Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs

Final Report

Centre for
Strategy & Evaluation
Services

RPA
Risk & Policy Analysts

Ökopol
Institut für Ökologie und Politik GmbH

December – 2015

EUROPEAN COMMISSION

Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
Directorate D — Consumer, Environmental and Health Technologies
Unit D1 — REACH

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EUR [number] EN

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Luxembourg: Publications Office of the European Union, 2015

ISBN [number]
doi:[number]

Printed in [Country]

PRINTED ON ELEMENTAL CHLORINE-FREE BLEACHED PAPER (ECF)

PRINTED ON TOTALLY CHLORINE-FREE BLEACHED PAPER (TCF)

PRINTED ON RECYCLED PAPER

PRINTED ON PROCESS CHLORINE-FREE RECYCLED PAPER (PCF)

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EXECUTIVE SUMMARY

The overarching objective of this study on the **impacts of REACH on innovation, competitiveness and SMEs** is *to* ***evaluate changes to the operational conditions and the structure of the chemicals industry and downstream industries*** following the introduction of the REACH Regulation, focusing on the 2010 – 2013 period. The specific aims of the study are to:

- Identify, test and apply methodologies for evaluating the *coherence, efficiency, effectiveness, sustainability* and *impacts* of REACH in relation to the chemical industry and major downstream user sectors.
- Identify the *strengths and weaknesses* of REACH implementation with respect to *the conditions and structure of the market, consumer choice, compliance costs and administrative procedures and any other relevant indicators* identified during the course of the study.
- Provide *recommendations to remedy any weaknesses identified* in REACH implementation so as to minimise the possible adverse effects of REACH implementation and to maximise the impacts of specific REACH mechanisms that improve business conditions for economic operators.

The study does not include assessment of the impacts of REACH related to human safety, health and the environment. The requirement was to provide responses related to 12 specific objectives (below).

Methodology

The study consisted of an inception phase and four main tasks: developing the methodology, data mining and gathering, data analysis and conclusions, and reporting and presentation. After discussion of the proposed methodology at a workshop including internal and external stakeholders, a separate methodology report was submitted and approved.

The research tools used were: a computer aided telephone interview (CATI) business survey; an online business survey; an interview and survey programme with REACH stakeholders; in-depth interviews with selected firms; and, five thematic case studies. The scale and the scope of the research programme are summarised below.

- CATI survey with firms (CATI): 1076 responses covering all 15 Member States. Targets initially set were met with minor deviations. (38% large firms, 62% SMEs).
- Open-ended on-line business survey (OBS): 566 responses were received from all 28 EU, EEA as well as non-EU based firms (45.6% large, 54.4% SME – of those indicating size).
- Stakeholders interview/survey programme: 104 interviews with stakeholders was completed. The inputs from phone and face to face interviews and written responses were consolidated for analysis.
- In-depth interviews with firms: 56 interviews were completed including firms with different roles, sizes and countries of operation (57.1% large, 42.9% SME).
- Case studies: 5 studies were undertaken on topics agreed with the steering group.

The 12 individual objectives – main impacts

Single Market and harmonisation:

The majority of respondents (80-85%) reported no changes as regards imports or exports as result of the implementation of REACH. Some have reported increases and others decreases in imports from/ exports to other EU/ EEA countries but there is no significant trend discernible either way.

While more remains to be done, REACH has made a substantial contribution to the on-going harmonisation of European chemicals legislation and integration of the Single Market.

External competitiveness:

The majority of survey respondents (two thirds) identified no impacts as regards international competitiveness. Larger firms have tended to experience impacts more often than SMEs, and among those that have experienced an impact, the impact on manufacturers and importers has tended to be negative (due to increased prices related to costs of REACH compliance and increased transaction costs with non-EU suppliers that can't be recovered through higher prices). Article suppliers have experienced impacts as more positive.

The increased investment in supply chains by EU/ EEA companies, especially in countries outside the EU/EEA, in order to ensure REACH compliance means that it is generally more difficult to switch to other suppliers in the short term. Consequently, this reduces flexibility in supply chain choice for those EU/ EEA-based companies and may reduce their competitiveness.

Registration 2013:

Total registration costs for the 2998 phase-in substances registered in 2013 have been estimated as in the region of €459 million, which is within the range predicted by the Extended Impact Assessment (ExIA). Some 30% of survey respondents (OBS) have experience of substance withdrawals. Where withdrawals have occurred, the most typical response has been to switch suppliers or reformulate.

Business Opportunities:

A wide range of businesses has grown to provide REACH-related services to firms (e.g. inspection, testing, consulting, legal). These are additional costs to be borne by the industry. Some survey respondents report an increase of awareness among firms of products being REACH compliant which could lead to business advantages. Few potential business opportunities resulting from the implementation of REACH have been realised among survey respondents. More proactive risk management activities have been introduced.

SIEF and Registration Consortia

While SIEF and Consortia have operated successfully through the two registrations deadlines that have occurred so far, and rules are widely accepted, a significant share of firms still thinks that cost sharing is a problem. There are, in particular, issues surrounding cost for small and micro firms related to letters of access. Looking ahead to 2018, more capacity building will be required. A case study on cost-sharing in SIEF found that some conditions in the 2010 cost sharing rules are unfair and discriminatory.

SMEs

SMEs have been more acutely affected than large enterprises by the compliance costs and other issues related to the legislation, while few benefits have been perceived.

Concerns have been expressed about increases in the cost base of companies which may force smaller firms out of the market, or inhibit entry of new ones, and reduce the overall supplier base of the industry. Given the innovativeness of small and micro-firms, this could have longer term consequences for the EU chemicals industry.

Downstream Users (DUs)

An important share of DUs still remains unaware of their current/ impending REACH obligations. Communication throughout the supply chain has increased, but there are still important gaps in the information passed down, especially from formulators. Articles 7 and 33 of REACH regulation appear not to be well-implemented.

Innovation

There has been an increase in R&D activity for some 26% of companies surveyed (CATI), although in the OBS, only 10% indicated that their R&D budgets had increased. For nearly half of the companies sampled, R&D resources were transferred to compliance activities, and there was an increase in resources devoted to compliance.

Improved and increased communication in the supply chain provides for the *potential* of more innovation, business development opportunities and more efficient and effective supply chain management practices in the longer term.

Companies have revised their product portfolios – for example, withdrawing low volume low value substances and those at the end of their product cycle (economic criteria) and also those with an undesirable hazard profile. There has been a gradual increase in the use of product and process orientated research and development (PPORDs), although still mainly by German companies (39%) and increasingly by large firms (>80%). Time to market has been affected negatively for about a third of companies.

Concerns have been expressed about the potential lack of entry of new innovative mixtures, substances and low volume research substances into the EU from non-EU/ EEA sources due to REACH costs and the impact that this could have on EU industry in the long term.

The regulation has helped identify areas in which companies can focus longer term research and innovation efforts – the candidate list, PACT, CORAP list help provide guidance on development directions in this respect. Many interviewees from industry have expressed the view that over a long term, as a result of the directions for research indicated by REACH, they hope that a new approach to chemicals will develop that is safer and more environmentally friendly.

Human Resources and Consultants

The number of staff in companies involved in REACH compliance activities has increased slightly compared to the 2010 registration period, some employees having been reallocated from R&D activities. Most enterprises prefer to train existing staff on REACH compliance duties to recruiting from outside. Smaller firms tend to be more reliant on external training and external consultants. Availability of staff or consultants is not the issue- it is rather their costs and quality.

SVHC and Authorisation

More information on uses (and exposure scenarios) of Substances of Very High Concern (SVHCs) for which authorisation has been granted is now publicly available[1], additional substances have been identified as SVHCs and added to the candidate list, and 31 substances are currently in Annex XIV, for about half of which no applications for authorisation have been received.

The first authorisations have been processed and granted and more are in the pipeline. Costs of Authorisation have been estimated by ECHA to be in the region of €230k and declining as experience with the process is gained. The ability of SMEs to carry out authorisations remains to be tested.

Inclusion of substances on the PACT, CORAP, the candidate list and ultimately Annex XIV has led to significant levels of activity as regards substitution, withdrawal and replacement. Areas within Authorisation that the Commission is currently looking into are: low volume uses, legacy spare parts, substances subject to type-approval, and biological essential ingredients.

Support

While a strong support system has developed to help companies deal with REACH related-obligations, some tools to support the 2018 registration, in particular the standardised electronic (e)SDS, are still missing. Also, there is an issue with guidance for SMEs as the available support often does not correspond to the specific needs of the SME. A significant share of the industry, especially DUs is not yet aware of their REACH obligations and of those that are, a significant share has yet to start preparing for registration of 2018.

Registration 2018

Estimates of registration costs for 2018 for 1-10t substances appear to be in the range of the ExIA (€228m compared to the estimate of €295 million), but the total cost of registering 10-100t substances is estimated to be significantly higher than formerly estimated (up to €1,136 million as compared to €581million) if validation and acceptance of negative and positive QSARs and read across does not occur within the time frame first envisaged.

Overall assessments

Effectiveness

In assessing the effectiveness of enhancing competitiveness, the key dimensions of enterprise competitiveness comprise: costs; capacity to innovate; and, international competitiveness. REACH compliance costs would have a negative impact on competitiveness, and while some firms, especially larger ones, have the reserves and resources to absorb or pass on such costs, smaller firms do not always. The majority of firms saw no effect on international competitiveness within the EU/ EEA, while some two thirds saw their position vis à vis the non EU/ EEA as not affected either. It is mainly larger firms that operate internationally that saw an effect, and among those manufacturers and importers saw it predominantly as negative, while article suppliers

[1] http://echa.europa.eu/view-article/-/journal_content/title/notify-echa-of-your-uses-covered-by-a-reach-authorisation . The document is "List of Authorisation decisions by the European Commission"

saw effects more often as positive. As regards capacity to innovate, the regulation has led to an increased level of R&D, as well as replacement and substitution activity, which while qualifying as innovation in terms of the OECD/ European Commission (2005) definition[2], many firms are of the view that the activity is purely driven by the need to comply with legislation and has not led to an increase in competitiveness in terms of more and/ or higher quality products or services that better meet customers' preferences.

Overall, the evidence suggests a differential impact of REACH on different markets and participants. In terms of effectiveness as regards enhancing competitiveness and innovation, some have been affected negatively, others in a more positive manner. Given the diversity of the sector it is not realistic or meaningful to draw an overall conclusion that REACH has enhanced competitiveness for the sector and downstream users as a whole.

Efficiency

The study did not assess total costs (resources used) involved in the implementation of the Regulation. However, the study estimated Registration costs incurred by enterprises in 2013 to be in the order of €459 million, of a similar magnitude to those estimated for the ex ante impact assessment. The estimates for the 2018 registration suggest that registration costs for 1-10tpy substances will be similar to what was foreseen in the initial studies, but that registration costs for 10-100tpy substances are estimated to be potentially significantly higher than initially foreseen if no corrective action is taken, and there is no readily available or apparent way of reducing this cost. As regards human resources involved in implementing the regulation, the survey findings indicate that at enterprise level there was a gradual increase in FTEs employed for compliance in the period leading up to the 2013 registration.

Given the limitations on overall assessment of benefits to enhancing competitiveness and innovation on the one hand and the absence of data on the overall costs of the intervention, statistically robust statements about efficiency in terms of enhancing competitiveness and innovation are precluded.[3] However, there is a strong view in industry that the costs incurred for implementation have, for the present, delivered little in terms of enhanced competitiveness and innovation and that benefits of implementation, in as much as they exist, need to be sought in the wider health, safety and environmental benefits of the legislation.

Coherence

The fieldwork did not gather data on coherence, but REACH links with a wide range of EU legislation aimed at improving health, safety and the environment, both at enterprise level and in society as a whole. As such it is coherent with high-level community goals. However, as regards harmonisation and the single market, there is scope for improvement.

[2] See 3.8.1

[3] It has been noted that DG Environment has launched a separate study to assess the benefits of REACH in terms of health and the environment.

Sustainability

The REACH Regulation is implemented with a view to being an element of the EU/ EEA industry operating environment for the foreseeable future, while similar approaches are being put in place also in some non-EU/EEA countries.[4]

Impacts are dealt with under heading "12 Objectives" above.

Recommendations

The study made the following recommendations:

Studies

1. To carry out a study to determine what the key **legislation is that is holding up further harmonisation** in the EU chemicals markets and to develop an action plan to increase harmonisation.

2. To carry out a study to determine the full **costs of the REACH Regulation,** according to the approach set out in *Assessing the costs and benefits of Regulation* (CEPS and Economisti Associati). It is only once such a study has been carried out that it will be possible to assess the efficiency of the REACH Regulation, in terms of its environmental, health and safety benefits, as well as those pertaining to competitiveness and innovation. Such a study should pay particular attention to small and micro firms, and distinguish between different Member States.

3. A study should be carried out to determine whether there are **sub-sectors that are particularly vulnerable to REACH compliance** issues and to consider what can be done to support firms in those sectors and firms, particularly in the run-up to the 2018 registration.

4. While the current study has considered the position of SMEs as a group, it became increasingly clear throughout the study that within the category of SMEs, **small and micro firms** were particularly difficult to make contact with to determine their views and responses to the Regulation and its implementation. Where responses were obtained they were often quite at variance to those of other size categories. As these firms are the backbone of the EU economy, it is recommended that a study is addressed to determining the impacts of the regulation specifically on small and micro firms, and looking ahead at the 2018 registration, with due regard to differences between Member States in this respect.

Support

5. There are **several legal acts with requirements on (hazardous) substances**. Especially DUs often do not only have to comply with REACH but have to fulfil other product related laws. Therefore, a database should be developed that sets out the different provisions on a substance level (this demand was also formulated during the REACH review 2012 and has lately been renewed by some industry associations).

[4] Dg GROW has commissioned a study on the impacts of REACH and corresponding legislation in selected third countries, which will provide a more detailed analysis of these aspects.

6. **Many companies are still unaware** of their REACH roles and the obligations they have to meet. This is particularly true with a view to the 2018 registration. Member States' relevant government departments and the appropriate industry associations and other relevant networks and organisations need to develop innovative campaigns (e.g. working through the Enterprise Europe Network as in the case of Italy) to deal with this lack of awareness. This will be particularly an issue in countries without obligatory membership of industry associations. This recommendation also includes capacity building to deal with the needs of companies identified as new to REACH.

7. Some firms stated that the complexity of industry processes cannot be reflected with an adequate detail in many **guidance documents** as these tend to generalise. In such cases more tailored support instruments with input from and voluntary actions by industry organisations from the particular sectors need to be developed. Such instruments could cover: collection of best practice for specific situations; generation of more sector specific solutions; and, translation of documents into national languages as this is a major stumbling block for SMEs.

8. A pan-EU body should assess the development of certification (or equivalent qualification) for **a "REACH practitioner",** or inclusion of such a skill base in existing certifications for those dealing with chemical products (possibly along the lines of such a scheme as in Slovenia). Although it may not be possible to implement in time for the 2018 registration it could still serve a useful purpose subsequently as compliance with REACH obligations will be an on-going activity for the foreseeable future, and in particular small and micro firms need external support at affordable costs.

9. With regard to **registration in 2018, those firms who already want to start working through their SIEF** often have difficulties finding serious partners among those pre-registered to work with. A system needs to be developed whereby it is possible to identify firms in the SIEF that are serious about registration and are prepared to or want to take a more active role.

10. The Commission should assess what the **scope and impact is of SMEs having to pay substantial sums for Letters of Access** – well beyond what they consider affordable – and identify and investigate what the options are for dealing with the problem. This issue is important for the run-up to the 2018 registration.

11. **Dealing with (e)SDS remains a key issue**. Best practice and guidance targeting the development and supply of (e)SDS should be further developed.[5] As the "exposure scenario" is still very new to the market, specific guidance is needed to transform rather scientific risk assessment information into more practical information that can be used on-site. Special focus should also be given to SME dominated non-industrial sectors like e.g. the building sector. Representatives of such sectors should be involved in developments of tools and standards. The support currently being provided for supply chain communication through various industry organisations such as the DUCC in coordination with ECHA (ENES) is commendable and should be continued with and expanded.

