the study responses so far does not provide evidence of the presence of substantial benefits in either of the two areas. The survey responses indicate a considerable level of scepticism towards the potential of the Regulation to lead to improved consumer confidence, with almost 80% of respondents disagreeing with the idea that REACH has led to increased consumer confidence in chemicals. As it is argued, most consumers are not informed about REACH or the type of chemicals used in the products they purchase. More importantly, even if the public was more informed about REACH, it would not be possible to use compliance as a marketing tool, as compliance is already a mandatory requirement for all articles and substances. While representatives of substance manufacturers recognise the need for the sector to improve its public image – especially in certain countries – they argue that there is low public awareness about REACH to help in this direction.

There were very few firms stating business gains by using their compliance with REACH in order to market a product outside of the EU. More generally, there is an increasing trend among retailers or manufacturers of articles down the supply chain to market their products as not containing any SVHCs, and this has in some cases been extended to products on the candidate list, rather than those on the sin list as might be expected. Whilst this is not directly linked to REACH, it shows that there is an increasing will on the part of some companies to use the wider REACH framework as a marketing tool. One survey respondent from the Netherlands explained that REACH had made the firm reposition its business in the area of environment and safety and added: "Now we can show that we want to be a forerunner."

Table 4.11 – Business gains resulting from REACH (number and percentage of respondents stating)

<table>
<thead>
<tr>
<th></th>
<th>Disagree/ strongly disagree</th>
<th>Neither agree nor disagree</th>
<th>Agree / strongly agree</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>%</td>
<td>Number</td>
<td>%</td>
</tr>
<tr>
<td>Increased confidence of consumers for chemical products</td>
<td>493</td>
<td>79.4%</td>
<td>84</td>
<td>13.5%</td>
</tr>
<tr>
<td>Led to increased cooperation with suppliers/customers</td>
<td>603</td>
<td>69.9%</td>
<td>187</td>
<td>22.1%</td>
</tr>
</tbody>
</table>

Source: CSES survey

Rather mixed is the picture in relation to the contribution of REACH towards communication between constituents of the supply chain. Around 70% of respondents indicated a very limited contribution of REACH to increasing cooperation with their suppliers or customers (see table above). However, when asked to assess the impact of the information obligations to the relationships in the supply chain, the
responses suggest that the increased costs for the communication create a negative bias in their overall contribution of REACH in this direction. The responses of downstream users (see chart 4.8) indicate that REACH has led to increased costs for the great majority of them (over 70%). However, there is also a 25 - 30% of downstream users that linked REACH with an increase in communication with suppliers and/or customers and a strengthening of the supply chain management processes.

Chart 4.8 - How have the additional information requirements under REACH affected your relationship with suppliers and consumers? (% of downstream users responding)

The comments from individual firms and some associations are also illustrative of the tension between the significant costs and the time dedicated for the information along the supply chain and the potential future benefits of this “forced” communication and the investments made by some firms.

Table box 4.8 - Comments of associations and firms on the business gains resulting from REACH

<table>
<thead>
<tr>
<th>Source</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Representatives of the non-ferrous metals industry</td>
<td>Communication along the supply chain is problematic and complicated. It can be very complicated and lead to extra costs.</td>
</tr>
<tr>
<td>Representatives of the chemicals' distributors</td>
<td>Information for eSDS is demanding; there are no common formats and it quite time consuming to understand what information is required – training is necessary for some of them.</td>
</tr>
<tr>
<td>Representative of the engineering industry</td>
<td>There are important problems in the communication across the supply chain. However this varies greatly among sectors. In the automotive</td>
</tr>
</tbody>
</table>
Analysis of findings

Source | Comment
---|---
A larger UK-based formulator | Very time consuming and costly with difficulties experienced throughout the supply chain. A bureaucratic nightmare.
A larger France-based manufacturer of articles | It is difficult to set up communication – especially with non-EU based suppliers.
A medium size-manufacturer of chemicals | REACH has led to an increase in communication with competitors within the framework of EU competition rules.
A small Italian manufacturer of chemicals | REACH was positive in that is forced us to look at our products and there was a need for that and it encouraged us to think about our strategy.

Source: CSES survey and interviews

Finally, the discussions with associations did not produce any specific evidence connecting the REACH Regulation with an increase of investor confidence towards the chemical or downstream users’ sectors. The only input provided focused on the continuous but not predictable extension of the candidate list of substances. As suggested, this process introduces a level of uncertainty and reduces confidence when assessing the long term prospects of investments on production activities that rely on specific chemicals. In that respect, the presence of a longer list of restricted substances identified early on – rather than the gradual increase of the list - could be preferable from the point of view of industry and investors.

Time to market

Another expected contribution of REACH, as identified in the Economic Impact Assessment of the Commission, was that it would contribute to a reduction in time to market for new substances. The former system was considered cumbersome, fragmented and slow as different Member States had different systems, testing requirements and there was a general lack of uniformity.

According to a report for the UK Intellectual Property Office, speed to market is a key source of competitive advantage. This is also reflected in the responses to the business survey. A bit more than 50% of total respondents stated that time to market is important or very important to their business; close to 70% amongst downstream users (formulators, manufacturers of articles).

However, the business survey responses indicate that, at least so far, there is no positive contribution of REACH. Rather on the contrary, for an important part of industry the Regulation seems to have created delays to this process. While for around 50% of respondents there has been no recognisable change to the time to market, around 40% referred to some increase and close to 15% referred to an increase in the total time of more than 15%. Amongst formulators – typically firms in the paint and varnishes, coatings and other specialty chemicals – the picture is more negative with only 26% stating no change and close to 23% suggesting a delay of more than 12 months as a result of REACH related obligations.

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Interim Evaluation: Functioning of the European chemical market after the introduction of REACH

Final report

Section 4

Analysis of findings

Table 4.25 Overall, what has been the effect of compliance with REACH been on the time to market for your firm’s innovations, as compared to the pre-REACH situation?

<table>
<thead>
<tr>
<th>Responses</th>
<th>Manuf. of chemicals</th>
<th>Importers of chemicals</th>
<th>Manuf. of articles</th>
<th>Importers of articles</th>
<th>Formulators</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No %</td>
<td>No %</td>
<td>No %</td>
<td>No %</td>
<td>No %</td>
<td>No %</td>
</tr>
<tr>
<td>Led to a reduction of the total time</td>
<td>0.0</td>
<td>0.0</td>
<td>0.0</td>
<td>1</td>
<td>4.5</td>
<td>0.0</td>
</tr>
<tr>
<td>No change</td>
<td>101</td>
<td>59.1</td>
<td>54</td>
<td>50.9</td>
<td>55</td>
<td>77.5</td>
</tr>
<tr>
<td>Increased by up to 2 months</td>
<td>17</td>
<td>9.9</td>
<td>21</td>
<td>19.8</td>
<td>7</td>
<td>9.9</td>
</tr>
<tr>
<td>Increased by 2-6 months</td>
<td>19</td>
<td>11.1</td>
<td>14</td>
<td>13.2</td>
<td>4</td>
<td>5.6</td>
</tr>
<tr>
<td>Increased by 6-12 months</td>
<td>9</td>
<td>5.3</td>
<td>8</td>
<td>7.5</td>
<td>3</td>
<td>4.2</td>
</tr>
<tr>
<td>Increased by over 12 months</td>
<td>12</td>
<td>7.0</td>
<td>8</td>
<td>7.5</td>
<td>2</td>
<td>2.8</td>
</tr>
<tr>
<td>Do not know</td>
<td>13</td>
<td>7.6</td>
<td>1</td>
<td>0.9</td>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>Total</td>
<td>171</td>
<td>100</td>
<td>106</td>
<td>100</td>
<td>71</td>
<td>100</td>
</tr>
</tbody>
</table>

Source: CSES survey

Besides the added time resulting from the registration process, the discussions with firms and industry associations have also pointed to the inquiry process for the increase in the time to market for new products. According to some firms the inquiry process may take several months and it is has become less clear and predictable in comparison to the past. Rather than benefiting from the elimination of the need for multiple enquiries across Member States some firms suggested the ongoing relationships with the authorities in a few key Member States often made communication easier and the whole process much more efficient than the current experience with ECHA. The process is often described as unclear and unpredictable and this can have a knock-on effect on internal decisions in terms of investment as regards for example establishing production units or recruiting and training staff so that customer deadlines can be met. From the Agency side, the discussions indicated a recognition of the delays in the process resulting from the high number of enquiries submitted (around 3500 by June 2011), much greater than expected, but also sometimes due to the poor quality of the inquiry dossiers submitted. It was also suggested that changes to the handling of inquiries are expected to help address this backlog.

Overall, while for the majority of firms there seems to be limited impact on time to market, there are negative consequences for an important segment of the industry which is most often the most innovative. To a certain extent the delays could be considered as part of the teething problems related to the implementation procedures and should be expected to improve over time.

4.2.8 Impact on jobs creation for the chemicals market

Available data on the employment in the chemical sector shows that total employment in the chemical sector has gradually declined over recent years. Between 2004 and 2010, employment decreased by an average of 2.2% per annum. However, it is not possible to make a direct link between REACH and these developments as they are driven, mainly, by increasing level of productivity in the sector, a long trend of
relocation of production units outside Europe – mainly Asia – and accentuated by the financial crisis of the last years.

**Chart 4.9 - Employment in the EU chemical industry (thousand)**

The CSES survey and discussions have also provided very limited evidence concerning the impact of the regulation on employment. Some national associations (e.g. Czech Republic, Italy and Austria) have argued that there is a clear danger that small firms will close, negatively affecting employment, although no such evidence has been provided. The survey only unearthed a handful of UK based firms and multinationals indicating the intention to move certain parts of their production activity outside Europe although, as suggested earlier, many more industry representatives consider this as a possible result in the longer term. As stated by most interviewees, it is probably too early to assess the impact of the Regulation in this respect. For many firms, the global economic crisis and reduction in overall demand have been more important factors.

On the other hand, as already indicated earlier, REACH has led to the creation of a number of new jobs in the REACH units of firms, or as a result of the development of a market for the provision of relevant technical and legal consulting services, test labs or the provision of Only Representatives’ services (see also case study 7). There is no sufficient information available to assess whether these represent new jobs, retention of jobs that might have been lost due to other reasons, or extensions of the activities of existing staff. A large number of consultants and Only Representatives were already active in the provision of support to the chemicals industry. Reflecting the influence of REACH, postgraduate courses in chemistry with a specialisation in the Regulation have also been developed in Italy and the UK. This development tends to indicate that regulatory jobs are seen as a potential long-term opportunity for graduates.
From their point of view, the representative of European Trade Unions indicated that trade unions are not concerned about the impact of REACH on the number of workers employed in the chemicals sector. On the contrary, the regulation is considered a good way of maintaining quality jobs for skilled and highly skilled labour. Furthermore, one interviewee held the view that the number of positions in health and safety had been declining for some decades in Europe with cost driven restructuring of the industry and disaggregation of value chains, and hoped that the implementation of REACH would help to redress the balance towards what it had been previously. Given the importance of REACH for the industry, this kind of expertise is expected to be broadly sought in the coming years and there is a need for qualified specialists.

The data available provide a limited basis for assessing the longer term potential of REACH to help the chemicals industry generate new jobs. Other factors related to the global competitiveness of the industry play a much greater role.

4.2.9 Operation of the single Market

The implementation of the Regulation was expected to support the increasing level of trade in the EU as a result of the harmonisation of the market. Examining the data on the level of intra-EU trade over the last 10 years suggests that overall trade of chemicals inside the EU has increased faster than the total intra-EU trade. This is a general picture that also applies to most subsectors with the exception of fertilisers and, less so, inorganic materials.