12. Support activities at EU and Member State level should also be directed to the implementation of **substitution / alternatives assessment** to ensure that

[5] E.g. in the already existing ENES network http://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios

substance withdrawal and candidate listing / authorisation of SVHC can be compensated for in the supply chains.

13. A further action to support innovation would be to **evaluate the usefulness of PPORD** as an instrument and if needed, to see what can be done to widen its use beyond the current group.

14. **REACH-IT use, especially in SMEs**, is another area where support is required through industry associations and other innovative ways to reach companies currently out of the ambit of usual industry communication initiatives.

15. With a view to avoiding potentially significantly higher costs than were anticipated as regards registration of 10-100tpa substances, steps need to be taken to ensure that **negative and positive QSARs and read across** are validated and accepted within a sufficient time frame.

16. **SMEs, especially small and micro firms, should be more strongly represented in panels that are intended to develop REACH implementation instruments** (like CSR/ES) so that SME requirements are considered from the beginning (is the outcome applicable for a wide range of firms? Is the outcome only "high level" or are they tested by e.g. SME?). As it can be expected that resources are limited in this area, it should be considered to provide financial support for use of external experts.

17. The treatment of **imported articles that contain SVHCs** under the Regulation should be reviewed. Views of different participants in the chemicals market need to be obtained to understand what the impacts on them are and to assess the implications in terms of fairness and competition. If appropriate, amendments should be made to the legislation.

18. **Continue with improving co-ordination and harmonisation** between Member States' market surveillance and enforcement practices.

1 INTRODUCTION

This document contains the Final Report for the study on *Monitoring the impacts of REACH on innovation, competitiveness and SMEs.* The report was prepared by the Centre for Strategy & Evaluation Services (CSES) LLP and Risk & Policy Analysts Ltd. (RPA) with the contribution of Ökopol GmbH (Institut für Ökologie und Politik GmbH).

1.1 Aim of the Study

The overarching study objective is *to* ***evaluate changes to the operational conditions and the structure of the chemicals industry and downstream industries*** following the introduction of the REACH Regulation, focusing on the 2010 – 2013 period.

The specific aims of the study are, in summary, to:

- Identify, test and apply methodologies for evaluating the *coherence, efficiency, effectiveness, sustainability* and *impacts* of REACH in relation to the chemical industry and major downstream user sectors.
- Identify the *strengths and weaknesses* of REACH implementation with respect to *the conditions and structure of the market, consumer choice, compliance costs and administrative procedures and any other relevant indicators* identified during the course of the study.
- Provide *recommendations to remedy any weaknesses identified* in REACH implementation so as to minimise the possible adverse effects of REACH implementation and to maximise the impacts of specific REACH mechanisms that improve business conditions for economic operators.

1.2 Study objectives

The specifications identify a series of **individual objectives** that will be the subject of in-depth examination through this study. The specific objectives identified in the specifications are listed below:

1. Single Market and Harmonisation - to assess the degree of harmonisation achieved within the sector due to REACH. An attempt should be made to quantify to what extent the intra-EU trade increase for chemicals can be attributed to the existence of REACH. An estimate should be given of the number and proportion of companies (with a distinction of SMEs) who went outside of the domestic market as a result of harmonisation effects of REACH. The analysis should allow the determination of areas with greatest potential for further harmonisation benefits, as well as to identify available measures to increase the level of harmonisation.

2. External Competitiveness – *to determine the major mechanisms whereby REACH alters the position of the EU industry when exposed to the global markets*. An initial attempt to quantify the extent of the impacts of those mechanisms should be provided. Besides costs and other challenges, the analysis should also aim to describe examples, if any, of where REACH improved competitiveness of the EU chemicals sector (e.g. when new products or improved safety provided added value to EU traders).

3. Registration 2013 - *to quantify the costs of the registration exercise in 2013 - with more details regarding the specific categories of costs*. These categories should be established in a way to facilitate policy responses (for instance – costs of training, familiarisation and information, costs of financing, costs of legal support etc.). In addition, the availability (in terms of prices, quantities and supply stability) of substances which were expected to be registered in 2013 should be verified.

4. Business opportunities - *Analysis of examples that fostered better practices within companies (in particular SMEs) should be described and analysed*. Added value for companies acting in different roles within the supply chains brought in by REACH in terms better knowledge of hazards and risks of substances as well as their uses should be evaluated and described. The contractor should also search for examples of best practices and describe conditions in which these business opportunities are most likely to occur, with a view to facilitate design of appropriate policy measures.

5. SIEF & Registration Consortia – *to describe the pricing policies of the Substance Information Exchange Fora (SIEF), as well as to establish their affordability with regard to various types, sizes, sub-sectors, business models and geographic location of registrants*. This should be supported by an analysis of the structure of the SIEFs costs and of any additional costs incurred by lead registrants and member registrants. Focus should also be given on the transparency and communication practices within the SIEFs. The added value of consortia should be analysed, as well as the reasons for which opt-outs or 'double' registrations have been pursued by registrants. Best practices with regard to SIEF pricing policies, consortia agreements and communication should be catalogued.

6. SMEs – *to describe and assess all roles of SMEs in relation to REACH. Additional dimensions should also be brought in, such as the economic conditions in specific Member States.* The assessment should then conclude on *the major concerns in relation with the implementation of REACH and order them thematically according to the specific REACH related process to facilitate targeted policy response.* The analysis should also establish if SMEs have specific constraints in fulfilling these roles and if these are specific to the companies fitting into the SME definition (or SME sub-categories) or are of a more general nature.

7. Downstream Users ("DUs") – to establish and carry out an assessment of the major cost drivers for DUs of REACH compliance. Costs for major downstream sectors should be put into context with regard to how these affect profit margins and the overall costs for safety & environment protection as required by other EU and national legislation. Awareness and compliance costs estimations should be provided at EU and Member State and at a sectoral level. An assessment of any major concerns in relation to the implementation of REACH should be provided, structured thematically according to the specific REACH-related processes.

8. Innovation – *regulation can be a driver and constraint to innovation. Evidence of substitution mechanisms (e.g. Restrictions, Candidate List, Annex XIV, Authorisation conditions etc.) and intelligence gathered through registration and supply chain communication should be described along with potential economic impacts or benefits*. Where innovation was hindered, evidence should be gathered and analysed. Best practices should be identified and assessed from the perspective of relative abilities of SMEs in capitalisation on the new opportunities created by REACH.

9. Human Resources & Consultants – *to assess the availability of adequately qualified persons to deal with REACH at company level, including issues such as REACH jobs market saturation, level of skills as well as transparency and easiness of assessing the qualification and performance of consultants and/or internal staff.* In addition, specific constraints for SMEs for both acquiring highly qualified internal human capacities and/or adequately externalizing REACH processes to consultant services should be examined. The analysis should also take into account the offer of education programmes most appropriate to acquire the necessary skills as well as the practice of REACH professionals in documenting their skills and their trans-border recognition.

10. SVHC and Authorisations – as the first authorisation applications are being evaluated by ECHA and the Commission *the assessment should cover the costs of preparing an authorisation application and the availability of human resources with required competences*. The assessment should also conclude on the affordability of the authorisation process, especially for SMEs, taking into account the experience of the first authorisation consortia. Other areas of relevance, such as the effects of listing substances under SVHC RoadMap, the Candidate List, Annex XIV on the availability of substances on the market and the number of suppliers (concentration). With regard to Downstream Users, the assessment should cover direct and indirect costs of the application of Article 33.

11. Support – *to characterise and provide feedback on the available support and assistance instruments to the industry provided by ECHA, Member States and industry associations*. The analysis should provide feedback on the services most valued and demanded. It should allow providing a feedback to Member States and business organisations on the best practices and the areas for further investments. The feedback from SMEs should be considered as a priority.

12. Registration 2018 *–to update the estimates with regard to the costs of the 2018 registration deadline if no changes are made to the implementation of REACH*. The analysis should establish specific cost categories with the greatest scope for achieving cost-efficiencies, as well as suggest specific implementation measures to achieve them, while maintaining a high level of health and environmental protection.

1.3 Scope

The purpose of the REACH Regulation, as set out in the Regulation Chapter 1, Aim, scope and application, *Article 1 is as follows:*

Aim and scope,

1. The purpose of this Regulation is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation.[6]

This study focuses on the impacts on competitiveness and innovation, and also the circulation of substances in the single market in as much as it is relevant to competitiveness and innovation.

In addition, the study considers impacts on SMEs. As such, it does not consider issues relating to human health, the environment and alternative testing methods.

[6] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

1.4 Structure of the report

The remainder of the report is structured as follows:

- Section 2 sets out the methodology adopted for the study.
- Section 3 provides assessments of the twelve individual objectives.
- Section 4 presents a succinct assessment of the findings of the research findings with regard to twelve objectives.

Four Appendices (A-D) provide detailed data about interviewees and data underlying the SIEF Cost Sharing Model, comments regarding SMEs and the Monte Carlo simulation model.

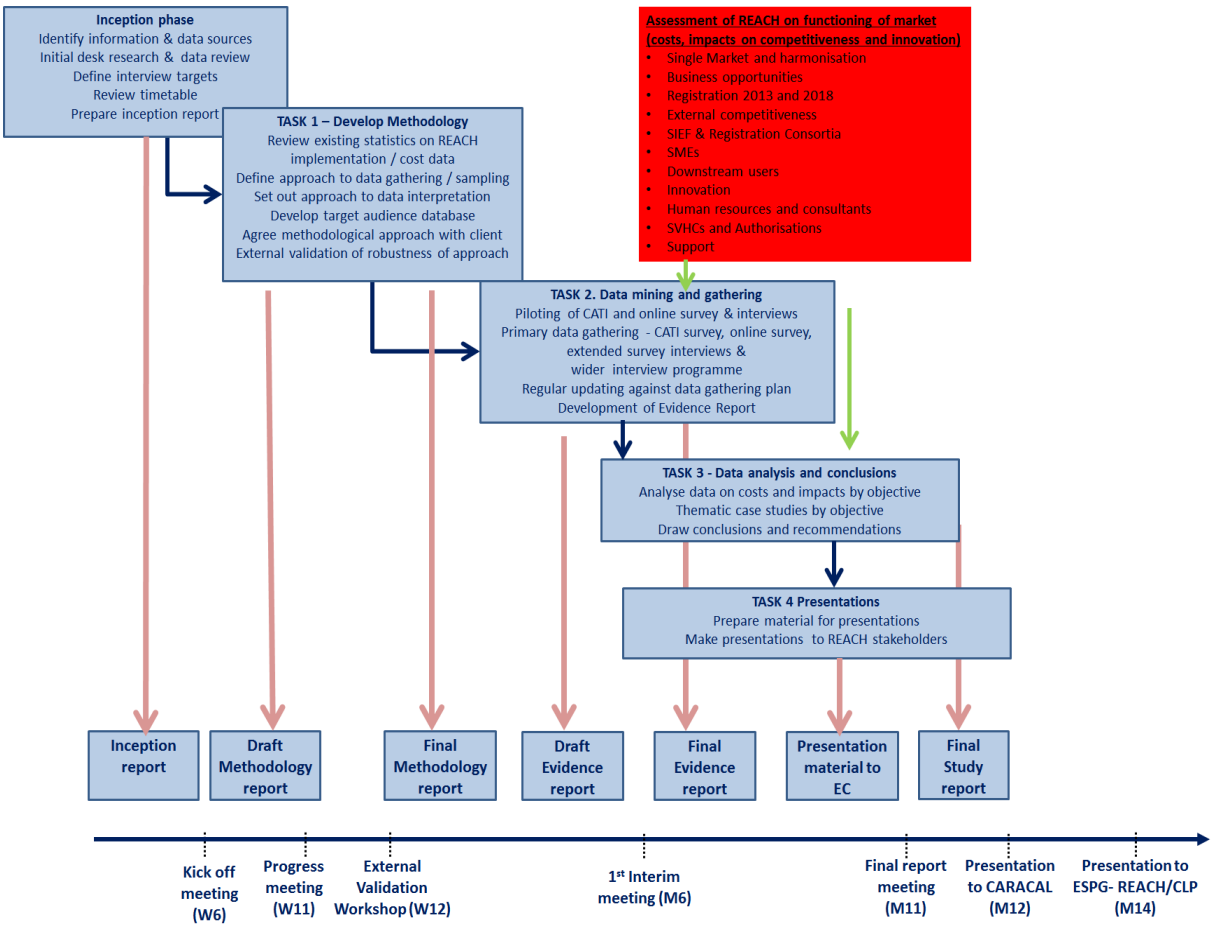
2 METHODOLOGY

This section sets out the key elements of the methodology adopted for the study. First the overall approach is presented then the individual research tools are discussed. More detail is provided in a separate Methodology Report.

2.1 The overall methodological approach

The methodology is structured around four Tasks, namely the preparation of a **Methodology Report** (Task 1), an **Evidence Report** (Task 2), a **Final (Study) Report** (Task 3) and the development of **Presentation Materials** (Task 4). An overview of the methodological framework is summarised in the following diagram:

Figure 2.1 Methodological approach



The methodology was discussed by participants of a workshop on the subject that included both Commission and external participants, and was subsequently agreed by the study Steering Group.

2.2 The research tools

In this sub-section the main data collection tools (as defined in the Methodology Report) and the results achieved with them are presented. An Evidence Report with more detail has been submitted as a separate document. The research tools are:

- A computer aided telephone interview (CATI) business survey
- An online business survey
- An interview and survey programme with REACH stakeholders
- In-depth interviews with selected firms
- Selected thematic case studies

The scale and scope of the tools used is summarised in the table below. While there were some deviations from the initial targets, the study team considers these to be minor and they do not affect the capacity to address the evaluation questions and the quality of the analysis.

The paragraphs that follow provide additional details.

Table 2.1 - Scale of data gathering activities and geographic coverage

Data collection tool	Target	Result
CATI survey with firms	Coverage: 15 EU Member States, Target: 1200 random survey responses from firms with quota set by size, REACH role and country	1076 responses achieved by March 20th covering all 15 Member States. Targets initially set were met with minor deviations
Open-ended on-line business survey (OBS)	Coverage: EU28 Member States Target: 1000+ responses from firms covering all REACH roles, firm sizes and Member States	A total of 566 responses had been received by March 20th. All 28 EU and EEA countries are represented as well as non-EU based firms.
Stakeholders interview/survey programme	Up to 80 interviews with REACH stakeholders (Member State authorities, REACH helpdesks, associations, NGOs, trade unions)	A total of 104 interviews with stakeholders was completed by March 30th. The inputs from phone and face to face interviews and responses in written have been brought together for analysis.
In-depth interviews with firms	50 in-depth interviews with firms	56 interviews were completed including firms with different roles, sizes and countries of operation
Case studies	5 case studies on selected topics	Topics were agreed based on discussions with the steering group.

2.2.1 CATI survey

For the Computer Aided Telephone Interviews (CATI) survey firms across Europe were contacted and asked to respond to a telephone survey (15-25 minutes). The survey covered 15 EU Member States, 8 of which account for more than 90% of EU chemical sales (DE, FR, IT, ES, UK, PL, NL and BE), as well as 7 Member States (AT, BG, CZ, HU, LT, RO, SE) that would ensure a good balance between new Member States and older Member States, countries with a small domestic chemicals manufacturing capacity, but where there is a significant presence of importers and DUs, among other considerations.

As can be seen in Table 2.2 there are some deviations from the initial targets set. Nonetheless, the sample largely met the targets in terms of overall sample size and distribution by firm size. 62% of the respondents are SMEs which in line with the initial target (60%) aiming to balance the higher number of SMEs and the fact that large firms account for a greater share of the European chemicals' production. The 1076 complete responses represented 8% of the total number of 13254 firms contacted.

Table 2.2 – CATI survey sample – proposed and actual distribution by size and REACH role

	Initial target			*Actual sample*		
REACH role	**Total**	**Large firms**	**SMEs***	**Total**	**Large firms**	**SMEs***
Manufacturers of substances	300	200	100	203	97	106
Formulators	250	50	200	251	75	176
Distributors/wholesalers/retailers of chemicals substances or mixtures	150	50	100	158	48	110
Importers of substances and mixtures	100	25	75	60	25	35
Suppliers of articles (Manufacturers/importers/distributors of articles)	250	100	150	251	100	151
End users (industrial or professional users)	150	50	100	153	64	89
Total sample	**1200**	**475**	**725**	**1076**	**409**	**667**
% by size threshold	100	40%	60%	100	38%	62%

One of the important methodological findings of the research was that individual companies usually have several REACH roles. It is important to bear this in mind when assessing the implications of the findings (see tables 2.3 and 2.7).

Table 2.3 CATI survey sample: secondary roles

Other role / Primary role	Manufacturer	Formulator	Distributor	Importer of chemicals	Supplier of articles	End user	Total
Manufacturer	0%	54%	50%	57%	20%	42%	203
Formulator	47%	0%	44%	35%	24%	33%	251
Distributor	8%	27%	0%	30%	20%	23%	158
Importer	11%	17%	25%	0%	77%	41%	251
Supplier of articles	5%	7%	2%	8%	0%	84%	153
End user	17%	23%	35%	65%	35%	0%	60

Within the SME category, there is a greater share of medium size firms in almost all categories, but with the exception of end users and importers, all categories have at least 10 representatives.

Table 2.4 – CATI survey sample – Number of micro, small and medium enterprises by role

	Manufacturers	Formulators	Distributors	Importers	Suppliers of articles	End users	All firms
Micro	10	21	26	6	16	5	84
Small	30	53	48	10	35	12	188
Medium	63	94	32	17	95	72	373
No data	3	8	4	2	5		22
Total SMEs	106	176	110	35	151	89	667

In terms of the **second-level criteria** (country and sector distribution) the survey sample (table 2.5) reflects the dominant share of a few countries within the chemicals industry while also taking into account countries with smaller shares. In certain countries (in particular Hungary and Lithuania) it proved particularly difficult to reach the initial targets. But overall, the sample size achieved by country allows for a minimum level of statistically meaningful results.

Table 2.5 - CATI interview numbers by Member States

Country where firm is established	Initial target	Actual number of responses	Share in the sample
Austria	60	53	4.9%
Belgium	80	70	6.5%
Bulgaria	60	49	4.6%
Czech Republic	60	52	4.8%
France	100	105	9.8%
Germany	120	127	11.8%
Hungary	**60**	**33**	3.1%
Italy	120	128	11.9%
Lithuania	**50**	**25**	2.3%
Netherlands	80	58	5.4%
Poland	80	72	6.7%
Romania	50	50	4.6%
Spain	100	91	8.5%
Sweden	60	56	5.2%
United Kingdom	120	107	9.9%
Total		1076	100.0%

As regards the sectors covered the sample includes a large number of firms from the five main segments of the chemical sector whose roles are, typically, those of manufacturers, formulators or, in fewer cases, importers. In total, they represent around 41% of the sample. Within this group the specialty chemicals' sectors (dyes and pigments, paints and inks, auxiliaries for industry and crop protection) may be overrepresented. The sample also includes firms in primary metal industry (mainly manufacturers) and the pharmaceutical sector (manufacturers/formulators).

As far as importers and distributors of chemicals are concerned, 86 firms (8% of the sample) specialising in the wholesale trade of chemical products predominantly stated that their primary role was that of distributor of chemicals. In total, the chemicals and related sectors represent 53% of the sample.

Beyond the chemicals and chemicals-related sectors, downstream user sectors represent 47% of the sample. They include a significant number of firms in key industry sectors (electric & electronic devices, textiles, industrial machinery, fabricated metal products, construction) who indicated that their primary REACH roles are article suppliers or end users. The transportation/automotive sector is also covered although with relatively few firms. In addition, there is a broad range of services covered with firms typically referring to the end user role. In total, the wide range of downstream user sectors covered reflects the very wide use of chemicals across the whole of the EU economy.

2.2.2 The on-line business survey

An on-line business survey (OBS) was used to provide feedback and data covering a wider number of issues than is possible through the use of a time-limited CATI survey. The online survey was launched at the beginning of February 2015 following piloting with 5 enterprises. It was disseminated via multiple channels, including European and national industry associations (including the associations that were present at the methodology workshop) and other media (such as the online publication Chemical Watch[7]). It was made available in eight languages (EN, DE, IT, FR, CZ, PL, ES, RO) and was formally launched on February 9th.

The tables below summarize the breakdown of the 566 responses received by March 25th 2015 indicating the distribution by primary REACH role (as indicated by the respondent), firm size and country of operation of the respondent. A number of respondents indicated more than one country of establishment on the basis that they are multinational firms with multiple units of operation, inside and often outside the EU.

The survey sample covers all REACH roles with a satisfactory level to support findings on general trends and views even if the level of confidence – from a statistical point of view – was not as high as we hoped it would be. Particularly in the case of distributors or article suppliers the number of responses is quite small despite the efforts of the team to promote the survey to relevant targets.

Table 2.6 Responses to the business survey by primary role and firm size

Stated primary role	Large	SMEs	Not indicated	All firms
Manufacturers of chemicals	87	67	42	196
Importers of chemicals	13	44	15	72
Formulator	22	53	16	91
Distributors of chemicals	6	36	4	46
Suppliers of articles	22	14	10	46
End users	56	32	27	115
Total	206	246	114	566

As in the case of the CATI survey companies tended to have several REACH roles in addition to their primary role as indicated in the survey response.

[7] https://chemicalwatch.com/22905/eu-commission-launches-major-reach-impacts-study

Table 2.7 OBS sample – other roles

Other role / Primary role	Man of chemicals	Formulator	Distributor	Importer of chemicals	Supplier of articles	End user	Total
Man of chemicals		37%	24%	58%	8%	41%	196
Formulator	31%		18%	34%	8%	91%	91
Distributor	7%	24%		63%	7%	46%	46
Importer of chemicals	18%	28%	32%		7%	72%	72
Supplier of articles	2%	11%	20%	17%		46%	46
End user	9%	15%	10%	19%	20%		115

In terms of country coverage[8], firms with establishments in the Member States with a high share in chemicals manufacturing (Germany, Italy, France and the UK) represent more than half of the sample. There is also an important share of firms that stated that they were multinational in nature and their responses reflected the overall group of firms. Spain, the Netherlands, Belgium, Czech Republic and Poland are relatively well represented, with more than 30 responses each. Smaller EU countries, which generally have a minor share in the manufacturing sector, are represented by a few (<15) firms.

The very broad nature of the respondents – in terms of firm type (independent firm, division) and its role within a broader enterprise group is also highlighted in tables 2.8 and 2.9 below. While the majority were SMEs operating in a single-site and in one country, there were also respondents that were divisions of multi-site firms, primarily firms with EU-based headquarters but also firms with headquarters outside the EU.

Table 2.8 – Distribution of on-line survey respondents by nature of firm (single size, division) and size

Type of firm	Large	SMEs	Not indicated	All firms
Single-site independent firm based in the EU	42	143	4	189
Division of an EU-based firm with sites in more than one country within and/or outside the EU	95	47	2	144
EU based division of a large multi-national firm with headquarters outside the EU	36	16	1	53
Division of a multi-site firm based in only one EU country	16	22	1	39
A single-site independent firm based outside the EU	1	4	1	6
Other	15	11		26
No answer	1	3	105	109
Total	206	246	114	566

Finally, the responses came from units with various functions within firms, providing an indication of the very different ways that firms organise their compliance with the REACH Regulation. Units with functions related to Health, Safety and Environment (HSE) were

[8] Respondents were given the choice to indicate more than country and this was the case with 76 respondents that indicated 2 or more countries.

the most typical, followed by Regulatory compliance units, dedicated REACH units and R&D units. Among the large number of firms that indicated "Other", most are manufacturing/production units but there is also a large number which could be classified under HSE.

Table 2.9 – Distribution of on-line survey respondents: function of firm (single size, division), size

Function of unit	Large	SMEs	Not indicated	All firms
Health, Safety and Environment unit	73	48		121
Regulatory Compliance unit	31	42		73
Dedicated REACH unit	36	30	1	67
Research and Development unit	21	35	1	57
Marketing Unit	4	15		19
Other	38	73	3	114
No answer	3	3	109	115
Total	206	246	114	566

Table 2.10 summarises the responses by firm size of the CATI and OBS.

Table 2.10: Size of the firms responding to the CATI and business survey

	CATI survey		Online business survey	
Firm size	**n**	%	n	%
Micro	95	8.8	28	4.9
Small	214	19.9	82	14.5
Medium	337	31.3	136	24.1
SMEs (not defined)	21	2.0	-	-
SMEs total	*667*	*62.0*	*246*	*43.5*
Large	*409*	*38.0*	*206*	*36.4*
Not indicated			*114*	*20.1*
Total	1076	100.0	566	100.0

Source: CATI survey& Online business survey

Table 2.10 reflects that while the overall shares achieved as regards SME responses are satisfactory, within the category of SMEs the largest share of responses was for medium-sized firms, with less for small and micro-firms. While this might reflect that fewer small and micro enterprises have come into contact with REACH at this stage, it does also highlight the challenges involved in obtaining feedback from small and micro firms.

2.2.3 The stakeholder interview programme

In parallel with the survey 104 interviews were conducted with stakeholders from the following groups:

- Commission officials
- ECHA
- European and national industry associations and national cluster organisations
- Member State enforcement authorities and national REACH helpdesks
- Environmental and consumer groups and trade unions

In a number of occasions, the stakeholders indicated their preference to submit their input in written format and, in some countries, the national competent authorities and the REACH helpdesk provided a joint response. The table below summarizes the number of interviews completed. The detailed list of interviews completed is provided in Appendix A.

Table 2.11 Stakeholder interviews

Type of stakeholder	Face-to-Face/Telephone interviews	Written responses	All
EU Commission	4	0	4
ECHA	4	0	4
EU-wide industry associations	18	8	26
National industry associations	19	11	30
National Authorities[9]	13	13	26
REACH Help Desks	3	5	8
Environmental groups/NGOs, trade unions and consumer organisations	6	0	6
Total	**67**	**37**	**104**

2.2.4 In-depth interviews with firms

56 in-depth interviews were completed (see table 2.12 below[10]) with firms with diverse roles and sizes and in various countries. The objective was to obtain more detailed data than was available from the surveys.

Table 2.12: In-depth firm interviews by role and size

	SME	Large	All firms
Manufactures of chemicals	5	15	20
Importers of chemicals	5	-	5
Formulators	6	5	11
Distributors/retailers	4	1	5
Suppliers of articles	3	8	11
End users	1	3	4
Total	24	32	56

In terms of geographical distribution, the survey covered a broad range of countries. A number of firms – mainly those located in Germany – identified themselves as multi-national firms.

[9] In some cases, national authorities and national REACH helpdesks provided a single joint answer.
[10] The detailed list of respondents is identified in Appendix A. The names of the firms are confidential.

2.2.5 Case studies

Case study topics were selected from a list put forward and subsequently discussed and amended and agreed with the Steering Group. Topics selected are listed below and the case studies are inserted at the relevant sub-sections in the study.

- REACH Compliance Costs in the 2013 Registration period
- Business impacts of withdrawals
- Business opportunities through improved supply chain communication
- SIEF agreements and registration cost
- The Public Activities Coordination Tool (PACT)

3 FINDINGS

In section 3 the findings by individual objective are presented. These are based on the data provided in the Evidence Report, as well as additional qualitative evidence and interviews carried out subsequently.

3.1 Objective 1 - Single Market and Harmonisation

3.1.1 Introduction

The aims of this section on the Single Market and harmonisation are to: assess the degree of harmonisation achieved within the sector due to REACH; attempt to quantify to what extent the intra-EU trade increase for chemicals can be attributed to the existence of REACH; estimate the number and proportion of companies (with a distinction of SMEs) who went outside of the domestic market as a result of harmonisation effects of REACH; and, identify areas with greatest potential for further harmonisation benefits, as well as measures to increase the level of harmonisation. These matters are discussed in turn below.

3.1.2 The degree of harmonisation in the chemicals sector due to REACH

The sectoral composition of the EU chemicals market is set out in table 3.1.1 below. Chart 3.1.1 sets out the customer base of the chemical industry. The **size and the complexity** of the EU chemicals industry apparent from these two exhibits is reflected in the amount of legislation operative in the sector.

Table 3.1.1 Composition of the EU chemicals sector (sales in billion)

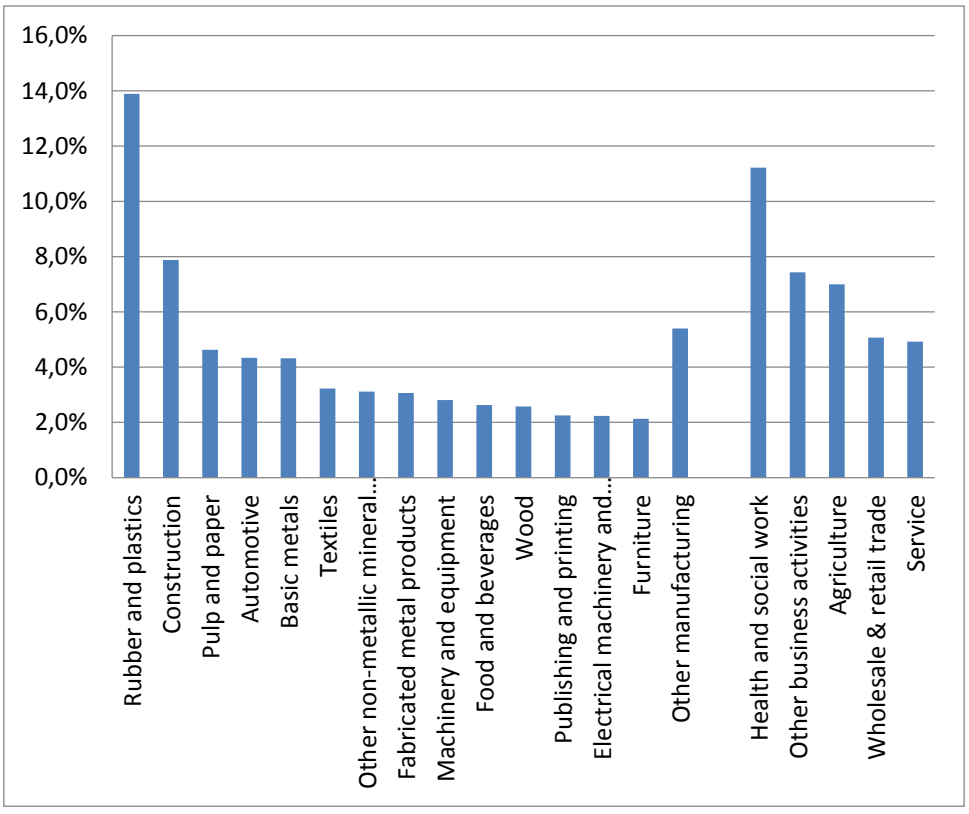
Weight	Chemical sub-sectors	€ billion
26.6%	**Petrochemicals**	**140.0**
13.7%	**Basic Inorganics**	**72.0**
6.1%	Other inorganics	32.2
2.7%	Industrial gases	14.2
4.9%	Fertilizers	25.6
21.5%	**Polymers**	**113.4**
19.0%	Plastics	100.1
1.0%	Synthetic rubber	5.1
1.6%	Man-made fibres	8.2
26.5%	**Specialty chemicals**	**139.7**
2.5%	Dyes & pigments	13.3
1.9%	Crop protection	9.8
7.8%	Paints & inks	41.0

Weight	Chemical sub-sectors	€ billion
14.3%	Auxiliaries for industry	75.6
11.7%	**Consumer chemicals**	**61.8**
100.0%	**Chemicals excluding pharmaceuticals**	**526.9**

Source: *Cefic, Chemdata International (2014)*

Legislation present in the sector includes: the REACH Regulation and its subsequent amendments; the Regulation on Biocidal Products and amendments; the Fuels Quality Directive; the Biofuel Directive; the Industrial Emissions Directive; safety standards related to ionising radiation; the Regulation on Classification, Labelling and Packaging of substances and mixtures (and amendments); dangerous substances; dangerous mixtures; the directive(s) on cosmetic products; legislation on waste, the environment, transport, health and safety, working time, etc. It is understood that a separate study is under way to assess the cumulative costs of legislation on the chemical industry.

Chart 3.1.1 Percentage of output of chemical production consumed by customer sector



Sources: *European Commission, Eurostat data (Input-Output, 2000)*

Given this size and complexity, and the many types of enterprises active in the EU and the EEA, it is not surprising that a wide range of views has been expressed amongst those consulted and surveyed regarding the extent of harmonisation in the EU chemicals market that could be attributed to the REACH Regulation.