Chart 4.10 – Evolution of intra-EU trade in the chemicals sector by volume (2001 -100)

However, this does not provide any proof of a positive role of REACH. Rather in contrast, the survey responses do not suggest any strong trends, at least so far, in this direction. The majority of firms – manufacturers, importers, formulators – do not think that the REACH regulation is relevant in their decision to enter new EU markets. No more than 3% of respondents indicated that REACH has played
any role in their decision to enter new EU markets although a bit more suggested that it might influence such decisions in the future. This, as expected, applies for the large multinationals already present in multiple markets but it also applies to smaller size firms selling primarily in one or few markets.

Asked to identify possible benefits in relation to trade coming from the introduction of REACH, the overwhelming majority (91.5%) of firms stated that there are none. Only a very small number identified any reduction of administrative costs and ease of exporting. In contrast, individual comments provided suggest that for some firms the administrative costs, paperwork and information collection have made trade inside the EU more costly.

The discussions with only representatives, Member States authorities and some industry associations suggests that in many respects the absence of sizeable benefits is a result of the fact that the market was already operating in rather efficient way. In particular this is the case for chemicals that are treated as commodities. Others suggest that it is still too early to see any important changes in the level of trade as a result of REACH, and that at this stage the cost considerations were more important. As a result it is not possible to point to a specific aspect of the Regulation that contributes to an increase of trade.

Chart 4.11 - Has the entry of REACH into force led you to a decision to enter additional markets in the European Economic Area?

Source: CSES survey

In contrast, a number of associations – particularly those representing manufacturers and importers of articles – focus on the pending issue related to the definition of articles and the requirements in the case of articles that contain more than 0.1% SVHCs w/w.
ECHA’s interpretation of article 33 is that the measure should apply to the compound article, for instance, a car, a sofa or a PC. However, six Member States have taken a different view and are using what has become known as the "once an article, always an article" (OSA) interpretation. According to this interpretation, each individual component of the final article is considered to be an article in itself for the information requirement of Article 33. According to this definition, a supplier has the duty, if required, to provide information for each component of a car, a sofa or a PC.

France was the first country to publish its interpretation in an avis, published in the Journal Officiel of 8th June 2011. According to the avis, France’s authorities indicated that they would consider articles to be, in accordance with article 3.3 of the regulation 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, thus stating that an article can be composed of different articles. The avis then goes on giving the example of a belt, being made, according to this definition of two articles, the buckle and the leather strap. This goes clearly against ECHA’s guideline that states explicitly that an article "may be very simple, like a wooden chair but can also be very complex, like a laptop computer, consisting of many parts"

The different interpretations and the stated disagreement of some Member States with the ECHA guidance is generally considered to be problematic, creating uncertainty and going against the development of a harmonised market. At this stage there is no practical experience of the implementation of the specific provisions to substantiate these concerns. The analysis from the automotive and the electronics sectors presented in Case study 11 point to additional costs that can arise for the additional testing, further need for information on various components and additional communication.

Some respondents also referred to the clauses that allow Member States to impose additional requirements in relation to issues of health and safety as an indication that a full harmonisation cannot be expected. Reference was made to requirements in France for specific tests with products that will be put in contact with drinking water.

### 4.3 Efficiency of the REACH processes and mechanisms

The implementation of REACH involves a number of processes and the practical experience of firms from their implementation does, at least at this stage, have an important influence on the acceptance of the Regulation as well as the costs associated with the Regulation. The evaluation focused on the experience from the pre-registration and, primarily, the registration process. There is still limited experience in relation to authorisation or restriction.

#### 4.3.1 Pre-registration

In relation to the pre-registration phase, discussions with most of the trade associations pointed to a rather problematic experience. There are references to the absence of appropriate guidance and the poor operation of the relevant IT system. It is currently accepted that there was a degree of uncertainty as to how pre-registration worked, and, that, in order to be on the safe side many firms pre-registered a much larger number of substances than necessary. The total number of pre-registrations was close to 2.7 million, many times greater than the number initially expected. The survey responses also confirm
the issue with a number of respondents (especially smaller ones) admitting that they were unsure of what to register and decided to register all their substances in order to avoid being caught out. This has not only led to unnecessary work for firms and the ECHA itself but also had a negative impact on the Agency’s planning capacity. The pre-registration information has become rather irrelevant in terms of resources planning for the registration phases while, at the same time, it led to the development of pre-SIEFs and SIEFs, with a large number of members who have no intention to participate in the process.

In relation to the IT systems used, a large number of firms referred to its poor performance that caused delays and, in some cases, required firms to re-input the necessary information. ECHA representatives indicated that the Agency is aware of these issues and, in general, industry associations accept that they have been resolved.

### 4.3.2 Registration

In the case of the registration process, the experiences of firms varied greatly but for an important minority of survey respondents (around 40%) the overall experience was rather negative. In the words of one survey respondent, "given the regulatory burden and complexity that has been created, it’s fair to acknowledge that [...] the mechanism of registration has been fairly straightforward, although there have been several periods of frustration". However, the main comment was that it was a demanding process requiring a lot of time and resources. The perception is that there was a lot of red tape and bureaucracy surrounding the registration process. Negative comments are also made by many firms on the IT tools used for the registration process (REACH-IT and IUCLID) that they were not working properly and the fact that some of the updates led to duplication of the registration work for registrants. The late issuing and frequent changes of guidance documents is also stated as a negative point. Concerns about the security and confidentiality of data were also raised as there were incidents of the system having been hacked and the data and information accessed by the hackers put on a website with free access. The Agency itself does recognise that there were certain problems, but pointed out the need to ensure the stability of the system. Despite the criticism, there is a general positive assessment of the role of ECHA and appreciation that there has been continuous improvement and an effort to help firms address the problems faced.

#### Table 4.12 - How would you evaluate your overall experience from the registration process so far?

<table>
<thead>
<tr>
<th>Options</th>
<th>Manufacturers of Chemicals</th>
<th>Importers of chemicals</th>
<th>Formulators</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Nº</td>
<td>%</td>
<td>Nº</td>
<td>%</td>
</tr>
<tr>
<td>Very negative</td>
<td>22</td>
<td>9%</td>
<td>9</td>
<td>10%</td>
</tr>
<tr>
<td>Negative</td>
<td>76</td>
<td>30%</td>
<td>29</td>
<td>32%</td>
</tr>
<tr>
<td>Neutral</td>
<td>109</td>
<td>43%</td>
<td>41</td>
<td>45%</td>
</tr>
<tr>
<td>Positive</td>
<td>47</td>
<td>18%</td>
<td>11</td>
<td>12%</td>
</tr>
<tr>
<td>Very positive</td>
<td>1</td>
<td>0%</td>
<td>2</td>
<td>2%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>255</strong></td>
<td><strong>100.0</strong></td>
<td><strong>92</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

Source: CSES survey

In the case of SMEs, additional issues arose in relation to the fact that key documentation – such as guidance documents – was only available in English. UEAPME urged for all necessary documentation to
be ready well in advance of the next registration deadline. Another issue for SMEs is the sheer amount of information and guidance available. It has been pointed out that for smaller companies, reading and processing all the information is impossible, and the use of external consultants is consequently essential. In an attempt to rectify this ECHA has now produced information sheets in all EU languages. Answers from the survey indicate that a number of companies had to get the support of external consultant to understand and help them during the registration process. In some cases, participation in a consortium was seen as a useful way of sharing information and facilitated the registration process.

A few industry associations reported an increase in the use of laboratories, and believe that there might be capacity constraints in the next registration rounds due to possible overbooking for tests. Others have reported that prices for testing have risen as a result, and are expected to continue doing so. Others say that they have their testing done in the USA as those labs are quicker and cheaper. In some countries such as Estonia there are no GLP labs and tests have to be carried out elsewhere, with the concomitant increases in transport and translation costs, as well as time delays.

**Operation of SIEFs and consortia**

The operation of SIEFs and consortia and the sharing of information and data on substances has been one of the key aspects of the implementation of the REACH regulation to this point. The survey responses and the interviews with industry associations and other stakeholders indicate that the experiences of firms vary greatly. Referring to the overall experience from the operation of SIEFs, survey respondents provided very mixed responses with equal shares (close to 27%) appearing satisfied and unsatisfied. The picture is much more positive in relation to consortia with a much greater share (70% of the total) providing a positive assessment of their operation but also of their contribution to the operation of SIEFs (see also the analysis in Case study 4).

**Table 4.13 - Overall experience so far from the operation of the SIEFs and consortia**

<table>
<thead>
<tr>
<th></th>
<th>SIEFs</th>
<th></th>
<th>Consortia</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Very negative</td>
<td>24</td>
<td>6.9%</td>
<td>5</td>
<td>1.6%</td>
</tr>
<tr>
<td>Negative</td>
<td>71</td>
<td>20.5%</td>
<td>13</td>
<td>4.2%</td>
</tr>
<tr>
<td>Neutral</td>
<td>157</td>
<td>45.2%</td>
<td>74</td>
<td>24.2%</td>
</tr>
<tr>
<td>Positive</td>
<td>90</td>
<td>25.9%</td>
<td>163</td>
<td>53.3%</td>
</tr>
<tr>
<td>Very positive</td>
<td>5</td>
<td>1.4%</td>
<td>51</td>
<td>16.7%</td>
</tr>
<tr>
<td><strong>Total responses</strong></td>
<td><strong>347</strong></td>
<td><strong>100%</strong></td>
<td><strong>306</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

Source: CSES survey

Still, participation in SIEFs is seen as having contributed to decreasing the costs of registration from the majority of firms. But, at the same time, a number of issues and problems were identified. More than 80% of respondents stated that the operation of SIEFs created significant information exchange costs that, to a certain extent, may have counter-balanced the savings. Important communication and coordination problems are reported for a large number of SIEFs, particularly among those with a large
number of “dormant” pre-registrants that had no intention to register and most often do not respond to requests for information but should still, on the basis of the REACH provisions, be involved in the process.

The delays and significant management and administrative costs are primarily a result of the behaviour of firms but are also linked with the absence of more specific communication and information exchange rules. It is also linked with what is generally seen as an unclear pre-registration process and the response of many firms – including many not intending to register a substance – of submitting a large number of pre-registrations simply to be on the safe side. Other hidden costs – such as the cost of travelling for meetings – were mentioned by Polish firms as reasons for not being able to attend SIEFs’ meeting.

Problems also often arose with the definition of SIEFs due to lack of clarity on substance identity. In most cases the problems and delays reflected a genuine problem for multi-constituent substances although there are also some suggestions that some facilitators actively tried to influence the definition in certain directions. There is however no evidence that certain REACH provisions are linked to such problems.