According to some **industry representatives**, their sector (e.g. the refining sector) had already been quite highly harmonised before REACH was enacted, and REACH has not added a great deal to that. Other sector organisations pointed out that there are still important areas of REACH lacking in harmonisation with other legislation – for example with RoHS, cosmetics and biocides – and that there has been little change since 2012. While some associations pointed out that the promulgation of the legislation as a regulation (rather than a directive) in principle encourages harmonisation, several also pointed out that interpretation (e.g. "articles") varies across Member States, and there are differences in implementation, where practices and interpretations differ between and even within MS. On the other hand, several national industry associations were very positive about the harmonisation effects of REACH. For example, dealing with one authority to register chemical substances rather than 28 is often considered a positive factor for the industry. Also, the fact that 28 national legislatures are not issuing separate pieces of legislation related to chemicals but have for some time been working at a central EU level increases harmonisation throughout the EU.

When **companies** agreed that REACH brought increased harmonisation, they often, if they operate across EU borders, at the same time pointed out that differences between Member States existed that work against harmonisation. As one medium-sized formulator put it, "REACH in combination with CLP has not been adopted in a consistent manner across the EU. That makes it difficult to ensure that local rules are followed" (OBS).

Based on the feedback obtained from the wide range of stakeholders consulted, it would be fair to say that the REACH Regulation has made an important contribution to increased harmonisation in the sector overall, not only in terms of the legislation itself, but also through the provision of fora at which EU and EEA chemical legislation can be discussed. It also provides a framework through which to work towards increased harmonisation in the future. However, at the same time, bringing REACH into existence also brought things out into the open and added factors that had not been present previously. This has created new complexity in the market, for example as regards interpretation, implementation and surveillance, and thus increased the challenge of achieving increased harmonisation.

3.1.3 Increases in intra-EU trade in chemicals attributable to harmonisation effects of REACH.

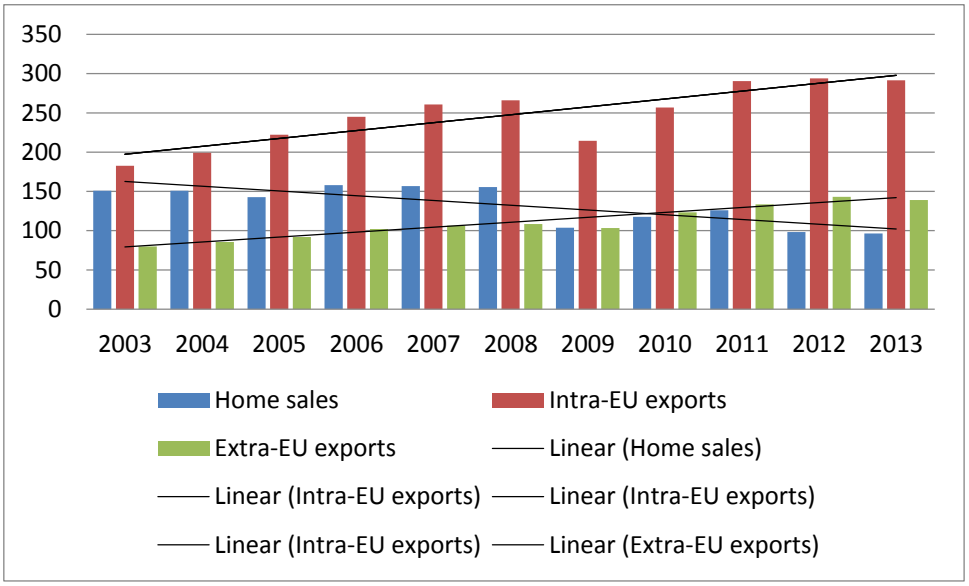
Trade flows between Member States in the chemicals sector are complex and involve a wide range of products, substances, and mixtures transacted between multinational enterprises, between different units within multinational firms (intra-firm trade), and single country-based firms. Most chemicals trade is of a "derived" nature - it is reliant upon demand for inputs to intermediate goods or final products.

Total EU chemical sales were worth €527 billion in 2013. Intra-EU sales (marked as "Intra-EU exports" on the chart) increased from €183 billion in 2003 to €292 billion in 2013 – a 60 per cent increase during the last 10 years. Intra-EU trade did contract slightly in 2013 (the latest year for which data are available) - the first time in five years.

The bar chart below (and linear trend line) shows that there was growth in the share of intra EU trade in chemicals after 2004, which was interrupted by the recession in 2009 and 2010. As a percentage of overall sales, intra-EU exports grew from 44% in 2004 to 55% in 2012 and 2013. According to a Cefic report[11]: "Removing both trade and non-trade barriers inside the European Union helped boost growth and competitiveness in the EU chemical industry between 2003 and 2013", while "The accession of new EU Member States in 2004 and 2007 gave the internal market an extra boost for intra-EU trade"[12].

The **Member State Competent Authorities and Helpdesks** interviewed indicated that they were not aware of any data suggesting that the gradual long term increase in intra-EU exports could be attributed to the effect of the REACH Regulation. **Industry representatives** either said that they were not aware of such increases, or there were no effects. However, one association commented that they thought that trade between EU manufacturers had increased because it was easier to buy from other REACH compliant suppliers based in the EU than from suppliers outside the EU; and another said they thought that more EU-based formulators would buy from EU-based suppliers because many non-EU based formulators do not want to incur the costs (e.g. registration) of supplying the EU market, leaving more scope for EU-based suppliers.

Chart 3.1.2 Shares of EU trade in chemicals 2003-13 (€ bn)



Source: *Cefic, Chemdata International (Cefic, 2014, p.11)*

A wide range of factors other than (or in addition to) REACH might be responsible for the increased level of intra-EU trade, in addition to the increased number of countries in the EU. For example, it is possible that shifts in levels of chemical production between Member States may have contributed to this. Thus, between 2009 and 2013 Germany's share of chemical sales in the EU increased from 25.5% to 28.4%, Ireland's declined from 6% to 0.9% and the UK share fell from 9.7% to 6.8%. Such shifts in production could have knock-on effects in terms of where the users are based which might lead to increased intra-EU exports. This might also be related to increasing concentration

[11] The European Chemicals Industry, Facts and Figures 2014, p.11.
[12] 10 countries that joined in 2004 are the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovakia and Slovenia. In 2007 Bulgaria and Romania joined.

(consolidation) of production in fewer plants, which could be related to the recession (or even, partly due to the REACH Regulation). An in-depth analysis of all the causes underlying increased intra-EU trade is outside the scope of this study. However, feedback at firm level was obtained as regards the effects of harmonisation.

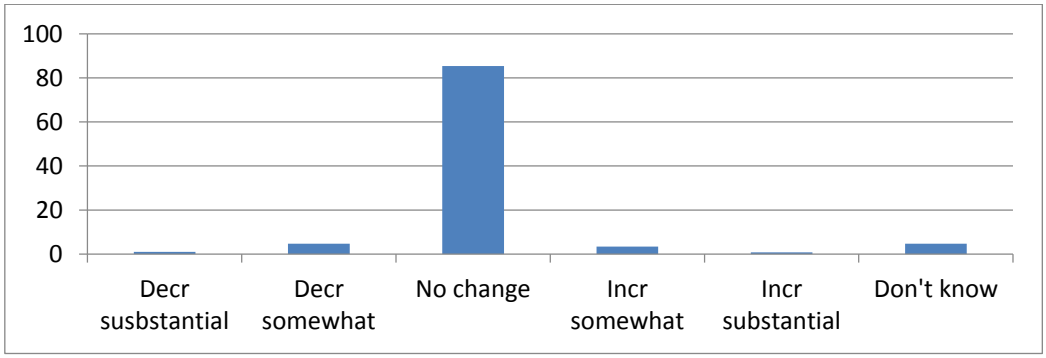
Exports and imports

As regards quantifying the extent to which intra-EU trade has been affected by REACH, the CATI and OBS respondents were asked what they thought the effects were on exports and imports.

- **Exports**

On the whole, the great majority of firms (85.4%) did not identify any changes to exports within the EEA that could be attributed to the introduction of the REACH Regulation. Some 4.2% of CATI respondents saw a positive impact, while 5.7% suggested that REACH has had a negative impact. This applies across the board, independent of the firm's size, its export orientation or its country of operation. Examples of reasons for a positive impact (increased exports) identified in the course of the in-depth interviews include an increase resulting from businesses buying in the EU that used to buy from outside the EU no longer doing so because those non-EU suppliers did not want incur REACH registration costs; and, in the case of some East European manufacturers finding it easier to supply established West European markets because their products are REACH compliant. The main reason mentioned for reductions in trade was cost increases that could not be recovered through higher prices and withdrawal of substances (due to, for example, authorisation).

Chart 3.1.3 Have your exports to EEA countries changed as a result of the REACH Regulation? (%)



Source: CATI

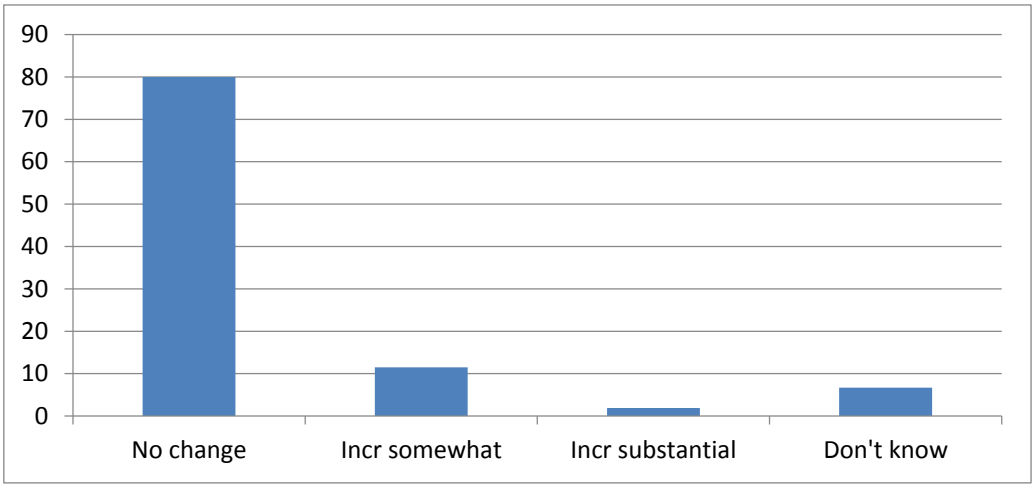
In terms of REACH roles, manufacturers reported a *slight decrease* in exports as a result of REACH (9.8% of the 133 responses), as did 5.9% of distributors (68 respondents). Importers saw a *slight increase* in their exports (6.6% of 31 responses).

- **Imports**

As regards the level of imports of substances/mixtures or articles from within the EEA, 80% of firms indicated *no increase* attributable to REACH while 13.4% indicated that there was an increase[13].

[13] It was not asked if there was a negative effect.

Chart 3.1.4 Have your imports of chemical substances/ mixtures/ articles from elsewhere in the EEA increased because they are REACH compliant? (%)



Source: CATI

Some companies reported switching suppliers from non-EU to REACH-compliant EU-based sources. Changes were quite evenly spread among all REACH roles, but with relatively high increases for formulators and distributors. The overall share of reported increases in imports from the EEA is significantly higher than the share of those showing increased exports to the EEA. The OBS survey results were generally similar to those of the CATI.

The actual processes underlying these numbers are complex and the result of market relationships that have developed over many years as the chemical industry has evolved. For example, one instance of "growth in intra-EU trade" that was mentioned is the case of a small firm in one Member State that is one of two manufacturers of a substance in the EU, the other manufacturer being based in a different Member State. The two manufacturers have up to recently competed but registration cost for the substance does not justify two registrations so they have agreed between them that only one (producing much higher volume of the substance than the other) will register (the other will contribute to registration costs) and manufacture and will supply the other who will continue to market the substance under its own brand name. This will be registered as an increase in intra-EU trade (exports and imports), and is attributable to REACH. Both companies will continue to supply their distributors as before.

Several companies (distributors, suppliers of articles) also indicated in the course of the interview programme that they have switched from non-EU to EU suppliers where possible to avoid the registration issue when dealing with non-EU suppliers. Dealing with non-EU suppliers through ORs also increases transaction costs. Companies think that the 2018 registration will further drive the decision to buy within the EU if the substances are available.

When comparing the effects of the implementation of REACH on businesses in terms of trade inside the EU, there is a marked difference in response between SMEs and large firms (OBS) as regards the effect on exports due to price increases related to REACH, and in particular as regards micro firms (bearing in mind the caveats as regards the shares or micro and small firm respondents – see table 2.10). On the one hand, nearly half of micro firms and a sixth of small firms said they had *decreased* exports to elsewhere in the EU due to REACH-related price increases (compared to 6.3% of large firms); and just over a third of micro firms said they had decreased imports from other EU countries because of REACH - related cost increases compared to 9.2% of large firms.

On the other hand, 10.7% of micro firms *increased* imports from elsewhere in the EU because they know that the products are REACH compliant.

So while overall the data suggest there is not a great deal of change, the more detailed picture of what is happening where there is change at enterprise-level is complex. SMEs report higher decreases in exports and imports from other EU countries due to cost increases associated with REACH, but also increased imports from elsewhere in the EU due to knowing that the products were REACH compliant.

3.1.4 Intra-EU internationalisation of companies as a result of harmonisation effects of REACH.

Where there has been increased harmonisation in the chemicals market as a result of REACH, the question arises as to whether this has led to new opportunities for firms and in particular if it might have prompted non-exporters to export for the first time.

According to the CATI survey responses, *a quarter* thought that the increased harmonisation of the EU chemicals' legislation due to REACH has led to new opportunities, although most (71.9%) did not think so. There are no differences identified depending on firms' size, but there were wide divergences between countries in this respect. For example 60% of respondent firms in Romania agreed[14], as did 40% in Lithuania and 38% in Poland, compared to 14% in Germany and 13% in the UK.

Some 14.5% of respondents to the OBS see new business opportunities as a result of the harmonization of the EU chemicals' legislation, while two thirds disagreed that this was the case.

In order to understand better what respondents to the CATI and the OBS meant when they said they thought there were "new business opportunities" as a result of harmonisation brought about by the REACH Regulation, a follow-up survey was conducted with 85 CATI and OBS respondents that had indicated that they would be happy to contribute to follow-up enquiries. 28 responses were received. Of these, 26 indicated that they could not report any concrete business opportunities or innovations that had emerged *as a result of harmonisation* as yet. Two identified specific business opportunities that had emerged which they had exploited. These were:

- Development of a software programme that could be used for dealing with SDS (pan-EU market).
- Harmonisation of legislation meant that materials previously considered as waste were now considered as products and meant it was easier to import such materials and cross-border business was easier to carry out (cleaning of final slags of lead).

In the course of the in-depth interviews one company based in Eastern Europe said that harmonisation as a result of REACH and CLP made it easier for them to sell into Western European markets. However, one large formulator said: "REACH has increased harmonisation but has not led to new business opportunities. In fact, the increased costs have probably reduced business opportunities". A micro distributor said "It has prevented us continuing with a long established business because the [third country suppliers] did not honour their obligation to register under REACH and the cost of purchasing letters of access for that made it too expensive for us to register ourselves" (OBS).

[14] Firms indicating "Yes, somewhat" or "Yes, substantially".

As regards **companies starting to carry out cross-border operations** as a result of the harmonisation effects of REACH, the survey feedback provides some insight into the related underlying tendencies. 13% of the CATI survey respondents indicated that they are selling only to the domestic market (100% of turnover). These firms did not point to any changes as a result of REACH, although a quarter of them thought that REACH harmonisation presented opportunities. Being mainly micro and small firms and most often distributors, end users and article suppliers, they seem not to be much affected – at least in terms of their market focus – by the REACH Regulation.

Among firms with some exports, but where the domestic market still represented over 80% of sales, 2.2% saw increased exports to EEA countries as a result of the introduction of REACH.