Table 4.14 - Please indicate the level of agreement in relation to the following results from the participation in SIEFs

<table>
<thead>
<tr>
<th></th>
<th>Decreased costs of registration</th>
<th>Created information exchange costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strongly disagree</td>
<td>24</td>
<td>4</td>
</tr>
<tr>
<td>Disagree</td>
<td>40</td>
<td>23</td>
</tr>
<tr>
<td>Neither agree nor disagree</td>
<td>47</td>
<td>37</td>
</tr>
<tr>
<td>Agree</td>
<td>164</td>
<td>199</td>
</tr>
<tr>
<td>Strongly agree</td>
<td>39</td>
<td>80</td>
</tr>
<tr>
<td>Total responses</td>
<td>314</td>
<td>343</td>
</tr>
</tbody>
</table>

Source: CSES survey

Another troubling point identified concerns the costs of letters of access (LoA). LoAs are most often used by importers and non-EU based firms through their only representatives and represent, together with ECHA fees, the most important driver of registration costs. They are also the most typical approach adopted by SMEs that are not willing or do not have the resources to be involved in creation and sharing of data within the context of SIEFs. The feedback from the survey and interviews indicates that for a number of firms the costs of the LoAs are particularly high and with limited transparency as to how those prices are set. As will be discussed in greater detail section 4.5 this is also often linked with perceived efforts of larger firms to push competitors outside the relevant markets. We should note that ECHA has already provided a rather detailed guidance document on SIEFs covering the issue of cost sharing with detailed examples. The industry associations (e.g. CEFIC) have also made efforts through additional guidelines. Still, an important number of firms and industry representatives referred to the need for more clear rules coming from ECHA or the Regulation. Greater transparency can potentially help firms to compare with the management and fees set in other consortia. It will also allow firms to

---

84 The European Chemicals trade body -CEFIC- has defined four roles covering the positions SIEF members could take. These four roles are: Leader, Active, Passive and Dormant. Dormant firms are those companies have pre-registered only to secure their business, without intention for later full registration.
conclude on the adequacy and proportionality of the costs and assess whether the REACH provisions on the opt-out from joint registration apply to them.

The survey responses also indicate that for a large number of firms SIEFs are seen as posing a risk of losing confidential or valuable business information (51% of respondents agreed). This seems to apply despite the presence of relevant guidance documents from EC HA and the various industry associations. Companies are often represented at SIEFs by technical specialists that are not always aware of or alert to matters surrounding CBI and IP. Small firms that have been competing for generations often feel uneasy to sit around a room together and share knowledge and information.

Still, we should also note that there are also references to examples of efficient and effective SIEFs relaying on the capacity of the lead registrant or the consultant responsible for coordination. Furthermore, it is often connected to the presence of a relevant consortium. As already suggested, the general view of consortia is much more positive and in many cases it is among consortium members that the work on data collection and dossier preparation actually takes place. With a smaller number of participants and past experience of cooperation, often on the basis of membership in the same industry association, the work of consortia is generally considered as more effective and efficient.

Table box 4.9 – Comments of associations and firms on operation of SIEFs

<table>
<thead>
<tr>
<th>Source</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Representative of the non-ferrous metals industry</td>
<td>SIEFS had in some cases over 800 members due to high number of pre-registrations – that means very difficult communication – some lead registrants had to buy specialised IT tools (30 -40k) and were low numbers of responses</td>
</tr>
<tr>
<td>Representative of the steel industry</td>
<td>Communication IT tools forced upon SIEF members by SIEF managers w/o clear benefits in relation to cost (take it or leave it approach)</td>
</tr>
<tr>
<td>CIRS</td>
<td>Most of non-EU companies depend on buying letter of access to complete their registration process. They usually choose passive or involved status in SIEF. However, they do not have any power to negotiate the price of letter of access.</td>
</tr>
<tr>
<td>Representative of the chlor-alkali industry</td>
<td>Industries in the sector worked well together before the introduction of the Regulation – so SIEFs are not an issue</td>
</tr>
<tr>
<td>Large manufacturer of Chemicals</td>
<td>Mostly used as a tool for market surveys, consultants trying to sell their services. Most of the SIEF membership is inactive and non-responsive to information queries</td>
</tr>
<tr>
<td>Medium sized manufacturer of Chemicals</td>
<td>For a medium-sized company it is just not feasible to invest time and money in the SIEF and to communicate in all of the European languages.</td>
</tr>
<tr>
<td>Large manufacturer of Chemicals</td>
<td>To actively work within a SIEF entails a lot of administrative work caused by the contracts and information that needs to be exchanged within the SIEF</td>
</tr>
<tr>
<td>Large manufacturer of Chemicals</td>
<td>The obligatory Joint Submission is a good thing, but for the metals industry the Consortia took over from the SIEFs allowing much a more efficient approach.</td>
</tr>
<tr>
<td>Small manufacturer of chemicals</td>
<td>Only available contact person during the REACH registration to make qualified statements. Without this help and the help of an affiliated</td>
</tr>
</tbody>
</table>
Analysis of findings

<table>
<thead>
<tr>
<th>Source</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small manufacturer of chemicals</td>
<td>Company, the REACH registration would most likely have failed</td>
</tr>
<tr>
<td></td>
<td>Participation in the SIEF is the perfect opportunity to get in touch with other registrants, to exchange data and reduce costs</td>
</tr>
</tbody>
</table>

Source: CSES survey and interviews

4.3.3 Assistance structures and mechanisms ECHA, national and other support structures

An important element determining the efficiency of the overall process of the implementation of the Regulation is the assistance and guidance provided to companies. ECHA had a very important role to play but national helpdesks were also expected to support firms at the national level. In parallel, national and European trade associations were also expected to provide assistance to their members.

Overall, respondents made use of the assistance offered, with 92% of respondents seeking information from ECHA, 87% from national trade association, 82% from helpdesks, and 69% from European trade or industry association. The responses suggest that while ECHA was contacted, more detailed information was necessary and possibly sought from more specialised organisations. In this respect national and European trade associations have helped companies with the REACH processes. However, private sector consultancy was also sought from the majority of firms (around 60%). This reflects the fact that firms still required tailored made assistance that public structures cannot provide or, as already presented earlier, that many of them prefer to outsource all compliance related activities.

Chart 4.12 - Have you used information and/or support from the following to fulfil your obligations

Source: CSES survey
Concerning the usefulness of the support received by different organisations, the two ‘official’ structures, ECHA and national helpdesk fare the worst, with 25% and 18% respectively finding them ‘very’ or ‘extremely’ useful. National and European trade association scored 50% and 43% respectively and this is partly due to the more tailored support offered by the trade associations. For some firms they have played a key role by simplifying the regulation requirements and pointing to the issues relevant for the different types of actors in different sectors. They help in addressing issues that are left unanswered by the Regulation or ECHA, such as the cooperation and management agreements in consortia and SIEFs, or the development of common terminology of uses for the development of extended Safety Data Sheets (e.g. DUCC platform for downstream users or ERTMA projects for the rubber and tyre manufacturers industry). In the case of SMEs, UEAPME has set up an information dissemination systems as well as a support desk.

Private sector consultants are also seen as particularly effective and, as stated earlier, in many cases they take over most of the practical responsibilities of SMEs that do not have the technical knowledge and the resources to comply with the REACH regulation. However, the recent survey of Chemical Watch indicates that the costs of this support is sometimes more expensive than the added value it brings to firms.

Chart 4.13 - What was the usefulness of organisations providing info/ support to firm in order to fulfil obligations?

Source: CSES survey

85 Chemical watch - companies consider switching REACH service providers despite good performance.
ECHA tools

Examining the role of ECHA tools in more detail the main issues raised concern the nature of the support provided and the role of the guidance documents. The general conclusion is that they have only partly fulfilled their role. On the first point, interviews with industry and trade association throughout the sectors have pointed to the perception that ECHA’s support was “too legalistic”, not providing the practical support that industry needs. However, from the point of view of ECHA, it is to be expected that the support provided does not fit the need of individual firms, and that the guidance needs to be of a general nature with direct reference to the provisions of the Regulation. The underlying reasoning is that it is up to the industry to interpret and apply the Regulation. As already indicated earlier, other stakeholders point to the long period of time – typically a number of months – it can take ECHA to respond to the inquiry process before deciding to register a substance. According to some firms, such delays may have negative business impacts by delaying investment or operational decisions. This is an aspect that ECHA is aware of and it is primarily explained by the unexpected workload and the extensive use of the inquiry tool by firms.

As regards the guidance documents, while their usefulness is generally accepted (60% consider them as at least quite helpful), there were certain complaints related to the timing of changes to some of them and the fact that new interpretations have created some confusion and extra costs for firms. Particular reference is made on the changes concerning intermediate requirements, which are seen as posing an important problem for which firms in the pharmaceutical sector were not prepared. ECHA points out that it had to wait for the end of the moratorium on new guidance in order to publish it. This is an issue that should be resolved before the 2013 deadline. Some national trade association consider the six month moratorium in publishing guidance before the deadline to be too short, especially for SMEs.

Furthermore, national authorities and national industry associations referred to the issue of the availability of the guidance and other support tools in languages other than English. While this has not as yet been an important issue, its significance is expected to grow with the introduction of the lower tonnage bands in 2013 and especially 2018. In response, ECHA have already translated a simplified version of the documents in all EU languages. However, the translation of guidance documents that often use scientific language may lead to different interpretations and create confusion.
In relation to the remaining tools provided there is a significant variation both in terms of their actual use and the extent that they are considered helpful. A large share of firms have not used training facilities or the online helpdesk but among those that have, there is a rather high level of satisfaction: almost half of those using the online helpdesk have found it useful, with training events a little less popular with around one quarter of companies very satisfied. Satisfaction with training events has varied depending on the countries in question. A number of industry associations have underlined the positive role of training in countries such as France and Germany, especially in helping SMEs understand their role and the requirements they had to fulfil within the framework of the regulation.

ECHA has set up a network of national helpdesks called HelpNet, through which it promotes a common understanding of the obligations and requirements linked to REACH and the CLP Regulations. In addition ECHA staff organises visits to the national helpdesks to help them understand their work and share best practice. This is complemented by the ECHA helpdesk. The helpdesk has answered over 32,000 questions since 2007 (with a peak in 2008 with 12,258 questions). Questions related to REACH IT (40%), “REACH” (in general), 27%, IUCLID and CHESAR It tools (21%) and submissions (11%). 25% of questions submitted came from SMEs, and 41% from large companies (the balance did not provide company size).

86 ECHA, The operation of REACH and CLP, 2011 (pp49 -51)
Overall, while a number of large European trade associations representing the chemicals sector have commented on early problems with ECHA, they were generally considered to be teething problems linked to the establishment of the Agency and the introduction of such a complex piece of legislation. The Agency is now perceived by those associations to be quite supportive with frequent and fruitful cooperation that serves both sides in communicating issues and obtaining clarification of particular points.

**National helpdesks**

At the national level, firms experience with national REACH helpdesks and their support tools varies (see chart 4.15). Discrepancies are often connected to the resources allocated at the national level. Another issue mentioned was the contradiction of responses among different helpdesks. ISOPA – representing manufacturers of substances used for the production of polyurethanes - stated that responses provided by different helpdesk sometimes contradicted each other and created confusion and critical delay s. ECHA has set up a network of helpdesk – HelpNet – which is offering annual training to national helpdesks in addition to webinars that can then be translated and disseminated by helpdesks. This approach is aimed at harmonising the advice and support offered.

From the point of view of some Member States’ authorities, in some cases, the slow responses from helpdesks is due to slow responses from the Commission services. The Commission suggests that this is often a reflection of the complexity of the questions that reach the Commission and the need for input from all Member States.
For non-EU based firms the main problem is that they cannot contact ECHA directly but need to appoint a Third Party or an OR based in the EU to contact ECHA. This often creates delays in time, additional costs and poses a threat to loss of IP or CBI.

A few downstream users also claimed that national helpdesks only provided generic information far from the specific needs of certain sectors. In order to translate this generic information into guides tailored to specific sectors or sub-sectors, some industry associations have developed specific tools to help companies, such as the BDI\(^\text{87}\) in Germany, who has developed a REACH helpdesk which has been used as an interpretation tool of ECHA’s guidance documents.