The OBS also shed some light on the extent to which firms with a focus on domestic markets were given an incentive to export. Among firms which indicated a certain level of exports – but still with a domestic market representing over 80% of sales – the large majority (88%) indicated no change to their exports to the EEA as a result of REACH. 9.5% considered that REACH provided business opportunities.

Table 3.1.2 The role of REACH in promoting exporting for firms with a strong focus on domestic markets (>80% of total annual sales)

Statement	Source	Total number of firms with focus on domestic markets	Percentage of firms indicating
REACH has increased the harmonisation of the EU chemicals legislation, leading to the opening of new opportunities for our business in the EU (agree or strongly agree)	CATI survey	334	24.2%
	OBS	42	9.5%
Exports to other European Economic Area countries changed as a result of the introduction of REACH: increased slightly/ significantly	CATI survey	179	2.2%
	OBS	42	0%
Opening of new markets for your products within the EU (positive or very positive impact)	OBS	42	0%

Source: CATI/OBS

It is not fully clear why there is such a large difference between the two surveys in terms of opening new business opportunities. Respondents to the OBS tended to have had more previous knowledge of working with the Regulation than those responding to the CATI, which might have had an influence on their expectations. The data point to a limited role of REACH in promoting exports among firms focusing on domestic markets.

This situation has not changed greatly in comparison with the findings of the 2012 Report where some 60% of respondents indicated that REACH was not considered relevant in entering new EU markets (p. vi) and 3% indicated that REACH had played a role in entering new EU markets (p.73), although some more said it might do so in the future[15].

3.1.5 Areas with the greatest potential for further harmonisation benefits, and measures to increase the level of harmonisation.

A critical success factor for the operation of a harmonised single market for chemicals is the consistent implementation and enforcement of the legislation and market surveillance. Among the CATI survey respondents, 22.3% stated that they thought that there is currently a level playing field for firms, while 60.1% said that it is uneven situation, either overall or in a few specific respects. End users appear to be more supportive of the view that there is a level playing field, compared to formulators and manufacturers. However, it is important to note that end users have rather limited actual experience of the enforcement of REACH. At the same time, there is no variation depending on size or export orientation.

Just over half of respondents to the OBS agreed that the variation in the level of enforcement of REACH across the EU has a negative impact on the operation of the single market, particularly in the case of distributors and importers, although the view is widely held among all the REACH roles.

Increasing harmonisation in implementation of the regulation at Member State level in terms of market surveillance and enforcement was considered the most important issue to tackle by the stakeholders consulted.

The need for further efforts to make market surveillance and enforcement more effective was indicated in the responses of a number of **industry representatives** during the interviews. About a third of industry representatives suggested that current level of enforcement to ensure compliance with the REACH Regulation was effective, a fifth that it was neutral and a third that it was ineffective (the remainder did not know). The main reasons for less than effective enforcement were identified as the different approaches followed by Member States' enforcement authorities in terms of inspections (more or less active) and the relative resources (quantity and quality) allocated to ensuring REACH compliance.

Member States Competent Authorities and REACH helpdesks agreed that market surveillance issues are the ones most frequently raised by firms in their countries. Other issues often raised by firms are related to imports from other EU countries.

MS authorities identified the following as the key areas to address to increase harmonisation:

- Issues surrounding languages (e.g. translations of SDS/ Exposure Scenarios).
- Lack of resources for staff, staff training and retention.
- Collaboration between different government bodies.
- The supply of test laboratories (costs and time to get a response).
- The lack of knowledge as regards REACH among firms.

[15] CSES (2012), *Interim Evaluation: Functioning of the European chemical market after the introduction of REACH.*

According to **companies interviewed**, the following factors cause problems as regards surveillance and enforcement:

- Different penalties for non-compliance in different Member States.
- Different OSH (Occupational Safety and Health) legislation in Member States, also different BOELV (Binding Occupational Exposure Limit Values).
- Lack of enforcement as regards imported articles.
- Valid test methods for SVHC contents in articles.
- Products entering from non-EU/ EEA countries (polymers, cosmetics, biocides and chemical articles).
- National rules still apply in some countries (Nordic area, Germany, etc.); there are "product registries" that lead to incurring of costs despite REACH harmonisation and EU-free trade rules (e.g. Denmark, Sweden, Italy, Netherlands, France).
- Re-imports of chemicals into the EU.
- Nanomaterials (Amendments to REACH Annexes are not implemented yet).
- Varying inspection requirements between and within Member States.
- Knowledge levels of inspectors as regards complex technical matters.

Therefore, while there are mechanisms within REACH, primarily the Forum for Exchange of Information on Enforcement (Forum), which coordinates a network of Member State authorities responsible for enforcement, the surveys suggest there is still a good deal of work to be done in this area (in addition to the several "Enforce" projects that have been carried out). Implementation of the findings of the recently published (June 2015) study for DG GROW on *Development of enforcement indicators for REACH and CLP,* which does not only deal with indicators but also other enforcement –related issues*,* should also contribute to the harmonisation of the market.

3.1.6 Conclusions

Although there was already a significant degree of harmonisation in parts of the EU chemicals market before REACH, REACH has made it easier to integrate existing and new chemical legislation. By putting in place fora for discussion of legislation and its implementation and enforcement, REACH has made a substantial contribution to harmonisation of EU chemicals legislation, although a good deal remains to be done in areas such as OSH, Cosmetics, Biocides, etc. This is particularly the case when considered against the alternative of potentially having 28 separate pieces of national chemicals legislation to comply with.

The survey data suggest that the role of REACH in promoting trade across the EU is rather limited. As regards exports, 85% said it had no impact, while about 5% in each case thought it had a negative or a positive impact (CATI). As regards imports, a similar share indicated no change (80%) although some 13% indicated there was an increase.

There was anecdotal evidence from the in-depth interviews and also some survey responses where REACH was mentioned as a contributing factor for increased exports and imports within the EU. However, no robust evidence was identified that would support the proposition that the increase in intra-EU trade of recent years can be attributed to the REACH Regulation. Nor, on the contrary, can it be asserted statistically that REACH hampered intra-EU trade. While a handful of specific instances were identified where REACH contributed to new intra-EU business, instances to the contrary were also mentioned.

The CATI survey did not find evidence that the regulation led domestically-focused companies to export to other EU markets, although a quarter of them considered there were opportunities for that. Among those that had a dominant share of domestic sales (>80%), 2.2% saw an increase in exports as a result of the introduction of REACH.

Trade flows within the EU and between chemical and downstream chemical user companies is complex and driven by a wide range of factors other than the REACH Regulation.

Stakeholders consulted considered that there are important benefits to be gained from further harmonisation in market surveillance and enforcement across Member States.

3.2 Objective 2 - Strengthening External Competitiveness

3.2.1 Introduction

The aims of this section are to determine the main mechanisms whereby REACH has altered the position of EU industry when exposed to global chemical markets and, to attempt to quantify the impact of those mechanisms. In addition, the aim is to describe examples, if any, of ways in which REACH has improved the global competitiveness of the EU chemicals sector (i.e. when new products or improved safety provided added value to EU traders).

The competitive position of the EU's chemical industry overall is dealt with in other reports such as *The European Chemical Industry – Facts and Figures* 2014 (CEFIC) and *Evolution of competitiveness in the European chemical industry: historical trends and future prospects* (2014) by Oxford Economics for CEFIC. It is understood that a study by the European Commission is also under way dealing with this topic as well as an assessment of REACH-like regulations in other countries.

The focus of this study is on how REACH affects the competitiveness of EU industry when exposed to global markets. Following the approach of the Commission's Competitiveness Toolkit, the drivers of competitiveness are costs/ prices, innovation, competitiveness of and access to markets[16]. The REACH Regulation affects these through its various mechanisms: registration, evaluation, authorisation and restriction – and the processes underlying these mechanisms.

3.2.2 The main mechanisms through which REACH has impacted on the position of EU industry when competing in global chemical markets.

The mechanisms through which REACH impacts enterprise operations are those at the core of the Regulation and their underlying processes.

Registration influences enterprises through costs including registration itself and the various compliance costs incurred to bring that about which include increasing in-house employment, training, testing (internal and external), participation in SIEFs or consortia, communication through the value chain, creating the required forms and updating them, etc. The data and knowledge created could also affect competitiveness if it leads to innovation. Assessment of the economics of registration might also lead to withdrawals of substance or substitution and related activities such as R&D, changing supply chains, etc. Costs might affect prices and ability to compete (or profitability) for EU enterprises, transferring production abroad, or lead to the unwillingness of non-EU suppliers to enter the EU market. Both these factors might reduce the international competitiveness of EU industry.

Evaluation can affect business competitiveness through cost increases and because it creates uncertainty about the ultimate cost of product development and the ultimate cost of registration – and hence the rate of return on innovation. It may also lead to product withdrawal, with the associated knock-on effects for the firm doing the withdrawal, upstream suppliers (if present) and downstream users.

[16] European Commission (2012): final Commission Staff Working Document Operational Guidance for Assessing Impacts on Sectoral Competitiveness within the Commission Impact Assessment System, Brussels, 27.1.2012, SEC(2012) 91, A "Competitiveness Proofing" Toolkit for use in Impact Assessments", p.8.

Authorisation includes not just the actual process of applying for authorisation, but the whole preceding process starting with Member States Competent Authorities proposing substances for SVHC identification, the development of the candidate list and inclusion of substances in Annex XIV (list of substances subject to authorisation), and the effects on production and its location, imports and exports**.** It may also have effects on participation in supply chains and competition. As a result, it creates some uncertainty in the market, at least in the short to medium term. It may have a wide range of impacts on businesses including withdrawal of substances, substitution and innovation. At the extreme and under specific circumstances (if there is a critical or important link to the Annex XIV substance), it may lead to some firms moving part of their operations (or even the firm as a whole) out of the EU.

Restriction affects competiveness of firms because it may limit or ban the manufacture, placing on the market or use of a substance thereby affecting turnover and profitability.

All types of participants in the chemicals value chain are affected: from manufacturers to end users. The CEFIC and Oxford Economics reports make it clear that EU chemicals companies are very highly involved in the global trade in chemicals. The relationship is complex as many chemicals that are exported may include substances or mixtures that were initially imported – including from third-country-based subsidiaries of EU enterprises. Such intra-firm trade is important for the competitiveness of EU chemicals industry and enterprises. As Cefic (2014, p15) put it "The industry relies increasingly on tightly interconnected clusters that in turn participate in global value chains". Hence competition in the global chemicals market is not just a case of promoting EU export, but also of ensuring access to key imports of substances not available, or not available at competitive prices, in the EU.

When discussing the impacts of the REACH Regulation on external competitiveness with **Member State Competent Authorities,** very few had any specific comments, other than that they did not have data, or systematic data, in that respect, or that if data existed it was the responsibility of a different department to collect and interpret (usually the relevant department or ministry of industry, commerce or economy). Some anecdotal remarks were forthcoming to the effect that increased imports of articles from non-EU countries had been observed, or that exports were less competitive due to higher prices; that supply chains were more transparent which was beneficial for the market; and that authorisation and SVHC presence could have an effect. One is supporting a subsector of the industry facing a difficult competitive situation as a result of problems in accessing imports due to REACH-related costs.

Industry representatives usually had well-developed views. One (UK) representative said that REACH had led to a refocusing on the domestic market for suppliers as they preferred intra-EU suppliers who were REACH compliant. Another UK-based association said that uncertainty about future supplies of substances and the need to find substitutes 'in case' theirs were subjected to authorisation or restriction meant that innovation was being stifled and companies were nervous about investment. One said that some imports from Russia had been stopped, others that some importers or EU suppliers had withdrawn which made the market better for those remaining. A report by the Commission on Critical Raw Materials which linked the risk of supply (beryllium) to regulatory concerns was referred to.

Turning to the views **of firms**, according to the CATI survey, two thirds of respondents do not think that the REACH regulation has had an impact (positive or negative – see below) on their competitive position compared to firms from outside the EU, whereas close to a quarter do (the rest don't know). In particular, among manufacturers of substances 39% consider that it has had an impact. Among firms with a high level of exports there are higher levels of concern (35%) in comparison to firms focusing primarily on the domestic market (20%), who may of course still import inputs.

The **size of the firm** also appears to have a role on whether firms think that REACH has an impact on their competitive position compared to firms from outside the EU. Among large firms, 28% indicated that they have concerns, whereas this was less so among medium (23%), small (21.5%) and, even less so, micro firms (9.5%). We think that this may be a reflection of the fact that smaller firms tend to export less outside the EU, or may be less directly dependent on imports from outside the EU and are often more locally focused and less aware of such competitive issues. The in-depth company interviews did however reveal that some micro firms are confronted by survival considerations as a result of competitive developments resulting from REACH, rather than marginal adjustments. As far as the country of establishment is concerned, there are no major or obvious deviations among respondents.

Among those firms indicating that they think their competitive position is affected by REACH the majority believes that it has weakened (54.8%).

Table 3.2.1 - Would you say that your competitive position vis a vis firms from outside the EU has:

Response	Manufacturers	Formulators	Distributors	Importer	Suppliers of articles	End users	All firms
Weakened substantially	54.4	47.8	21.4	36.4	30.6	38.9	42.5
Weakened	19	9	17.9	18.2	4.1	5.6	12.3
Strengthened	22.8	37.3	46.4	45.5	57.1	44.4	38.5
Strengthened substantially	1.3	1.5	3.6	0	2	0	1.6
Do not know	2.5	4.5	10.7	0	6.1	11.1	5.2
Total	100	100	100	100	100	100	100
n	79	67	28	11	49	18	252

Source: CATI

However, there are important variations among firms with different roles. *Manufacturers of substances* tend to be more negative (73.4% say that their competitive position was weakened), while *article suppliers* are more positive (59.1% consider that it was strengthened). *Formulators* are also negative. It should be noted that the strongly negative views are more frequent (more firms usually indicate that their position was substantially weakened) compared to strongly positive views (no more than 1.6% indicate that their position was substantially strengthened). Furthermore, the analysis suggests that large firms tend to have a more negative view compared to smaller ones.

65% percent of large firms provide a negative assessment in comparison to 45% of SMEs. This might be because smaller firms do not often see themselves as competing with non-EU firms.

3.2.3 The impacts of the REACH mechanisms.

The reports mentioned in the introductory part of this sub-section by Cefic and Oxford Economics make it clear that the competitiveness of the EU's chemical industry is driven by a wide range of factors including energy prices, labour cost and productivity, exchange rates, infrastructure, taxation, R&D spending and innovation (considered separately elsewhere in this report), and the regulatory environment. The REACH Regulation is but one piece of legislation among many that affects the industry. That does not mean, of course, that it cannot have a critical influence on an individual firm, or group of firms, or even a sub-sector, as indicated above, but it does mean that at best, it is likely, even if far reaching, to have a limited overall impact on the industry as a whole compared to such other factors.

To identify how REACH impacts competitiveness, the OBS asked respondents to indicate the impact of REACH on a number of aspects that are linked with their competitive position vis à vis non-EU competitors. These were: access to raw materials, access to markets, operating costs, capacity to innovate, availability of human resources, and access to financial resources. Operating costs were seen as negatively affected by 56% of respondents, followed by access to raw materials (38.9%) the capacity to innovate (35%), and availability of human resources (31.3%). Positive impacts are much less often identified. Examining responses by REACH role, distributors tend to have the most negative view (generally more than 60%) while article suppliers more often consider that REACH is not relevant or does not have a particular impact.

Table 3.2.2 -Has REACH impacted on any of the following factors affecting the competitiveness of your business in comparison to non-EU competitors? (percentage of respondents indicating – all roles).

Options	Very negatively	Negatively	Not particularly	Positively	Very positively	Not relevant	Do not know	n
Access to raw materials	9.5	29.4	23.3	2.8	0.3	24.5	10.1	**326**
Access to markets	9.3	18.6	34.5	5.3	0.0	21.4	10.9	**322**
Operating costs	16.7	39.3	19.8	0.3	0.0	14.6	9.3	**323**
Capacity to innovate	16.6	18.4	31.6	10.0	0.6	16.9	5.9	**320**
Availability of human resources	8.8	22.5	38.8	1.9	0.6	17.5	10.0	**320**
Access to financial resources	5.0	14.8	41.8	0.9	0.3	21.1	16.0	**318**

Source: OBS

On the specific topic of **access to external export markets**, the majority of CATI survey respondents also did not assign much value to REACH and the fact that their products are REACH compliant. The majority (88.9%) of CATI respondents indicated that their exports to outside the EU had not increased due to their products being REACH compliant, although 7.2% said it had increased somewhat. Interviews with firms indicated that, despite the adoption of more demanding chemicals legislation in some countries, there is a limited benefit arising from being REACH compliant, at least at this stage, as, for example, test results are not necessarily accepted and/ or tests have to be repeated, or done differently.