### 4.3.4 Misuse of REACH related mechanisms

The discussions with industry representatives indicated a few aspects of the Regulation where market actors may have used the Regulation mechanisms for their own advantage. Given that registration has been the main activity, most are related to the operation of SIEFs and the sharing of data. The main issues identified are the following:

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\(^{87}\) Federation of German Industry
The fees for letters of access (LoA): As already indicated, in the absence of clear rules on how the prices are to be determined, lead registrants or members of consortia are often seen as using high prices of LoAs – in some cases more than €100,000 - as a mechanism to control the market and push smaller size competitors out of the market.

The pre-registration and participation in SIEFs has been used by a few companies as a tool to acquire market information regarding which firms are active in which markets and what chemicals they are intending to register. There are reports by some survey respondents that some firms with no intention to register any chemical submitted pre-registrations for large numbers of substances and subsequently acquired free access to long lists of pre-registrants for various chemical substances. In certain cases, such CBI can by itself be rather critical from a competition perspective.

A few firms also referred to the submission of a rather large number of registration dossiers as intermediates as an attempt to use the specific provisions and the reduced fees for this category of substances to their own advantage. ECHA has already indicated that a large number (up to 86%) of registrations of intermediates may need to be updated to justify this status or be re-submitted. There is no apparent scope for the misuse of the Regulation.

It is difficult to assess the severity of the above issues. Judging from the frequency of the comments made in relation to the letters of access it appears to be a rather common concern for a number of firms, especially SMEs and importers of chemicals. While it does not directly concern a mechanism of the Regulation, the absence of clear provisions and transparency can be considered as providing opportunities for misuse of the whole process.

4.3.5 Impact of candidate list and other non-core REACH mechanisms

The available evidence indicates that the placing of a substance in the candidate list has certain market implications. The survey respondents with experience in the placing of a substance in the candidate list were rather limited (only 183 out of the total of 1,601 responses). Still, their responses indicate that some important impacts such a reduction in the demand of a specific substance, the removal of the substance by suppliers or its substitution have already taken place for a number of them. Individual comments from some firms and associations indicate that the introduction of a substance in the list initiates a process of gradual removal from the market either from the producers themselves or as a result of pressure from downstream users and retailers of final products. Interviews with representatives of large retailers also indicate that they often react to the introduction of a substance in the candidate by asking their suppliers to ensure that such substances are not included in the products.

A number of examples in the area of metals, construction chemicals, flame retardants and dyes for textiles have been provided and as the list extends further more substances are expected to be affected, leading to their replacement by existing less hazardous substances and/or the development of new ones. On the other hand, according to a number of firms and some industry associations a few of the substances in the candidate list are already reaching the end of their life cycle. From this point of view, the candidate list does not add much to their ‘natural’ process of their disappearance from the market.

In relation to the market impacts, industry is in often more critical of the role of the extensive list of chemicals developed by NGOs (SIN-list) which is not developed on the base of the same thorough risk of
assessment selection process. While this process is not governed by the REACH Regulation it is seen as adding to the confusion and uncertainty as it is still used by some retailers.

Another issue raised is that the candidate list process introduces a certain level of uncertainty. There is, as suggested, limited predictability as to the which substances and when they may end up in the candidate list or when they may be included in Annex VIX. Indeed the process followed, which includes a public consultation, does not set specific deadlines for either of the two stages. This means that while firms are aware that a specific substance may enter the candidate list, they cannot not know when this may take place and at which point the information provisions obligations resulting from an entry of a certain substance in the candidate list will arise. While the specific costs arising from such a process may not be particularly high, they are seen as adding to the complexity and unpredictability of the REACH Regulation.

4.3.6 Market surveillance mechanisms

Effective market surveillance across the EU is paramount in ensuring the creation of a harmonised internal market and the development of the level playing field that supports competition.

The survey responses do not provide a particularly positive picture. Among those firms with experience in market surveillance, around 20% made a positive assessment of their experience from market surveillance and enforcement. In contrast 35% to 50% of respondents - depending on the role in the supply chain provided a negative assessment and 40-50% characterised it as “fair”. At the same time, around 45% of the survey respondents stated no experience.

89 These include the preparation of SDSs in the case of substances, the provision of information to customers in the case of articles which contain substances on the Candidate List in a concentration above 0.1% (w/w) or the notification to ECHA if the article contains a substance on the Candidate List.
Analysis of findings

Chart 4.16 - Experience with market surveillance (% of firms indicating certain experience and assessment of effectiveness)

Source: CSES survey

There is generally a perceived lack of capacity by enforcement authorities to adequately enforce the regulation with reference often made to limited resources available. Further to that, existing work in the context of Enforcement Forum indicates substantial variation in the approach of inspections, requirements and imposing penalties across the EU.

Besides providing some indications, we consider that it is too early for conclusions on this aspect. A number of coordination and joint inspection projects have been set up by ECHA in order to improve consistency and the RIPE database will help exchange in information among enforcement authorities.

The comments of national authorities, industry representatives and individual firms presented in the following text box are illustrative of the generally negative experience, the problematic aspects, and the variation among Member States in their approach. The focus on most comments is on the limited resources available and the fact that authorities do not appear to follow a consistent approach in terms of how, and what, inspections should involve. It is also clear that at this stage most authorities avoid, as far as is possible, the imposition of penalties. Finally, the discussions with many authorities indicates a varying decree of involvement and coordination with customs authorities although, according to some Member States’ representatives this may not be necessary for effective surveillance.

From a more positive point of view, there is generally recognition of the role of the enforcement forum and the RIPE database in enhancing coordination. Most Member States’ Competent Authorities made
also a positive assessment of the role of the enforcement projects and were in favour of their continuation.

Table box 4.10 - Comments of Member States, industry representatives and firms on market surveillance

<table>
<thead>
<tr>
<th>Role</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>National authority</td>
<td>There is important focus on enforcement with targeted checks (150-200 inspection activities/year) and priority is given on manufacturers of chemicals. So far we adopt an advisory approach and do not impose penalties. We are also working with other MSs to adopt a harmonised approach. The Enforcement Forum does help in coordinating effort.</td>
</tr>
<tr>
<td>National authority</td>
<td>We dedicate 10-20 people which we think is adequate. But the REACH regulation comes on top of other activities. Our focus at this stage is on labelling and packaging. There are issues with the monitoring of SDSs as they change all the time.</td>
</tr>
<tr>
<td>National authority</td>
<td>We are still learning. There is a risk that what is a good piece of legislation might be undermined by the lack of resources MSs have in surveying the market.</td>
</tr>
<tr>
<td>Representative of the non-woven fabrics industry</td>
<td>Need to make sure that authorities enforce REACH and that they commit resources. It is not clear that this is happening at this point. There are also reports of authorities not being up-to-date of requirements (SDS content) and focusing on administrative activities and requirements (end up missing the spirit).</td>
</tr>
<tr>
<td>Representative of the chemicals distributors</td>
<td>We are still in the learning phase. The enforcement forum is a positive step but there is no much experience to this point. Need more resources to make surveillance work and few governments have these now.</td>
</tr>
<tr>
<td>Representatives of Only Representatives</td>
<td>Market surveillance is not happening. There are not enough people on the ground for that. Authorities get 1 day crash course for REACH and do not have funds or resources for REACH training or enforcement.</td>
</tr>
<tr>
<td>National industry association</td>
<td>There are perceived problems among some stakeholders in relation to enforcement, namely that while in the initial stages, enforcement agencies are able to provide companies that have queries in relation to REACH compliance with advice, inspections are too rigid and policeman-like with not all inspectors having the requisite knowledge to accurately assess REACH compliance. This can be especially problematic for SMEs that are downstream users and do not have in-house chemical specialists. Inspectors have the power to close down plants and when this has happened, the decision to do so was not always appropriate, for example, as a result of incorrect labelling or an out of date SDS.</td>
</tr>
<tr>
<td>Large manufacturer of surface treatment products selling across the EU</td>
<td>There is inconsistent enforcement, ranging from no enforcement right through to detailed testing. Enforcement authorities’ lack of knowledge was balanced out by competence of the staff. Uniform, effective enforcement has not been detected to date.</td>
</tr>
<tr>
<td>Large size producer of basic chemicals selling across the EU</td>
<td>List of punishable offences not harmonised throughout Europe. It does not make any sense that the national Competent Authorities have been given the responsibility of implementing an EU regulation.</td>
</tr>
<tr>
<td>Large manufacturer of tyres</td>
<td>Have seen virtually no activity by MS enforcement agencies relative to REACH. On the very few occasions, agencies seem to be less educated and experienced with the legal aspects of REACH than we are, and thus we end up educating them on the details.</td>
</tr>
<tr>
<td>Medium size producer of additives for lubricants selling across the EU</td>
<td>We are aware of several downstream users importing product from outside the EU totally ignorant or in blatant disregard for the REACH Regulation</td>
</tr>
<tr>
<td>Multinational firm producing basic chemicals selling</td>
<td>There is no control for the substances imported. The controlling institution at the customs office has no possibility to check whether the substance has been really registered.</td>
</tr>
</tbody>
</table>
## Analysis of findings

<table>
<thead>
<tr>
<th>Role</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>across the EU</td>
<td>In the updated ECHA Report “Results of the Forum coordinated REACH enforcement project on registration, pre-registration and safety data sheets” 378 violations yielded only 12 fines, and no verification testing was done. The bottom line is that they are not checking to see if the intention of REACH is being served, are banned or restricted chemicals still used and are they still being distributed to the EU.</td>
</tr>
<tr>
<td>Small size importer of chemicals from Asian countries</td>
<td>The core problem is the non-standard implementation of checks and sanction regulations. These differences alone result in a distortion of competition which, if practised by corporate cartels, would be criminal.</td>
</tr>
<tr>
<td>Large size distributor of chemicals</td>
<td>As long as the substances are brought from China without any documents certifying their geographical origin, I don’t believe that the activity carried on by the authorities is sufficient.</td>
</tr>
<tr>
<td>Medium size distributor</td>
<td>Local market supervisory authorities occasionally appear to have different interpretations</td>
</tr>
<tr>
<td>Medium size producer of commercial display cabinets</td>
<td>As there are no controls in place, any article can move freely all across the EU. Therefore we suffer badly from imports originating from outside the EU.</td>
</tr>
</tbody>
</table>

Source: CSES survey and interviews

### 4.4 Utility of REACH outputs

**Creation and use of new knowledge**

One of the intended contributions of the REACH regulation was to gather information that would “create a strong demand for substitute chemicals that have been sufficiently tested and that are safe for the envisaged use”. Furthermore, information on the use of substances by the downstream users was expected to create a better understanding of the properties required from substances, and possibly substituting some in the production process to enhance environmental and human safety.

However, the business survey indicates that, so far, the contribution of REACH in the development of new knowledge has been rather limited. Not more than 11% of respondents stated that the additional information acquired in the process has significant helped develop less hazardous substance or that it helped identify potential new uses for their substances. For the great majority of firms – around 70% of respondents – the information acquired has not had any contribution to this point. The analysis of responses did not indicate any significant deviation on the basis of firm size, role of sector.
Chart 4.17 - How useful has been the information acquired during the registration process been to the development of innovation in your business? (% of firms responding)

<table>
<thead>
<tr>
<th>Response</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not at all</td>
<td>2.2%</td>
</tr>
<tr>
<td>Slightly</td>
<td>9.1%</td>
</tr>
<tr>
<td>Moderately</td>
<td>16.4%</td>
</tr>
<tr>
<td>Very</td>
<td>2.3%</td>
</tr>
<tr>
<td>Extremely</td>
<td>8.7%</td>
</tr>
<tr>
<td>Total</td>
<td>72.2%</td>
</tr>
<tr>
<td>Total</td>
<td>69.7%</td>
</tr>
</tbody>
</table>

Source: CSES survey

In general, the view of most stakeholders is that it is too early to assess the contribution in respect to the use of additional information and that this is a process that may take quite some time. Individual interviews with major global chemical companies indicate that they have not really found the huge amount of information generated to date by REACH of use in developing new substances or new uses for existing substances. One firm had even developed a bespoke software programme to try and mine such data but found that it was not producing useful results and abandoned it.

Beyond this, a number of associations, representing mainly commonly used substances, question the added value of the process. They claim that the substances they produce or use have been in use for a long period of time, and the risks were either already known or their extended use had proven them not to be harmful. In the case of chlor-alkali products, substances have been under the ICCA High Production Volume (HPV) scheme which means that data had been gathered before the introduction of REACH. In the words of one formulator, “the substances used in our preparations were previously subject to a selective eco-toxicological test close to that instituted by REACH”. For the iron and steel industry, the cost of registration for the iron and iron compounds dossier, which are non-hazardous substances, it is claimed to be too high for what is considered as common knowledge. Other examples include sodium-chloride and lime. Thus, while certain gaps in knowledge may have been filled, a lot of information was known well before the regulation came into force.
Having said that, there are also cases of firms that recognised specific benefit from the communication of the uses and properties of substances, and there is reference made to the positive movement that was created by the Regulation. One company stated that there "was always the need for everyone to better analyse every single product" but that it was never done due to shorter-term business constraints. REACH appears to contribute in this direction.

More generally though, even when the potential of new knowledge is recognised, firms refer to the long time needed before certain results in terms of new products and uses do arise. At this stage the majority of firms are in the process of coming to grips with the regulation, preparing dossiers for 2013 and refining their processes. One rather commonly expressed view is that only after the 2018 deadline, once the regulation is fully implemented that firms may be able to invest research capacity to make use of the information gathered. Furthermore, the capacity to utilise the information created may vary. Large firms in sectors such as pharmaceuticals and automotive, who already have well-established supply chains, are expected to be able to handle and exploit the additional volume of information more easily. According to Orgalime this may not be the case in the machinery sector, which is dominated by a large number of SMEs with limited resources.

From the very different perspective of national authorities, the feedback received indicates a generally positive view on the additional knowledge created and the opportunities provided. Member State Authorities consider the knowledge created through REACH "fundamental" and "absolutely necessary for authorities" in their own policy making. Another competent authority explained that while in the past only 23% of substances were classified as dangerous, now, with new information already available, over 60% are. The key issue for most of them is the actual capacity to utilise this knowledge. Not all Member States are equally equipped and resource limitations are often stated as an important constraint in this direction.

**Improvement of risk management and occupational health and safety**

The survey responses indicate a rather positive view of REACH in relation to the introduction of improved risk management procedures. While most industry associations raised doubts on the actual capacity to utilise the knowledge acquired, the survey responses provide a rather positive picture with more than 60% indicating a certain level of contribution. This could be considered as significant given the very early stage of the use of the extended Safety Data Sheets and the 12 month period allowed for firms to integrate these changes to their risk assessment management processes.
Chart 4.18 - Has the introduction of REACH led to an improvement of the risk management procedures inside your business?

As is the case with other forms of information gathered through mechanisms linked to REACH, the use of the knowledge gathered on human and environmental risk management varies according to the sectors. The chlor-alkali manufacturers for instance claim that no new knowledge was gathered through REACH, due to the previous ICCA High Production Volume (HPV) scheme. Metals manufacturers on the other hand claimed that information on toxicological elements can be really helpful but that it comes at the expense of too much red tape and that it will not be possible to utilise this information.

Much more limited is the impact on occupational health and safety attributed to REACH. Three out of four survey respondents did not see any clear contribution at this stage. Some firms indicated that the introduction of new systems even before the introduction of REACH while others believe that the actual impact will be negligible, as most aspects of OSH were already covered by existing legislation. As yet, companies are overwhelmed by registration costs and there is not much to be done with toxicological and other information acquired. As far as non-EU manufacturers are concerned they are not expected to change their human and environmental risk management measures due to REACH. Only if similar regulation in these countries is developed (as in the example of South Korea), are they expected to move in the direction of REACH.

Certain industry representatives questioned the possible savings resulting from risk management measures. One downstream user association explained that there would be no savings related to...
decreased environment or occupational health and safety damages; this is a view that is shared by the majority of trade associations we have spoken to.

Finally, from the employee’s side, the pan-European Trade Union (ETUC) welcomed REACH and particularly the requirement for the development of exposure scenarios and eSDSs. European Trade Unions see the improvement in health risk management measures as potentially having long term effects and referred to the results of the impact study before the introduction of REACH that estimated a potential for avoiding up to 90,000 cases of occupational diseases caused by chemicals as a result of REACH.90 Still, ETUC suggests that, in order for information to be properly used “more should to be done to make the relevant aspects of the eSDS readily available to the relevant people”. One trade union representative welcomed the measures taken in the chemical sector to improve risk management measures, however, some companies have suggested that the added value is mainly related to a few EU countries as in most of them they were already in place even before the introduction of the REACH Regulation.

In summary, the input on the utility of the REACH Regulation suggests that is too early to tell whether the information created will translate to exploitable knowledge to lead to innovation, or whether there will be benefits to risk management of occupational health and safety. The responses of industry indicate diverging views on the potential and limitations of results to this point. But these are all aspects for which any conclusion at this stage is premature.

Table box 4.11 – Comments of Member States, industry representatives and firms on SDSs

<table>
<thead>
<tr>
<th>Source</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Representative of the soaps, detergents and maintenance products</td>
<td>SDS is the main communication tool but in view of all the new information to pass down stream, it is probably not the most relevant document to do so</td>
</tr>
<tr>
<td>Representative of trade unions</td>
<td>Information and SDS will be useful for workers to be more aware to the manipulations they perform and the risk management measures they need to put in place</td>
</tr>
<tr>
<td>Representative of the non-ferrous metals industry</td>
<td>SDSs become very long (50 pages or more) and it is not possible for firms to use them as an effective communication tool.</td>
</tr>
<tr>
<td>Representative of downstream users</td>
<td>eSDS tend not to be usable for downstream users – no common structure – construction chemicals industry have decided to select what information to give the end-users producing one or two page docs – this is not in accordance with regulation</td>
</tr>
<tr>
<td>Large German manufacturer of chemicals</td>
<td>Companies have different formats of SDS</td>
</tr>
<tr>
<td>Large German manufacturer of chemicals</td>
<td>The extended obligations to provide information have made safety data sheets for substances with a lot of areas of application very confusing.</td>
</tr>
<tr>
<td>Medium French distributor</td>
<td>SDSs more than 10 pages long stop being effective in the case of real</td>
</tr>
</tbody>
</table>

90 The impact of REACH on occupational health, School of Health and Related Research University of Sheffield, UK, 2005
needs. Too much information kills information!

Small UK-based formulator Paint Formulators will have to incorporate many extended SDS’s for their blends resulting in unreadable multi hundred page documents

Source: CSES survey and interviews

### 4.5 Consistency of the REACH mechanisms with the EU legal framework

**Competition rules**

In theory, the partnership within the context of SIEFs and consortia could raise competition issues related to collusion and abuse of dominant position. There is so far no evidence to indicate that any breach of compliance with basic rules of competition has taken place within the context of consortia of SIEFs. Based on the provisions of the Regulation, consortia are required to organise co-operation with other SIEF members, and the work of consortia cannot have the consequence of excluding other SIEF members from the mandatory joint submission. Courts and authorities can decide that companies having “excluded” one or more legitimate participants are in breach of the REACH regulation, and may be liable for this, including having to pay damages. The industry has paid significant attention to competition legislation from the very early stages and legal advice has been provided by CEFIC and other industry associations to all consortia and SIEF members in relation to the exchange of data among competing firms.

In relation to the abuse of dominant position the main focus point concerns the costs of letter of access. Prices of letters of access of over €100,000 are often seen as disproportionate and interpreted as an abuse of their position and access to greater resources by large firms. Indeed, 38% of the respondents of the survey over 40% in the case of SMEs agreed with the statement that participation in SIEFs allowed some firms to abuse their dominant position. However, even though there is a possible indirect effect on the SIEFs operation, it cannot be considered as a breach of competition regulation. According to the Commission services there has only been one known case so far where national competition authorities have initiated an investigation into the way the fees have been set. Currently, this is primarily seen as the result of limited transparency on the total costs incurred and the ways fees are set, rather than a genuine attempt by large firms to influence the market.

Another issue raised by some industry associations and authorities is the attempt of some lead registrants to influence the definition of the common substance identity to better suit their market plans. However, we have no evidence that this is a widespread problem and in many respects the supervising role of ECHA in relation to the formation of SIEFs does not provide much space for such abuses.

Beyond registration, experts indicate that the authorisation process is expected to present much greater challenges for firms in relation to competition regulation. The nature of the information that must be submitted by applicants in an application for authorisation includes economic feasibility data and R&D data for the analysis of alternatives, as well as commitments and timelines regarding transfer to alternatives contained within the substitution plan, and economic impact data contained within a SEA.

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All these constitute sensitive information that can provide the basis for the alignment of competitive behaviour. In the case of joint applications aiming to reduce authorisation costs, issues of competition are expected to arise as a result of sharing such information in the process of developing the relevant dossiers.

Exchange or disclosure of highly sensitive commercial data between entities, particularly exchanges and disclosures of horizontal nature, is very likely to raise EU competition law concerns. Some firms have indicated that it is expected that Third Parties will be used in cases of Authorisation proceedings to reduce the risk liability in case competition authorities decide to investigate and prosecute at a later stage.

Overall however, whilst there are certain concerns that SIEFs and consortia can be used by some firms to serve their market interests, there are no clear cut competition issues arising and there is limited evidence to suggest that this is a major problem within the context of the operation of the SIEFs.

**4.6 Distribution of the benefits and costs of the REACH regulation**

At this stage in the implementation of the regulation, industry representatives do not seem to have a clear view as to how the costs from the implementation of the regulation, and even more the benefits, are distributed across sectors. In terms of costs, the manufacturers and importers of chemicals that have already been involved in the first phase of registration – namely the large producers and importers of chemical substances – have incurred greater costs. In terms of manufacturers of articles the number of articles with chemicals intended to be released have been extremely limited.

The sectors mainly affected are primarily refined petroleum (NACE Rev.2 code 19), chemicals and chemical products (NACE 20), pharmaceuticals (NACE 21), basic metals (NACE 24) and, in the case of importers, the related wholesale sectors (NACE 46.72 and 46.75). In the chemicals sector, manufacturer of basic chemicals (NACE 20.1), other chemical products (explosives, glues and essential oils – NACE 20.5) are the sectors with the highest share of manufacturers of chemicals. In the specialty and consumer chemicals sector the great majority of survey respondents suggested that their role is formulation of chemicals (downstream users). In relation to the remaining costs of information exchange, all sectors and roles in the supply chain – from manufacturers to retailers of final products – appear to be affected in a greater or lesser extent depending on the degree of use of chemicals.

Among downstream users, manufacturers of articles located within the EU are, overall, experiencing a greater cost in comparison to non-EU competitors. This is the view expressed by representatives of the metals, automotive, engine ering, textile, and aerospace and defence sectors derived from the greater obligations concerning not only the final products but also the chemicals used in the various processes. Non-EU producers importing to the EU usually have less costs especially if the obligations are assumed by EU importers. On the other hand, while it is clear that downstream users who rely more on chemicals have increased obligations, there is no evidence at this stage to indicate that a certain sector is disproportionately affected.