The OBS responses further corroborated the findings presented above. Some 3.1% of firms see a positive impact of REACH in relation to opening of new markets outside the EU, their market share (3.7%) or the relative price of their products (0.3%). As regards "opening new markets", being REACH compliant has been a contributing factor, rather than the main cause. However, in most cases REACH has not had a particular impact or is not relevant. The respondents considered, though, that the REACH regulation would have a predominantly negative effect as regards prices compared to non-EU competitors in non-EU markets.

From the point of view of access to external markets, feedback from the company interviews has indicated that the negative effects on competitiveness might involve the following: not only have transaction costs as regards existing imports increased, for example in the case of having to work through an Only Representative, or having to register and import as an importer, but there is a view that new innovative products or formulations will not be marketed in the EU because non-EU exporters to the EU will not want to do the necessary registrations where small volumes of substances are present in mixes. In addition, it has proved very hard, in many instances, for importers into the EU to obtain data about the composition of the substances, mixes or articles in question. Non-EU suppliers are often not aware of REACH and do not want to invest time into learning about it or complying with the regulation. They also have concerns about intellectual property and the costs of administration and potential returns involved, particularly for small orders. When these are intra-firm imports it is less of an issue.

Some EU-based multinationals have indicated that they have had to set up and train REACH-compliant international supply chains for their products at considerable expense (e.g. for electronics and information and communication technology products). In addition, once the supply base is set up, it is more rigid and it is less possible to switch to suppliers with better prices as they will not all have been put through the REACH compliance process by the purchaser, given the costs involved. There is also less flexibility as regards supplies through non-EU based toll manufacturers as they now would also have to be REACH-compliant.

Interview respondents have indicated that some EU businesses could benefit from these trends as, where possible EU importers may switch to sourcing from within the EU, although it could amount to a reduction in the competitiveness of markets and will not necessarily be to the benefit of EU industry as a whole.

Large firms are more concerned than SMEs (27.1% compared to 21.1%, and 13.7% for micro firms) about the effect of the Regulation on their competitive position vis à vis firms from outside the EU, and more see this in a negative light (65.8%) than SMEs (46.1%). This may be because they compete more with such non-EU firms. At the same time, about a third of large firms and almost half of SMEs thought their position had strengthened (CATI data). This may be due to the view that their non-EU competitors would find the EU market less attractive. Within larger firms, different business units would also be affected differently, depending on how open that unit is to international competition.

The survey findings suggest that impacts on operating costs are among the key challenges identified in terms of impacts on international competitiveness. The OBS reveals the different responses of firms to these costs. They suggest that only a small share of firms said they were able to pass the costs on to consumers in terms of increased prices, mainly among manufacturers and formulators. A much greater share said they absorbed the costs by reducing profit margins. The decision to withdraw certain products from the market or withdraw completely from the market was also less common, with the exception of distributors and importers which appeared to be more willing to take such steps.

Referring only to **registration costs**, manufacturers and importers that responded to the CATI survey stated more often than other REACH roles that they avoided increasing prices or removing products from the market (only 20% of manufacturers and 6% of importers selected this option). The majority (over 70%) decided to make the necessary investments and absorbed the relevant costs.

The type of response largely depends on the structure of the market in question. The options are:

- Firms can raise prices to reflect costs without losing competitiveness. This can happen in markets where demand is inelastic, or greater than supply.
- Firms absorb REACH costs in prices but with limited impact on profitability due to high profit margins.
- Firms operate with smaller profit margins and in markets where they cannot increase prices without losing market share or profitability. In this case REACH costs may lead to a decision to reduce or stop the supply of a specific substance.

The possibilities illustrated above are reflected in the responses of industry representatives. Most provided a negative assessment of the impact of REACH on each of the above aspects, in most cases being even more critical than firms (for example three quarters of industry representatives considered that REACH has a negative impact on operating costs). Again, it is only in relation to the capacity to innovate that a more positive contribution is identified by 12% of respondents. Furthermore, most industry representatives support the view that, rather than having a minor impact on firms' competitiveness – in comparison to other parameters such energy prices, labour costs, raw materials prices or the impact of the financial crisis – REACH is of some (35% of respondents) or of high importance (35%).

Examples of the processes underlying the above data collected through interviews in the form of anecdotal evidence are: 3rd country exporters to the EU may be put off by registration costs, or that they do not want to work through an OR. There is also anecdotal evidence of exporters to countries outside the EEA/ EU being able to charge more for REACH – compliant products, and there are questions about new markets becoming accessible and existing ones closing, but we have not been able to substantiate these comments. However, it is very probable that the results will differ depending on the segment of the market in question, and the presence of alternative (actual and potential) suppliers. Trade data indicate that the EU is particularly strong (in terms of exports) in the area of specialty and fine chemicals. These high knowledge intensive areas tend to be less sensitive to price competition, but non-EU (e.g. Saudi and Indian) industry has developed rapidly and even here EU competitiveness is being eroded (Oxford Economics, p.24, 44).

In the OBS fifteen respondents (2.6% of total respondents) reported that they had reduced production in the EU and shifted it abroad or ceased production in the EU and had relocated operations to outside the EU in response to REACH requirements, in particular due to registration costs in the case of manufacturers and the appearance of

substances on the candidate list and moving towards **authorisation** (usually downstream users)**.** These were from respondents operating in the following sectors: textiles, electronics, chemicals manufacture, manufacture of processes for electroplating, manufacture of paints, varnishes and similar coatings, printing ink (including specialist fluoropolymer based versions), manufacture of dyes and pigments, wholesale of chemicals and selling and formulating dyes and pigments. These activities were no longer considered competitive in the EU. The case study on withdrawals below provides more information.

In the course of the in-depth and follow-up interview programme a few other companies said that they had transferred some production to their subsidiaries outside the EU to keep tonnages low for Registration purposes, and that this might be just the beginning of a larger migration. Several SMEs that are affected by authorisation indicated that they are also seriously entertaining such thoughts (some of which are being courted by foreign investment attraction agencies), while many micro and small firms and family businesses are confronted with survival issues (some might be bought out by larger firms with access to more funds).

Table 3.2.3 provides a selection of some comments by firms obtained during the company interviews cast some light on the nature of the impacts that emerge related to international competitiveness as a result of the REACH mechanisms.

Table 3.2.3 Text replies to the OBS (selection)

Firm size	Firm primary role	Comments as regards aspects of the implementation of REACH Regulation that affect competitiveness vis à vis non-EU industry.
Large	Supplier of articles	The burden to the EU manufacturer is increased compared to Non-EU industry.
Micro	Distributor	It has prevented us from continuing with long established business because the non-EU supplier did not honour their obligation to register under Reach. The cost of letters of access from the SIEF made it too expensive for us to register.
Large	Importer of chemicals	REACH has a very limited focus on non-EU based trading entities with trade activities within the EU.
Micro	Only Rep	It is difficult to do business globally - REACH is a barrier to importing materials from outside of the EU.
Large	Man of chemicals	Conducting business with neighbouring non EU-countries, such as Turkey, Switzerland and Russia requires increased administrative burden. There is additional effort required to identify alternative suppliers and to conduct the REACH checks for procured substances.
Large	Supplier of articles	We invested large sums to recruit resources in our foreign subsidiaries to manage substances under authorisation with a given sunset date only to find that the sunset date was then changed. These funds could have been deployed to improve our competitive position – e.g. to obtain new product lines, etc.
Small	Importer of chemicals	As a small firm it is practically impossible for us to obtain registrations for all substances we import – the letter of access costs are prohibitive as we have to acquire more than a hundred to remain in the market. The substances will disappear from the EU or big forms will take over.
Medium	Formulator	REACH has increased the costs of input materials for large

Table 3.2.3 Text replies to the OBS (selection)

Firm size	Firm primary role	Comments as regards aspects of the implementation of REACH Regulation that affect competitiveness vis à vis non-EU industry.
		volume primary materials. Those producing outside the EU sell at constant costs; we have had increased costs, thereby losing competitiveness.
Medium	Man of chemicals	Reduction in the number of products in the catalogue and increased prices for those remaining – reduction in the potential sources of supply – and increases in their prices.
Large	Formulator	Reach favours the importation of "articles" into the EU to the disadvantage of EU producers.

Wider ranging competitive impacts than just individual firm-based impacts were also identified in the course of the company and stakeholder interview programme. Research carried out for Italian dye importers[17] that supply the fashion, leather, textile and automotive industries indicates that registration costs for low-value imports may not only have very negative effects on firm profitability (leading to closures or take-overs by larger firms) but may also have longer term implications for the dye sector and related design and possibly even manufacture of high fashion-content articles in the EU.[18] In particular, the costs of letters of access where businesses have large numbers of substances sold at low volumes and low unit price (per kg) makes registration economically unviable, which has a major impact on the business model which is based on providing a large choice of substances for very demanding and particular clients in those industries. The research suggests fragrance suppliers and leather dye suppliers face a similar scenario.

Another type of impact identified that could have a similar knock-on effect beyond individual firms is that of aerospace and aviation where aircraft and space equipment constructors outside the EU will not have been subject to the costs and preoccupations associated with SVHCs and Authorisation that that EU based constructors are. This also has an effect further downstream in the industry when it comes to repair and maintenance activities which might be much easier and cheaper to carry out in non-EU locations, stimulating the development of aerospace industry in those areas (e.g. Morocco).

It also emerged in the course of interviews with high-technology companies active in the area of Key Enabling Technologies (KETs) as identified by the EU (micro-/nanoelectronics, nanotechnology, photonics, advanced materials, industrial biotechnology and advanced manufacturing technologies)[19], that substances that are critical for these technologies have been identified as SVHCs and uncertainty about their

[17] Centro Reach/ Waste and Chemicals (2014); Toward a less colourful world? The European SMEs importing, formulating, or manufacturing dyes struggling for complying with REACH obligations: a socio-economic impact assessment. A summary of this report has been presented to CARACAL.
[18] The manufacture of dyes has moved out of the EU to low cost countries already some decades ago. Aftalion, F. (2001); A History of the International Chemical Industry, Chemical Heritage Press, p.384.
[19] Brussels, 26.6.2012, COM(2012) 341 final COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS 'A European strategy for Key Enabling Technologies – A bridge to growth and jobs', pp.3-4

future from the point of view of Authorisation and Restriction can hamper investment in them or even in developing substitutes as there may be uncertainty surrounding the future of such substances as well. Representatives of companies and the industries in question voiced their concerns at a recent event.[20] In addition, a large number of SMEs are active in KETs and the many high quality jobs are being created in that area. KETs are considered as critical for achieving the EU 2020 goals.

The research found that REACH has also had some positive impacts on competitiveness of EU industry. These are:

- It has increased transparency in the supply chain of the industry and DUs through increased communication and sharing of knowledge (e.g. eSDS and data sharing) which means there is more scope to identify inefficiency and bring about improvements in the supply chain. In Malta this has been one of the main positive effects mentioned. In Germany this was also mentioned as a key benefit.
- Related to transparency is improved communication – various sector initiatives at national and pan-EU level have been set up which has meant that different members of supply chains better communicate their needs and expectations leading to better integration, quality control, need identification and less waste.
- Linked to this is increased traceability, a key constituent of quality control.
- Improved communication with customers (end users) through the abovementioned channels is also expected to bear fruit, although the research team has not identified evidence of that as yet.
- An area where there has been improvement is risk management and environmental management. About half of respondents to the CATI said that REACH would contribute to improved risk management procedures, and about a third said there would be improved management of environmental emissions and waste resulting from REACH.

3.2.4 Conclusion

In sum, the trends identified in the 2012 Interim Evaluation (pp. 63-67, table 4.10)[21] have continued and been confirmed by this research.

This research has found that about two-thirds of CATI respondents did not think their competitiveness compared to non-EU business is affected by REACH. Among those that did, there were quite substantial differences between REACH roles, with particularly manufacturers (nearly three quarters) and exporters thinking on the whole that the effects were negative, while 59% of article suppliers saw it as positive. Overall, SMEs see themselves as less affected by REACH as less compete internationally, but those that do operate in non-EU/ EEA markets may be very heavily affected.

In terms of specific REACH mechanisms, Registration has the greatest impact, in particular as regards the costs involved, as this affects prices or profitability. For companies wishing to acquire a Letter of Access (e.g. importers) the cost may be crucial, and particularly for SMEs, a survival issue. Companies dependent on long international supply chains also have to incur costs to ensure they comply with REACH, and this may also reduce flexibility in sourcing of inputs and competitiveness.

[20] http://agenda.euractiv.com/events/reach-innovation-and-integrated-eu-goals-123366

[21] CSES (2012), *Interim Evaluation: Functioning of the European chemical market after the introduction of REACH.*

The decision not to register can also affect future flows of new innovative substances to the EU if registration costs are considered too high given volumes and pricing, or there is a reluctance on the part of third country suppliers to share intellectual property about substances.

Furthermore, importers have made it clear that in instances transaction costs, e.g. from having to work through Only Representatives, have also increased, which is a further negative effect on trade.

Evaluation affects competitiveness due to the increased cost thereof for the firms (as well as possibly due uncertainty as regards costs in the future), but no evidence has been found to date of widespread impacts, although an individual case of product withdrawal has been identified that could have effects on competitiveness of the enterprise in question and DUs.

Authorisation has not had a wide ranging impact, given the relatively few substances in question, but in areas where it has had an impact, the reported impact has been quite important. A few instances have been reported of companies shifting production abroad or relocating out (or intending to relocate out) of the EU. Instances were also reported where consequences may be positive as a result of substituting hazardous substances with safer ones.

3.3 Objective 3 - Registration 2013

3.3.1 Introduction

The key study objectives in respect of Registration 2013 (Objective 3) are to:

- **Quantify the costs of the registration exercise in 2013** – providing, where possible, more details on the specific categories of costs such as costs of training, familiarisation and information, costs of financing, costs of legal support, as well as costs of SIEF or Consortium participation, letters of access, etc. This is to assist policymakers to consider appropriate adjustments in factors underlying these costs and so, where possible, propose actions to reduce burdens or excessive costs; and
- **Consider the availability of substances** - examine stability of supply of substances in terms of whether substances that were expected to be registered in 2013 have been registered, the prices and quantities available.

Drawing on the information gathered from the surveys and interviews, this section presents an analysis and conclusions in relation to each of these questions in turn. When necessary, key data in relation to the questions are also presented in this section where this is pertinent to the answers to the questions that are the focus of study.

3.3.2 Quantification of the costs of the registration exercise in 2013

Introduction

Both the OBS and CATI surveys requested estimates of the cost of the registration 2013 exercise[22]. The CATI survey asked for information on the cost of registering all substances in all tonnage bands in 2013 and the number of substances registered. The OBS requested more detailed estimates on costs of registering substances, asking for information on the cost of registering substances in each of the four tonnage bands, the number of substances registered in 2013 in each tonnage band and the percentage of costs associated with different registration activities (described in the relevant sections below).

Overall costs of registration 2013 to Registrants

Data from both surveys provides information on total cost of Registration in 2013 for each responding registrant. Table 3.3.1 provides data from both surveys presented separately and as an overall estimate so as to allow comparison to be made between the results of the CATI and the OBS to check consistency.

[22] Registration costs include external costs such as ECHA fees, costs of participation in SIEFs/consortia, letters of access, consultants paid and any internal costs (e.g. wages and other human resources, travelling) directly linked with the registration process.