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92 Of course, there are many firms that have multiple roles in the supply chain. However, this does not alter the fact that registration costs have fallen primarily in these sectors.
Impact on SMEs

A much more common differentiation made concerns the possible impact of the Regulation on SMEs. All industry associations interviewed expressed the view that SMEs have been more affected by the Regulation than large firms who tend to have the resources to deal with it. While relatively few SMEs manufacturing chemicals have been affected by the first registration process (according to the ECHA data only 4% of the dossiers submitted so far come from SMEs), there is in general a sense that given the fixed aspects of certain implementation costs the overall costs of REACH have a greater impact on SMEs and their capacity to maintain their presence in certain markets.

Information transfers and communication on the basis of SDSs is an important burden on SMEs with limited resources. A typical 4-5 employee downstream user firm (e.g. a paint manufacturer/mixer) might have to deal with 50-100 substances each with an SDS of some 100 pages. Medium size firms with 50-100 employees might have 5-10,000 substances to handle. Translation can add further to those costs. While such issues are also applicable to large sized manufacturers and downstream users these firms more often have the specialised skills and resources to deal with these information exchange requirements. Highly innovative exporting SMEs that concentrate on relatively few product lines cannot spread the costs to non-REACH affected products in their business portfolio. This makes them vulnerable to competition from non-EU countries in export markets.

The survey responses indicate that a greater share of SMEs believe that the Regulation has led to an increase of the prices of their products against competitors or a loss of markets in comparison to larger firms (see also chart 4.18). One recurrent comment made by firms in the chemicals producing sectors is that SMEs are not able to absorb the costs of REACH registration and often decide to abandon certain markets altogether or reduce their level of sales below the 1000tpy threshold.

In relation to the case of benefits from the Regulation, so far there are no indications of any significant differences, although this should be considered in the broader context where benefits from the Regulation have not yet materialised for both large and small firms.
Chart 4.19 – Impact of REACH on firms indicating that they agree or strongly agree with the following statements in relation to the impact of REACH to their business sorted by size (% of responding firms)

- Led to increase of prices in comparison to EU competitors
- Led to increase of prices in comparison to non-EU competitors
- Led to a loss of market share
- Led to increase in the costs of substances use in the production process
- Removed products from non-EU markets
- Removed products from the EU market

Source: CSES survey

The study also examined the possible variation between the experiences of firms in the new and old Member States (see also case studies 6 and 9). A study by the JRC prior to the entry of REACH into force indicated that there may be additional difficulties for firms in newer Member States. The analysis of the responses from new Member States did not indicate any differences in relation to the relative costs and benefits from the broader survey sample. However, the low response rate in some countries might be an indicator. Interviewees from chemical industry associations and ministries of economics suggest that those states have specific problems related to implementation of REACH, and adjusting their industry structures to the rest of the EU. In general, most new Member States tend to be net importers of chemicals and greater share of formulation/importing/distribution activities. These roles have rather burdensome industrial information transfer obligations (e.g. obtaining information about uses, translations, informing the customers about REACH). While the business survey did not collect enough information on new Member States, discussions with industry representatives shed light on certain issues. In many cases one or few firms – often the subsidiary unit multinationals - have been responsible for the majority of the countries, underlining the concentration of the industry. Such firms are most often assisted by the parent firm and had rather limited problems. The situation is expected to change in the run-up towards the 2013 and 2018 deadlines, when the impact on smaller-volume substances produced by SMEs, especially the ones produced in multistage processes, will become
visible. At the same time, in some Member States (e.g. Bulgaria) industry associations have limited capacity to play a supportive role as it is more generally the case across the EU. The number of SMEs affiliated to industry associations is rather small and, unless there is specific funding provided, they do not have the resources to support them in their compliance activities.

In relation to the distribution of costs and benefits between EU and non-EU manufacturers the survey results do not provide any insights as they rely almost exclusively on responses from EU-based firms. On the basis of discussions with industry representatives the main advantage for non-EU firms commonly identified concerns producing articles and selling them to the EU without the need for complying with any of the REACH requirements.

However, representatives of non-EU firms suggest that the Regulation has introduced additional costs in accessing the EU market and has created uncertainty about the level and timing of costs of accessing that market. The limited experience with EU legislation and issues of proximity and language may often create an additional obstacle. Thus, while the EU market still remains highly attractive for non-EU companies and there is no general evidence of firms withdrawing from the EU market, the additional costs and the complexity of the REACH Regulation are often considered as a disincentive especially for smaller firms. This can lead to a reduction of non-EU suppliers leading to less choice and increased market power for fewer firms in the EU (see also case study 8).

4.7 Acceptability of REACH regulation

Acceptability of the measures introduced by REACH

The responses to the CSES survey suggest a rather moderate level of acceptance of the regulation among firms. Negative and neutral opinions are more common; at 42% overall negative and around 40% neutral, while only 1 in 5 stated a positive opinion. Given the problematic experience of the pre-registration and to a lesser extent the registration period, the important administration and communication costs described earlier this could be seen as a rather positive message. There are also some indications that firms further down the supply chain – distributors or importers of articles – tend to have a more positive attitude towards REACH but this does not apply to end users. Furthermore, given the smaller number of responses among those groups, we cannot derive strong conclusions.
Chart 4.20 - How would you characterise your attitude towards the Regulation? (% of respondents stating by role in the supply chain)

Source: CSES survey

While SMEs’ responses do not significantly deviate from the overall picture, one must note that micro enterprises (less than 10 employees) have a more polarised view of the regulation with 46% having a negative view and 26% a positive one.

At the national level over 30% of companies located in France, Belgium, Spain and the Netherlands having a positive experience of the Regulation, compared to less than 10% acceptance from UK, German, Polish and Czech companies.

The views of industry representatives also vary. Differences in perceptions among sectors seem to be affected by their closeness to the end-user. The electronics sector for instance is rather proactive in ensuring that they have the information necessary to abide by the information requirements of the regulation. Some retailers even see REACH as a marketing tool to promote ‘green’ products.

On the other hand, fears that EU-based manufacturers would be challenged by companies located outside the EU remain strong. Furthermore, the benefits from the development of a harmonised market are far from clear. One national association representing companies throughout the supply chain explained that early signs of differences of interpretation in enforcement between Member States and the current perceived lack of stability of the legal text (or at least the guidelines) play a negative role in the overall acceptance of REACH.

This said, the acceptance of the Regulation will depend on the experience of the second and third registration period that will affect small size firms at a much greater level.
Acceptance of ECHA fees

The responses of the survey indicate a rather negative attitude towards the ECHA fees. The great majority of respondents (more than 75%) consider the ECHA fees to be high or very high. As indicated earlier in the study and in Case study 1 ECHA fees are considered as representing the most important cost aspect (typically around 20% of the total costs) and very often more than 25%. CSES also conducted an analysis by type of legal entity and location – national or multinational firms - which did not reveal differences from the picture above.

Concerning the charges to SMEs, table 4.15 indicates rather small differences on the perception of ECHA fees depending on size and this seems to be in line with the analysis of the share of ECHA fees to the total cost of registration. The analysis of the business survey responses presented earlier - section 4.2.1 ,table 4.3 and case study 1) indicates that ECHA fees generally have a similar share of the total registration costs (around 20%) among firms of different sizes. However, on the basis of the actual ECHA fees charged for substances in the 1000tpy band as set in the relevant regulation, the analysis suggests that ECHA fees have a greater contribution to the total costs for larger size firms (see table 4.16). ECHA fees represent close to 36% of the median value of the total registration costs for large firms and 38% for medium size. In comparison they represent around 22% of the costs for small firms and around 9% of the average registration costs for very small (micro) firms.

Table 4.15 - Perception of ECHA fees by registrants firms depending on firm size (% of respondents stating)

<table>
<thead>
<tr>
<th>Firm size</th>
<th>Do not know No. %</th>
<th>Very low No. %</th>
<th>Low No. %</th>
<th>About right No. %</th>
<th>High No. %</th>
<th>Very high No. %</th>
<th>Total No. %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Micro</td>
<td>3 8.8</td>
<td>0.0</td>
<td>3 8.8</td>
<td>7 20.6</td>
<td>11 32.4</td>
<td>10 29.4</td>
<td>34 100</td>
</tr>
<tr>
<td>Small</td>
<td>4 6.3</td>
<td>0.0</td>
<td>1 1.6</td>
<td>10 15.9</td>
<td>22 34.9</td>
<td>26 41.3</td>
<td>63 100</td>
</tr>
<tr>
<td>Medium</td>
<td>3 3.2</td>
<td>1 1.1</td>
<td>1 1.1</td>
<td>16 17.2</td>
<td>47 50.5</td>
<td>25 26.9</td>
<td>93 100</td>
</tr>
<tr>
<td>Large</td>
<td>12 8.2</td>
<td>0.0</td>
<td>2 1.4</td>
<td>16 11.0</td>
<td>79 54.1</td>
<td>37 25.3</td>
<td>146 100</td>
</tr>
<tr>
<td>Total</td>
<td>22 6.5</td>
<td>1 0.3</td>
<td>7 2.1</td>
<td>49 14.6</td>
<td>159 47.3</td>
<td>98 29.2</td>
<td>336 100</td>
</tr>
</tbody>
</table>

Source: CSES survey

However, when considered against their overall turnover, the ECHA fees – and the registration costs more generally - represent a greater share of the turnover of smaller size firms (see table 4.16) by a factor of 4 to 5. This type of analysis that focuses on the impact of REACH and ECHA fees on the total activities and income of firms, supports the views of a few industry associations whose members are primarily SMEs that considered ECHA fees as disproportionate. One importer association suggested that by itself the fee structure may lead many firms to withdraw their products from the EU market.

Of course, one needs to take into consideration that large firms most often register a greater number of substances and that, in the case that they have multiple production units, they often have to pay multiple registration fees for the same substance.

Overall, our conclusion is that the current ECHA fee structure does represent a sizeable cost reduction in favour of small firms, even if it does not lead to an equalisation of the relative burden. In its absence the burden of REACH on SMEs would have clearly been disproportionate.
Table 4.16 – Registration Fee for a single submission per million of annual turnover: comparison among firms of different sizes

<table>
<thead>
<tr>
<th></th>
<th>Micro</th>
<th>Small</th>
<th>Medium</th>
<th>Large</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total registration costs for substances over 1000 tpy – Median values according to CSES survey</td>
<td>34,722</td>
<td>57,353</td>
<td>56,251</td>
<td>86,843</td>
</tr>
<tr>
<td>ECHA fees for substances of over 1000 tpy</td>
<td>3,100</td>
<td>12,400</td>
<td>21,700</td>
<td>31,000</td>
</tr>
<tr>
<td>Share of ECHA fees in total registration costs</td>
<td>8.9%</td>
<td>21.6%</td>
<td>38.6%</td>
<td>35.7%</td>
</tr>
<tr>
<td>Maximum turnover (€ millions)</td>
<td>2</td>
<td>10</td>
<td>50</td>
<td>10094</td>
</tr>
<tr>
<td>Registration fees/maximum turnover (€/million turnover)</td>
<td>1550</td>
<td>1240</td>
<td>434</td>
<td>310</td>
</tr>
</tbody>
</table>

Source: Own analysis on the basis of survey and data

Acceptability of the structure of ownership

The great majority of companies involved in SIEFs have not had problems with issues related to intellectual property. Only 12% of respondents stated any such problem. Likewise, there were no differences in the experience depending on particular roles in the supply chain.

Chart 4.21 – Have you experienced problems in relation to the protection of the intellectual property rights of your business from the participation in the SIEFs (n=365)

We have used the standard Commission definition and assumed the maximum turnover for the different categories (€50 million for medium size firms, €10 million for small and €2 million for micro) and an average value of €100 million for large firms. This could probably be considered an underestimate but it does not affect the overall conclusions. A greater value would indicate an even smaller share of registration fees against total turnover.

94 We have used the standard Commission definition and assumed the maximum turnover for the different categories (€50 million for medium size firms, €10 million for small and €2 million for micro) and an average value of €100 million for large firms. This could probably be considered an underestimate but it does not affect the overall conclusions. A greater value would indicate an even smaller share of registration fees against total turnover.
The feedback provided so far indicates that firms are generally alert to issues of ownership of rights and there has been guidance provided by industry associations and legal advice in the agreements developed for the operation of SIEFs. While there have been comments from trade association and survey respondents fearing issues with IP, no concrete examples were found during the field research. Only one national chamber of commerce commented on the excessive costs of some of the processes. While it is possible for them to protect their IP, the cost of participating in the SIEF (Letter of access, licensing costs etc) is very costly, especially for less competitive companies.

One issue that emerged was related to the fact that the registration is for a company at a location. Consequently, if a company changes hands it may be necessary for the new owner to pre-register and register again, which of course increases costs and reduces the efficiency of the industrial system. IP problems also emerge in the case of toll manufacturing arrangements.

4.8 Sustainability of REACH Regulation

The question of the long-term impact of the Regulation is not possible to address at this early stage of its implementation. Industry is still getting to grips with the requirements of the Regulation and has not evolved much in its view of the future of the Regulation. In the medium term (i.e. in the period up to 2018) additional costs are expected as the result of the registration requirements and the need for compliance with REACH provisions. In addition, the interviews conducted have shown that in the chemicals sector, a number of resources were diverted from R&D activities to compliance and testing. Some industry representatives claim that this should not be expected to be temporary, while others expect that following the third registration period resources will be redirected to the original more productive activities. A number of SMEs that responded to the survey expressed their fear that REACH has not yet had a major effect on them, but that they would be hit much harder following the second and third deadlines. One company explained that “many SIEFs are unwieldy, which will add to costs, and manufacture in the 1-100 tonne will in many cases not be worth -while, and we can’t all exist in the less than one tonne area. Selling in Europe will not be possible for companies who compete against the importers and manufacturers in the greater than 100 tonne area. Costs/kg will be of the order of 10 -20 times greater than for the large producers.”

Potential benefits are thus only expected to occur after 2018, once registration related costs decrease significantly. One national association stated that the introduction of REACH is rather positive for the chemical industry but that it would take time for the main actors to realise it. Following the transition period, a number of actors expect for the data gathered during the three registration phases to be used more widely and potentially to lead to the development of innovative products and uses of substances. A number of industry associations believe that the success of the Regulation will depend in large part on the capacity of the industry to make use of the information gathered. However, they generally agree that very few companies currently have the time and know-how to use this knowledge to benefit their business.
In this section we present the main conclusions of the review study in relation to the key questions of the impact on competitiveness, and the operation of the single market. We subsequently provide a series of recommendations.

5.1 Conclusions

The general conclusion of the analysis presented in the previous sections is that, in the short term, the implementation of the REACH Regulation poses important challenges and introduces implementation costs that affect manufacturers and importers of chemicals, as well as their downstream users. At the same time, any benefits for firms and the overall competitiveness of the chemical industry are difficult to discern at this stage and should be expected to materialise only over the medium to long term.

In addition, we conclude that the industry seems able to absorb the additional costs incurred with, generally speaking, no significant adverse effects on its overall competitiveness and with a general acceptance of the longer term objectives of the Regulation. This said, there are deviations in terms of the impacts and certain firms or sectors appear more vulnerable than others. The analysis of the data available indicates that small size firms, firms in sectors with less integrated supply chains, or firms that rely on the use of chemicals included in the candidate list for authorisation often face greater challenges as a result of the REACH regulation.

The following points summarise the conclusions made in relation to the key evaluation questions and the competitiveness aspects. In addition, Annex B provides a table with the responses to all evaluation questions as set in the terms of reference of the study.

Relevance of the Regulation

- The REACH Regulation maintains its relevance in relation both to the objectives of competitiveness and the contribution in the harmonisation of the single market. Both are objectives that can be served by the effective and efficient implementation of the Regulation on the basis of the promotion of innovation in chemicals, the minimisation of the implementation costs, and the pre-emption of the creation of national regulations as regards chemicals that could lead to a fragmentation of the EU market.
- However the analysis also indicates that most of potential benefits including the promotion of innovation remain to be seen.
- Similarly, differences in interpretation of provisions in relation to monitoring and enforcement of the Regulation by Member States mean that the creation of a harmonised market is still incomplete.

Effectiveness

Costs of compliance with REACH Regulation

- The compliance requirements of the REACH regulation introduce sizable costs for almost all firms in the chemicals market.
Conclusions and Recommendations

• The key drivers of compliance costs are, to this point, registration costs – including data collection and ECHA registration – as well as communication and exchange of information along the supply chain.

• The available data suggest that the costs for the first registration period incurred by suppliers of chemicals – manufactures and importers of chemicals – were around €2.1 billion close to double of the initial estimations made by the Commission in 2003. The main reason for this difference appears to be the limited use of the QSARs testing method, in contrast to the rather ambitious initial expectations.

• REACH requires a sizeable dedication of human resources. For large manufacturers of chemicals as well as downstream users this often means the creation of a dedicated REACH unit with, typically, one to five members of staff occupied on a full time basis along with one or more members of staff allocated in the different production units. For small size firms it means at least one member of staff with technical background working on REACH on a full or part-time basis.

• The communication in the supply chain includes not only the handling of Safety Data Sheets but also extensive and continuous information exchange along the supply chain – inside and outside Europe – with firms that are not always aware of the information requirements or able to respond.

• External support by specialised consultants and the acquisition of specialised IT systems often come on top of the internal resources dedicated by firms.

• There are additional costs resulting from the implementation of the REACH Regulation including the costs of authorisation, the notification of articles or the resulting changes in risk management procedures. However, there is very limited experience to this point and has not been possible to assess the magnitude or the importance of these costs.

Impact of REACH on industry and markets

• So far, the most common approach followed by firms in relation to the REACH related costs is to try to absorb them in order to maintain their prices. As a result, REACH has had a negative, albeit small, impact on the profitability of most firms, at least over the short term. In the majority of cases, total registration costs have not exceeded 1% of the total annual turnover of firms.

• The approach followed by firms is, in general, dictated by the market structure and the level of competition. In general, firms in the specialty chemicals sectors have greater capacity to pass prices down the supply chain and maintain profitability in comparison to producers of most types of basic chemicals.

• The implementation of the REACH Regulation does have a certain impact on the availability of chemical substances used as intermediate inputs by downstream users. The feedback provided so far indicates that certain level of rationalisation of suppliers' portfolios has taken place. However there is no evidence that this has thus far taken place on a large scale.

• REACH has also led to a reduction in the number of suppliers of some substances leading to an increased level of concentration in some chemicals' markets. In the medium term this can have implication in the level of competition the prices of chemicals. There is no such evidence at this point.

• The withdrawal of substances is driven primarily by the registration costs, but also, for a smaller number of firms, by the introduction of substances in the candidate list.
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- The impact to industry of an entry of substances in the candidate list varies. Often the substances in the candidate are already towards the end of their life cycle, and substitutes are generally available. However, this is not the case in all sectors and for all substances. In some sectors—such as in certain segments of the coatings sector—the costs of identifying appropriate and effective substitutes may be particularly high and the process rather uncertain.
- At the same time, the entry of a substance in the candidate list sometimes initiates a more general market reaction with retailers or other producers of consumer products requiring suppliers not to use such substances in their products. This is still not a general phenomenon.
- There is no evidence at this stage that substance withdrawal has had an impact on final consumers in terms of the variety of final products available or their prices. However, it is probably too early for any conclusive assessment.
- The most common approach followed by downstream users in the case of a withdrawal of a substance is its substitution with alternatives. Switching to other suppliers, most often inside the EU, is the second most common approach followed by firms according to the survey.
- There is no evidence available at this stage indicating sizeable shifts in terms of both imports and exports of chemicals as a result of REACH. Still, the majority of respondents stated that, despite their efforts to absorb costs, REACH requirements and administrative procedures make their products more expensive in comparison to non-EU competitors with a potential longer term impact in their capacity to compete inside and outside the EU.
- For a smaller share of firms, and particularly SMEs, there is already a feeling that they are losing EU market share either as a result of the costs, but mainly as a result of their decision to withdraw products from the market or reduce production levels.
- At the same time though, non-EU firms also consider that REACH introduces sizeable costs and some of them consider refraining from entering the EU market. This has often led downstream users towards EU based suppliers.
- On the basis of the available evidence, a possible outcome of REACH is the reduction in the number of suppliers of chemicals and a greater concentration of the market.

Business gains and utility of REACH

- The survey responses and other evidence available suggest that, so far, there have been limited benefits and business gains from the implementation of REACH.
- Firms do not consider that the Regulation has played a role in building consumer confidence and are very sceptical of the overall potential to play such role.
- As far as investor confidence is concerned, the main issue identified is the uncertainty arising for the process of the introduction of substances in the candidate list and its impact on long term investments.
- While there is recognition that there is certain new information created as a result of the implementation of REACH there have been, so far, limited benefits in terms of the development of innovation from the information developed in the context of the registration process. The main reason is that most of the substances registered in the first registration process were for substances for which substantial level of information already existed. Notwithstanding this, even for the following registration periods, there are doubts expressed as to the extent that the information created should be expected to contribute to the creation of innovation.
- Only a small share of firms considers that there is a positive role of REACH in promoting cooperation among firms (customers/suppliers) in the supply chain. Thus, while some firms do identify a
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potential for long term operation and productivity benefits, especially for those sectors and firms with less integrated supply chains for most firms these have yet to materialise.

- While it is still early on, the survey responses also suggest a relatively positive view of REACH in relation to the introduction of improved risk management procedures. The main contribution is expected to come from the new information on the toxicological and other properties of chemicals that can help the adoption of relevant risk management measures.
- In contrast, it seems to be too early for any measurable impact on the improvement of occupation health and safety to be assessed.
- The study also indicates that at, at least so far, the implementation of the Regulation has quite often led to delays in the time needed to bring products to the market that in some case can exceed one year. The delays and perceived unpredictability in the inquiry process are often stated as the reasons behind such increases. A certain level of improvements should be expected as the process is streamlined.

Job creation and business relocation

- There is limited evidence at this stage to conclude whether REACH has a positive or negative role on the capacity of the chemicals market to maintain or generate jobs. There is a continuous downward trend in employment in the chemicals sector but this cannot be attributed to REACH.
- There is a certain level of job creation in firms as well as external technical consultants related, primarily, to the administrative and the health and safety aspects of REACH. There is, on the other hand, no indication at this stage of job creation resulting from business creation opportunities for the chemicals industry.
- While there are some indications that REACH may be a reason for the relocation of certain activities – mainly related to the downstream users’ activities that can avoid certain REACH related costs – there is no specific evidence available at this stage. There is however a greater possibility that REACH related requirements may make the EU a less attractive location for such types of activities. Still, REACH is only one consideration in such business decisions.