Table 3.3.1: Total costs of registration

Firm size	Range	CATI	OBS	Combined Data
SME	Average	€ 245,175	€ 380,734	€ 321,795
	Median	€ 100,000	€ 168,000	€ 122,500
	Min	€ 999	€ 2,000	€ 999
	Max	€ 2,500,000	€ 3,750,000	€ 3,750,000
	Count	40	52	92
Large	Average	€ 3,050,356	€ 3,215,522	€ 3,138,147
	Median	€ 400,000	€ 260,000	€ 300,000
	Min	€ 5,500	€ 9,000	€ 5,500
	Max	€ 42,500,000	€ 100,000,000	€ 100,000,000
	Count	52	59	111
Overall	Average	€ 1,830,712	€ 1,853,570	€ 1,843,362
	Median	€ 200,000	€ 195,000	€ 200,000
	Min	€ 999	€ 2,000	€ 999
	Max	€ 42,500,000	€ 100,000,000	€ 100,000,000
	Count	92	114	206

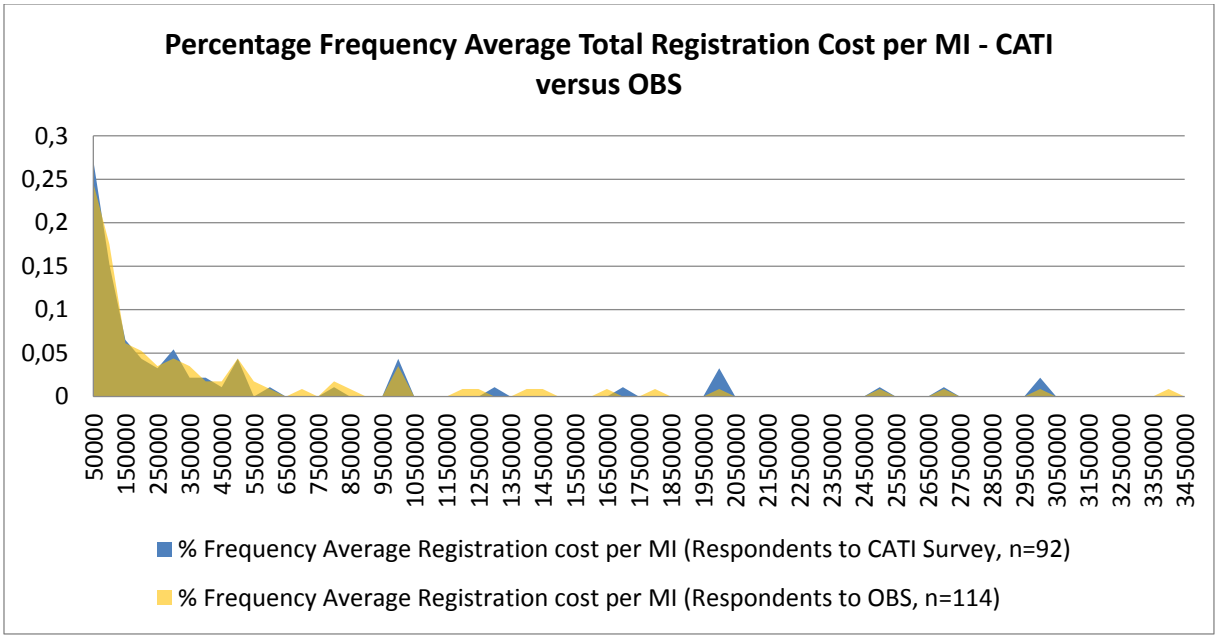
Whilst the CATI survey was a larger survey overall in terms of the number of respondents, a similar (but slightly higher) number of respondents provided estimated costs of Registration 2013 in the OBS and a total of 206 respondents provided information on total costs once the two surveys are combined.

Comparing the information from the two surveys, the maximum and minimum cost estimates vary from one survey to another where this can be expected as these values represent the extreme high and low ends of the spectrum of costs (outliers). Estimates of average cost per registrant are very similar for large companies and also overall. However, the OBS records higher average cost of registration for SMEs than the CATI survey.

With regard to all cost estimates between the surveys, cost estimates will vary significantly depending on the number of substances registered by one registrant versus another and, as is suggested by data provided in the next section (where costs are expressed on the basis of the average cost per substance), this is likely to be the reason for variation between estimates from the CATI versus the OBS. Here, for example, the average number of substances registered in 2013 by respondents to the OBS was around 12 for SMEs and 31 for large enterprises but many registered more and many registered less.

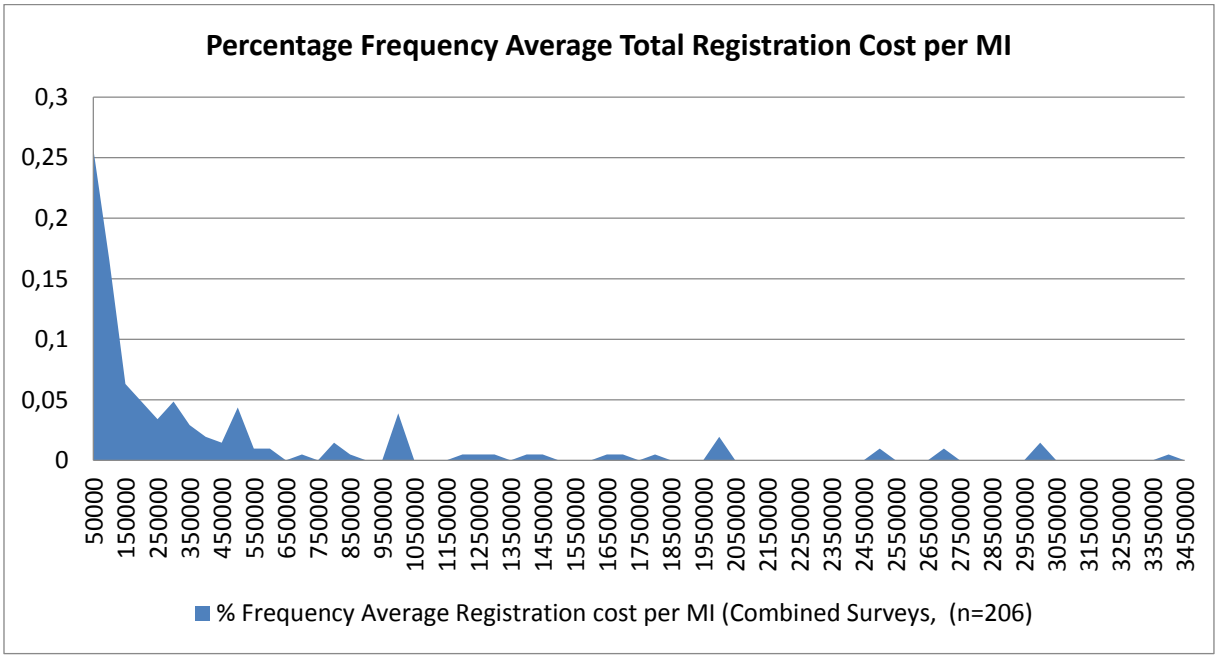
The data from the surveys suggests that overall statistical average cost of Registration in 2013 was around €322k for SMEs and €3,138k for large companies for registration of entire portfolios of substances. However, these average values are not representative of the 'typical cost' to a SME or large enterprise as there is such variation in the numbers of substances to which the estimates relate. Figure 4.3.1 provides a plot of the distribution of cost estimates for both surveys in terms of the percentage of estimates falling between each cost range and Figure 4.3.2 for the surveys combined[23]. As can be seen from both figures, there is significant variation from the average values provided above and, as suggested by the median values above, costs for 50% of respondents were less than half of the average for SMEs and less than a tenth of the average for large companies. The results of both surveys suggest a very similar (and wide) distribution of total registration costs across the sample with the vast majority at the lower end of the spectrum of costs and a smaller percentage with higher (and for an even smaller percentage, much higher) costs. This segment of respondents recording highest costs acts to increase the average significantly to €1,843k across all registrants (SMEs and Large combined) but, as can be seen from Figure 3.3.1, the vast majority of respondents (84%) recorded costs below the average value of €1,843k, indeed, 75% of respondents recorded costs below or substantially below €750k and 50% below or substantially below €200k.

Chart 3.3.1 Percentage frequency average total registration cost per MI – CATI vs OBS



[23] Note that for readability the x axis is adjusted so that it covers up to the 95 percentile value – i.e. the 5% highest costs are not provided on the graph

Chart 3.3.2 Percentage frequency average total registration cost per MI



Costs of registering individual substances in 2013

Total cost estimates for registrants will vary significantly depending on the number of substances registered by one registrant versus another. As respondents to both surveys were asked also to provide an estimate of the number of substances registered in 2013, for respondents providing cost estimates and estimates of numbers of substances registered it has been possible to divide the costs by the total number of substances registered in 2013 for both surveys[24].

Table 3.3.2 provides the resulting estimates of the average cost of registering a substance in 2013. As can be seen from the table, results are very similar between surveys suggesting a high degree of consistency once results are expressed as per substance registration costs.

[24] The CATI survey did not request specific information on costs of registering substances in each tonnage band so it is not possible to provide a breakdown of costs by tonnage for results of the CATI and OBS combined. These data were requested in the OBS and are discussed in more detail in later sub-sections.

Table 3.3.2: Average cost per substance per MI

Firm size	Range	CATI	OBS	Combined Data
SME	Average	€ 59,079	€ 57,484	€ 58,137
	Median	€ 50,000	€ 40,763	€ 47,333
	Min	€ 1,000	€ 543	€ 543
	Max	€ 200,000	€ 186,000	€ 200,000
	Count	36	52	88
Large	Average	€ 78,846	€ 79,189	€ 79,031
	Median	€ 40,000	€ 39,074	€ 40,000
	Min	€ 2,750	€ 4,500	€ 2,750
	Max	€ 666,667	€ 555,556	€ 666,667
	Count	50	59	109
Overall	Average	€ 70,571	€ 68,286	€ 69,269
	Median	€ 47,973	€ 40,763	€ 43,473
	Min	€ 1,000	€ 543	€ 543
	Max	€ 666,667	€ 555,556	€ 666,667
	Count	86	114	200

Once again, the average - and other values- are of limited use for drawing conclusions on the costs of registration. This is both because there remains significant variation around the averages which, in turn, is likely to be related to factors including:

- Tonnage bands in which substances were registered – SMEs, in particular, registered more substances in the lower tonnage bands than the higher tonnage bands compared with Large enterprises;
- The number of registrations which were for substances already registered at >1,000t versus first time registration;
- Differences between substances themselves in terms of factors such as the number of other registrants (and the extent of cost sharing that is possible), hazardous properties, numbers of downstream uses/users.

Chart 3.3.3 provides a plot of the distribution of cost estimates for both surveys in terms of the percentage of estimates falling between each cost range and Figure 3.3.2 for the surveys combined. There is significant variation in cost of registration per substance for the reasons outlined above.

Chart 3.3.3 Percentage average registration costs per substance CATI versus OBS

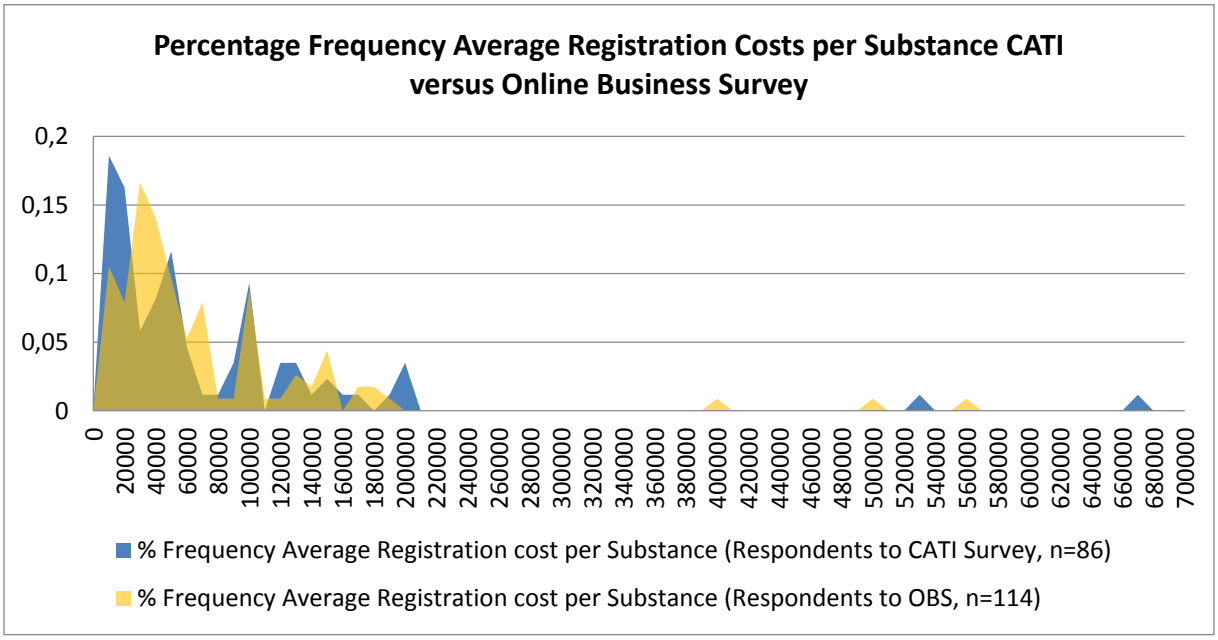
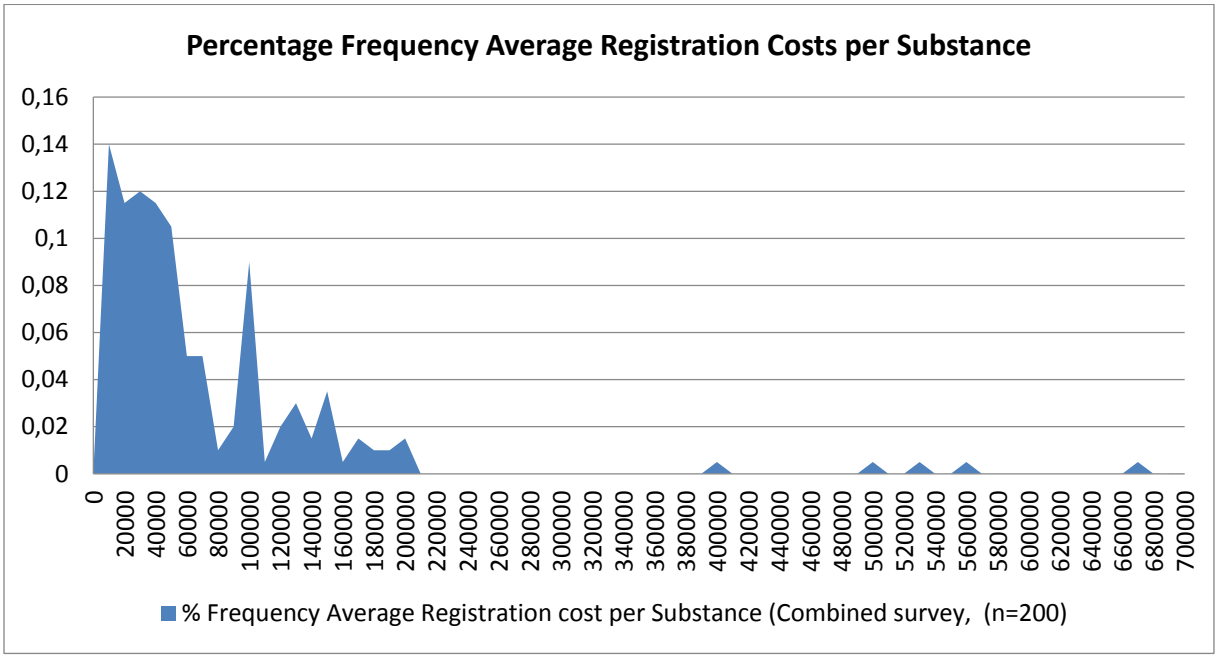


Chart 3.3.4 Percentage frequency average registration costs per substance



Average registration cost per substance per registrant by tonnage band in 2013

As noted previously, the OBS requested more specific information from registrants on the total costs for registration in each tonnage band and the numbers of substances registered in each tonnage band. From these data, for each respondent, it has been possible to calculate the average cost of registering a substance in each of the tonnage bands for each registrant. The results are summarised in Table 3.3.3.

It should be noted that the cost of registering a substance for each registrant is not the same as the total cost of registering each substance across all manufacturers and importers registering the substance. Information provided by the survey relates only to the costs borne by each respondent in relation to their share of the costs of registering a substance. One cannot glean from the survey itself how many other registrants there were and what costs were incurred by them (where this would provide an estimate of the total costs of registering a substance).