Distribution of costs and benefits

- So far, manufacturers and importers of chemicals - and to a lesser extent formulators - have born the brunt of the costs of compliance as a result of the important registration costs. Firms producing, importing or using more hazardous substances have also been affected more as a result of higher registration and supply chain communication costs.
- Still, almost all firms in the chemicals’ market have been affected as a result of the important supply chain communications costs.
- At an aggregate level, large firms have been affected more than small sized firms since the first registration period concerned substances produce in higher volumes. However, in relative terms the costs of compliance with REACH Regulation tend to have a greater impact on the profitability of SMEs even though this also depends on the sector and the type of substance involved.
- Furthermore, SMEs face greater difficulties and higher relative costs as a result of the supply chain communication.
- Large sized firms may also gain from the decision of smaller producers to withdraw from certain markets as a result of the registration costs. We have no evidence at this stage to assess the impact.
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- The inputs of industry indicate that certain sub-sectors have faced greater problems as a result of the withdrawal of some chemical substances. The paints and varnishes, adhesives and coating manufacturers firms appear to be the ones most often affected and, as a consequence, the same applies to respective downstream users that rely on these products (metal processing, aerospace, construction industry). It has not been possible to assess at this stage the extent of the impact to these sectors.

Impact on the single market

- Up to this point, there is no evidence that the introduction of REACH has played any particular role in increasing the level of intra-EU trade. This is mainly because the level of intra-EU trade was already high prior to the introduction of the Regulation but also because it is not considered as the main criterion for deciding to enter a new market.
- There are concerns that manufacturers in the low producing EU countries and those dominated by SMEs may lose shares in the EU market as a result of some SMEs withdrawing from certain products to avoid implementation costs. This is still not evident and it is mainly a concern for the 2nd and 3rd registration period.
- There are some suggestions that importers of chemicals in EU markets may gradually shift to EU suppliers to avoid registration costs but this is not happening, at least so far, at any great scale.
- There are also important differences in terms of the implementation of the Regulation among Member States. The most commonly identified aspect concerns the different interpretations in relation to the notification requirement for SVHCs in articles. Besides the practical issues that may arise for which there is practical experience it is perceived as sending a negative signal to the market.
- The existing experience indicates significant variation in the way Member States monitor and enforce the Regulation as well as to the resources they dedicate. The existing coordination structures (Enforcement forum, Enforcement projects, and RIPE database) are considered as having a positive role in this direction but there is still great scope for improvement.

Efficiency

Role of REACH structures and mechanisms

- Overall, there is no evidence of a critical failure of the mechanisms, structures and processes set in place to support the implementation of REACH Regulation. Most aspects and problems identified can be seen as teething problems. But, there are problematic areas or implementation aspects that cause confusion, duplication of efforts and additional costs for firms.
- The SIEFs, the key structure intended to support the registration process, are recognised for their overall contribution in reducing registration costs. However, they were rather problematic during the first registration in terms of overall communication and coordination. As a result, they were far from reaching their full potential. More difficulties should be expected for the coming registration period given the involvement of more SMEs with limited experience and capacity.
- In contrast, the presence of consortia has, in general, a positive role in improving the effectiveness and the overall experience of registration.
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- There are problems in terms of transparency on sharing costs and setting the prices of letters of access that are sometimes quite expensive and have led some small size firms and importers to the decision to withdraw from or not to enter a specific market.
- In relation to this, there are certain claims that the SIEFs and consortia allow large firms to abuse their position in the market but there is no evidence that this is actually happening. More generally, while there are concerns raised, that have been no clear cut complaint issues arising from the operation of SIEFs and there is no evidence indicating that this is a major problem.
- Similarly, there is no evidence of particular issues related to the protection of intellectual property rights within the context of SIEFs. Nor has there been any evidence indicating problems with other ownership rights provided in the context of REACH.
- On the other hand, by its nature, the participation in SIEFs can reveal confidential business intelligence concerning a specific substance and the quantity produced by a firm to competitors.
- There are problems in terms of the use of SDSs and even more of the extended SDS for the communication in the supply chain. Extended SDSs are often particularly long making the extraction of relevant information burdensome. While there are ongoing efforts from industry in the direction of standardising the format and the content of SDSs and eSDSs there is still significant variation. At this stage, SDSs do not properly serve the information exchange role they are expected to have.
- The process of the introduction of a substance in the candidate list for authorisation appears to be problematic in terms a certain level of uncertainty it creates as to which substances may be included. The process is also rather unpredictable as to when certain additional compliance requirements on certain substance may arise.
- The overall picture of the level of use and the utility of the tools and structures set by ECHA appears positive. Still there are issues with delays on inquiries, problems with the IT tools that sometimes lead to additional costs for firms.
- Similarly there is, in general, a positive overall view of the role of national helpdesks as well as other support mechanisms set by industry at the national and European level. There are criticisms on the rather “legalistic” approach followed by some helpdesks although these are not always justified and would most probably not be possible to address.
- In relative terms, SMEs tend to rely more on national support structures.
- The role of Only Representatives is generally recognised as a positive one, contributing in clarifying REACH for non-EU firms and easing access to the EU market.
- However, the market of Only Representatives is diverse and there are concerns over the quality of some of them. The provisions of the Regulation do not provide the necessary clarity in terms the minimum capacity required or their role in relation to aspects such as authorisation and communication in the supply chain.

Acceptability of the Regulation

- Given the stage in the implementation of the Regulation and the important costs incurred to this point, the overall level of acceptance of the regulation is rather high with more than 60% of respondents indicating a neutral or positive view.
- There is however a clearly negative attitude towards ECHA fees. The great majority of respondents consider the ECHA fees to be particularly high.
Sustainability

- According to the feedback provided, most of the positive gains resulting from the Regulation, including the use of new knowledge for the development of innovation, improvements in supply chain communication, reduction of risk management costs, should be expected to materialise in the medium to long term – and generally after the third registration period.
- In comparison, compliance costs should be expected to continue, and possibly affect more firms – especially SMEs - in the short to medium term, until the third registration period.

5.2 Recommendations

On the basis of the preceding analysis and conclusion the CSES team has identified a set of key recommendations and relevant actions.

- **Avoid, to the extent possible, changes to any of the key or provisions of the Regulation**. The implementation of the Regulation is still at the early stages and there is significant learning for all stakeholders involved. Any changes can potentially nullify the significant experience and learning built by all categories of stakeholders and possibly lead to additional resources being dedicated. Stability and certainty are important at this early stage of the implementation. In addition, the key problematic aspects identified in this review - the operation of SIEFs and the exchange of information on the basis of SDSs - can be improved without changes to the text of the Regulation.

- **The focus at this stage should be on clarifying any unclear requirements, increasing predictability and improving tools and implementation structures to reduce or eliminate unnecessary costs**. We consider that priority should be given to improving the various implementation mechanisms to ensure effective and efficient compliance capitalising on existing experience gained and, whenever possible, to clarify, simplify or streamline aspects that can help minimise administrative and other related costs. More specifically the evaluation team proposes the following steps and actions:
  - Promote greater standardisation of extended Safety Data Sheets content and presentation and work with industry representative to identify possible simplifications to the information requirements provided or the way they are presented in the SDSs. The focus should be on making the introduction and the extraction of the relevant key information as easy as possible.
  - Consider the possibility of setting specific dates for the publication of the updates of guidance documents or other important developments related to the implementation of the Regulation and the feasibility of reducing the frequency of the update of some of those documents. The objective should be to reduce the work required by firms for the revision or update and increase the predictability of the system.
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- Consider setting specific dates for the publication of the update of the candidate list and the appropriateness of introducing a transition period between the time that a substance enters the candidate list and the time that information obligations may arise.

- Provide further guidance concerning communication practices and sharing of costs within SIEFs on the basis of the exchange of best practices.

- Propose minimum information provision requirements concerning the fees for letters of access with a breakdown of the costs in order to achieve higher levels of transparency.

- Clarify the role of ORs in relation to authorisation procedures and in terms of their responsibility in the exchange of information with importers. While changes to the text of the Regulation could also be considered it should also be possible to address this issue by providing clarifications concerning the practical requirements deriving from article 8.2 of REACH for a "background in the practical handling of chemicals". In cooperation with industry and Only Representatives, the Commission should consider the feasibility of developing a quality standard in the form of a "code of conduct", a certification scheme or the development of a publicly available database listing Only Representatives on the basis of a registration process.

3. Prepare for the following registration periods with focus on the needs of SMEs - The 2\textsuperscript{nd} and 3\textsuperscript{rd} registration periods are expected to be more challenging as they will most probably involve a larger number of firms, more SMEs with limited capacity and no prior experience on REACH. It is important that both ECHA and Member States have all the tools and necessary resources in place to support the second stage and minimize problems and associated costs. More specifically we recommend that:

- Additional support to firms should be made available through ECHA and national helpdesks in preparation of the 2\textsuperscript{nd} and the 3\textsuperscript{rd} registration periods in cooperation with the relevant industry associations.

- Priority should be given on the availability and effectiveness of the existing support tools and mechanisms and less on the development of new tools or guidance document that can possibly lead to confusing messages.

- While the majority of guidance documents are already available in all languages, gaps should be addressed whenever they exist.

- Ensure that ECHA is adequately supported with the resources and other relevant capacity necessary to ensure – to the extent possible – the quality and efficiency of the developed IT tools and all other services related to registration. A moratorium period for changes in guidance documents and IT tools should be adopted for a significant period prior to the registration deadline.

4. Expand the awareness raising and information provision tools. There are a large number of firms, especially among downstream users, that are not aware of REACH and its implications for them. Limited awareness is very often the cause of delays and additional work for firms especially in relation to supply chain communication. More specifically we proposed:
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• All efforts should be made in close cooperation with industry associations to increase awareness through additional communication campaigns at EU and national level.

• Given that SMEs are the main target audience, alternative networks with proven capacity to reach SMEs, such as the Enterprise Europe Network, could also be considered.

5. Strengthen and coordinate market surveillance and enforcement - Another key challenge for the coming period is to ensure effective and uniform market surveillance and enforcement across the EU. There is limited experience at this stage that could also lead to more specific recommendations, but the following points should be considered:

• Member States should ensure that the necessary resources from the relevant authorities are in place.

• Customs’ authorities should be brought more into the picture in those countries where they are not already properly involved.

• At the European level the existing coordination and information exchange tools (enforcement forum, enforcement projects, RIPE) could be utilised in full aiming for consistency in monitoring and inspection practices.

• The Commission and the Member States should seek to clarify as soon as possible the situation and requirements in relation to the notification requirement for SVHCs in articles aiming for a unified approach across the EU.

6. Continue monitoring of market and industry developments - This study has come at an early stage and cannot reach final conclusions on a number of aspects related to the competitiveness of industry or the operation of the single market. It is necessary to continue monitoring of the developments in the chemicals markets in a systematic way. More specifically:

• The Commission should consider an extension of the scope of the REACH baseline study conducted by Eurostat and include indicators covering key aspects of internal market operation and competitiveness. These indicators should primarily focus on those aspects most directly affected by the REACH Regulation (e.g. availability/withdrawal of substances, new substances and new uses development, costs of compliance). In case the extension of the baseline study is not considered appropriate a separate monitoring tool could be established.

• Additional studies in the coming periods both during and after the second registration should aim at increasing the understanding of the operation and implementation of other practical aspects of the Regulation. Particular focus should be on the way SMEs or specific sectors are affected by the Regulation or of the substitution costs involved in compliance with the Regulation.

• Support industry in the use of knowledge - The Commission could use existing programmes (e.g. CIP, Framework programme for research, LIFE) to support research and development activities aiming on the development and use of alternative chemical substances to replace substances of very high concern. Member States should also initiate or continue similar support schemes.