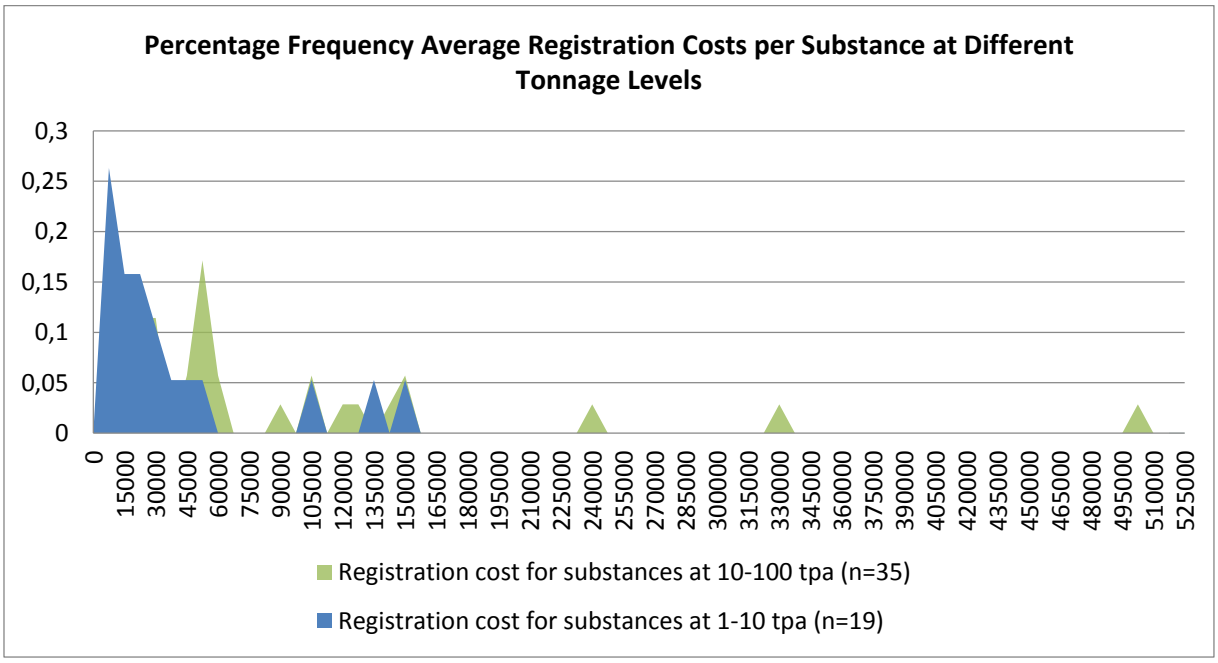
Table 3.3.3: Average registration cost per substance per registrant by tonnage band

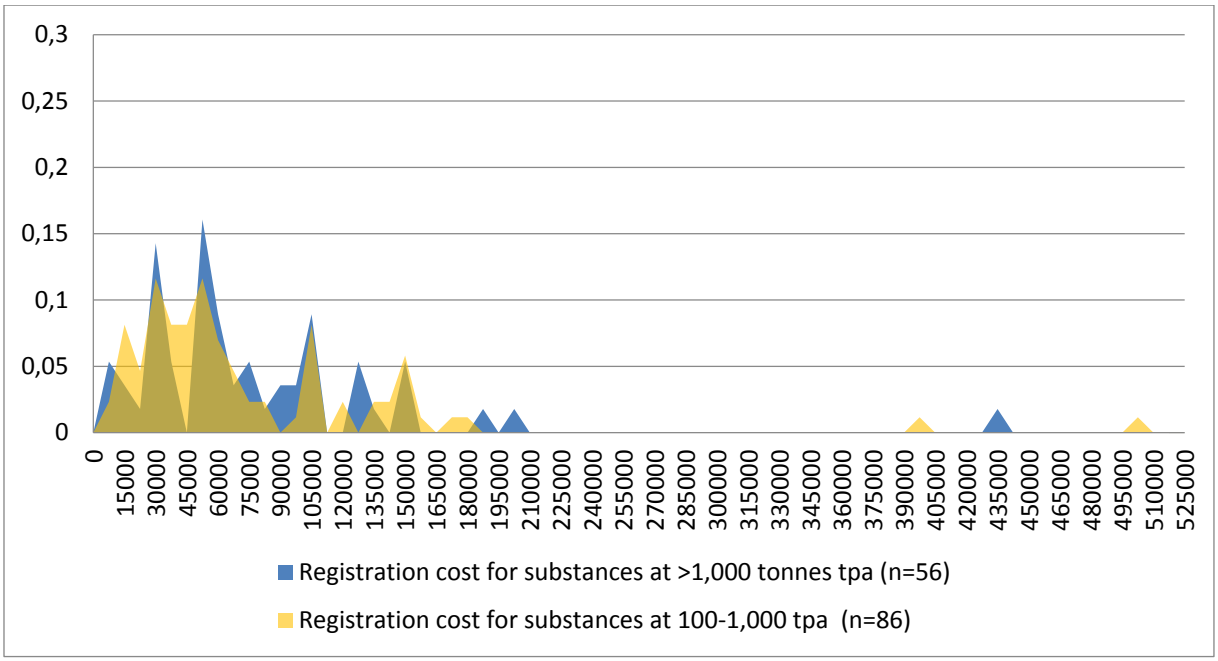
Size	Frequency	>1,000 tpa	100-1,000 tpa	10-100 tpa	1-10 tpa
SMEs	**Average**	€ 86,733	€ 63,723	€ 73,250	€ 40,309
	Median	€ 80,000	€ 50,000	€ 45,000	€ 20,000
	Min	€ 21,070	€ 9,000	€ 2,000	€ 543
	Max	€ 200,000	€ 153,333	€ 330,000	€ 130,000
	Count	19	39	12	5
Large	**Average**	€ 80,619	€ 88,603	€ 69,839	€ 32,825
	Median	€ 61,943	€ 50,000	€ 50,000	€ 19,333
	Min	€ 23,251	€ 5,435	€ 3,225	€ 4,500
	Max	€ 428,571	€ 555,556	€ 233,333	€ 150,000
	Count	22	46	11	14
Overall	**Average**	€ 81,364	€ 76,848	€ 69,676	€ 34,794
	Median	€ 63,886	€ 50,000	€ 45,000	€ 20,000
	Min	€ 21,070	€ 5,435	€ 2,000	€ 543
	Max	€ 428,571	€ 555,556	€ 330,000	€ 150,000
	Count	43	86	24	19

From Table 3.3.3, as might be expected given the higher information requirements for the higher tonnage substances, data from the survey generally suggests higher registration costs for higher tonnage substances and lower registration costs for lower tonnage substances. The exception to this in the data is registration costs for 100-1000t substances registered by large manufacturers. In terms of explanations for this divergence, the most likely explanation is the relative sample size (46 versus 22 respondents) combined with the still relatively large variation in costs from one substance to another due to factors such as the number of other registrants (and the extent of cost sharing that is possible), hazardous properties, numbers of downstream uses/users, etc. Figure 3.3.4 provides plots of the distribution of the cost estimates for each tonnage band showing how such factors may cause costs to vary quite widely from one substance and registrant to another.

From Table 3.3.3, costs per substance per registrant also generally appear 5-25% higher for SMEs than for large companies. At the same time the survey data records 23% less for SMEs for the 100-1,000t band. Given the variation in costs described above combined with the size of the sample, one probably cannot make firm conclusions on the scale of cost difference between SMEs and Large companies. One can probably only conclude that costs may be at least slightly higher.

Chart 3.3.5 Percentage frequency average registration costs per substance - different tonnages





Cost of different elements of registration

The study specification requested that, where possible, more details on the specific categories of costs such as costs of training, familiarisation and information, costs of financing, costs of legal support, as well as costs of SIEF or Consortium participation, etc. should be undertaken. Accordingly, the OBS asked respondents to consider registration of a typical 100-1,000t substance and estimate the approximate percentage of costs that were associated with the following registration activities:

- preparation of registration dossier – costs of drafting, finalising a technical registration dossier and submitting it (including all administrative data and producing study summaries for the relevant Annexes VII to XI but not CSA/CSR);
- undertaking Chemical Safety Assessment (CSA) and producing Chemical Safety Reports (CSR) excluding liaison with downstream users or undertaking testing;
- liaising with Downstream Users;
- joint registration and SIEF administrative costs;
- producing extended Substance Safety Data Sheet (eSDS);
- translating extended Substance Safety Data Sheet (eSDS);
- gathering the information required in the relevant Annexes (VII to XI) – costs include testing costs, letters of access to information and proposals for animal tests; and
- registration fees.

Analysis of the results grouped across all respondents to the OBS suggests the distribution of costs in Table 3.3.4. The table provides the distributions for SMEs, Large enterprises and the overall average from the survey. These suggest that, typically, the two most costly activities in registration of 100-1,000t substances for both SMEs and Large enterprises were:

- Fulfilling information requirements (19-22% of total costs); and
- Preparing registration dossiers (16-20% of total costs).

Registration fees were a higher component of the total cost for the larger enterprises (19%) than for SMEs (11%) where this would appear consistent with the graded fee schedule (which require higher fees from larger enterprises versus SMEs).

Table 3.3.4: Distribution of costs across different registration activities for 100-1,000t substances – as a percentage of total cost

	SMEs		Large		All Respondents	
Cost category	**Average**	**n=**	**Average**	**n=**	**Average**	**n=**
Cost of preparation of Registration Dossier – costs of drafting, finalising a technical registration dossier and submitting it (include all administrative data and producing study summaries for the relevant Annexes VII to XI - not CSA/CSR)	16%	30	20%	45	17%	78
Cost of undertaking Chemical Safety Assessment (CSA) and producing Chemical Safety Reports (CSR) – excluding liaison with downstream users (see below) or undertaking testing	9%	22	9%	38	9%	63
Costs of liaising with Downstream Users	13%	3	6%	4	9%	9
Joint registration and SIEF administrative costs – the costs of liaising with other parties as part of joint registration and SIEFs	14%	17	12%	24	12%	44
Costs of producing extended Substance Safety Data Sheet (eSDS)	11%	7	6%	1	12%	9
Costs of translating extended Substance Safety Data Sheet (eSDS)	8%	8	6%	1	9%	11

	SMEs		Large		All Respondents	
Cost category	**Average**	**n=**	**Average**	**n=**	**Average**	**n=**
Costs of gathering the information required in the relevant Annexes (VII to XI) – costs include testing costs, letters of access to information and proposals for animal tests	19%	32	22%	43	19%	77
Registration fees	11%	25	19%	32	14%	58

In order to provide an estimate of the 'typical' cost of each of the activities (in €s per registrant per substance), the percentages in Table 3.3.4 have been applied to the average registration costs for SMEs, Large Enterprises and over all respondents in Table 3.3.3. As noted in the discussion above, what is 'typical' in terms of cost is difficult to express using average values alone and so median values have also been provided.

Table 3.3.5: Costs across different registration activities for 100-1,000t substances – in €s per substance per registrant

	SMEs		Large		All Respondents	
Cost category	**Average**	**Median**	**Average**	**Median**	**Average**	**Median**
Cost of preparation of Registration Dossier – costs of drafting, finalising a technical registration dossier and submitting it (include all administrative data and producing study summaries for the relevant Annexes VII to XI - not CSA/CSR)	€ 10,015	€ 7,858	€ 18,044	€ 10,183	€ 12,725	€ 8,279
Cost of undertaking Chemical Safety Assessment (CSA) and producing Chemical Safety Reports (CSR) – excluding liaison with downstream users (see below) or undertaking testing	€ 5,503	€ 4,318	€ 7,856	€ 4,433	€ 6,737	€ 4,384
Costs of liaising with Downstream Users	€ 8,467	€ 6,644	€ 5,331	€ 3,008	€ 7,124	€ 4,635
Joint registration and SIEF administrative costs – the costs of liaising with other parties as part of joint registration and SIEFs	€ 8,875	€ 6,964	€ 10,995	€ 6,205	€ 9,292	€ 6,046
Costs of producing extended Substance Safety Data Sheet (eSDS)	€ 6,716	€ 5,270	€ 5,331	€ 3,008	€ 8,858	€ 5,763

	SMEs		Large		All Respondents	
Cost category	**Average**	**Median**	**Average**	**Median**	**Average**	**Median**
Costs of translating extended Substance Safety Data Sheet (eSDS)	€ 5,183	€ 4,067	€ 5,331	€ 3,008	€ 6,875	€ 4,473
Costs of gathering the information required in the relevant Annexes (VII to XI) – costs include testing costs, letters of access to information and proposals for animal tests	€ 12,029	€ 9,438	€ 19,264	€ 10,871	€ 14,678	€ 9,550
Registration fees	€ 6,934	€ 5,441	€ 16,452	€ 9,284	€ 10,560	€ 6,871

Clearly, the values provided in Table 3.3.5 are a combination of estimates of the total costs of registration combined with estimates of the apportionment of these total costs between the different registration activities. As such they can be expected to provide some insight into the relative order of magnitude of costs of different activities rather than an absolute cost for each element. That said, the cost of registration fees for joint and individual submissions for companies of different sizes is known with certainty because it is established by Regulation 254/2013. Comparison of the fees estimated in the OBS with those in the Regulation suggests that all of the estimates are surprisingly close to those set out in the regulation – the medians are below but close to or below and the averages slightly higher (but not significantly) than might be expected. As such, one can tentatively conclude that the estimates may be regarded as being a fairly true representation of the order of magnitude of the costs and that the estimates can be used for to compare the costs of one activity versus another across companies of different sizes. Such a comparison suggests that the cost of the following activities appears to be moderately higher for SMEs compared with larger enterprises:

- Liaising with downstream users; and
- Producing eSDS.

This seems consistent with other findings from the survey in respect of good practice tools and methods for gathering information (for example, in respect of communicating with downstream users using IT tools developed for the purpose – where it is known that this has been applied by some of the larger enterprises) and perhaps learning and familiarisation with respect to producing eSDS (where it is likely that Larger enterprises will have gained more experience in doing this as part of 2010 registration compared with the SMEs).

All other costs appear generally lower for SMEs than larger enterprises perhaps because, typically, it will be the larger companies that play the more significant role in consortia and costs may be weighted slightly towards these larger companies in spite of any cost sharing arrangements within consortium agreements.

Total costs of the Registration 2013 exercise

The average costs given in Table 3.3.5 for the different elements of registration provide costs per substance **per registrant** for each of the combined elements used in the ExIA (i.e. registration, testing and SDS).

Costs and converted to a projected average cost per substance (across all registrants) by multiplying by the average number of registrants per substance (=2.31) calculated by analysis of ECHA registration data supplied to the study. Average cost per substance grouped into the following three categories of cost are provided in Table 3.3.6: Registration; SDS; and testing/information costs).

The average costs per substance have then been multiplied by the number of registrations received for 2013 to provide the estimated total cost of phase in full registration in 2013 which is estimated as €459 million.

Table 3.3.6: Estimation of costs per substance from the OBS and comparison with ExIA estimates

	Registration	SDS	Testing/ Information	Testing, registration & SDS
Average cost per substance per registrant from OBS (€s Average)	€ 35,878	€ 15,732	€ 14,678	**€ 66,288**
Actual number of registrants per substance from ECHA data	2.31			
Projected average cost per substance from OBS (€s)	€ 82,915	€ 36,358	€ 33,922	**€ 153,195**
Actual number of phase-in full registrations from ECHA data	2,998			
Projected total cost for Registration 2013 from OBS (€million)	€ 248.6 million	€ 109.0 million	€ 101.7 million	**€ 459.3 million**

Comparison of cost estimates with ex-ante estimates

Comparing the actual costs (as projected from the OBS) with those that were anticipated in the ExIA is useful to understanding the extent to which the estimates match and, where they do not, possible reasons for this.

The average per substance costs for registration, testing and SDSs derived from the ExIA and updated to current prices are provided in Table 3.3.7.

Table 3.3.7: Average per substance costs of registration, testing and SDS in the ExIA

	1-10t/y	10-100t/y	100-1,000t/y	>1,000t/y
Registration costs	€ 6,205	€ 19,843	€ 38,487	€ 53,711
Testing costs	€ 8,023	€ 59,699	€ 135,036	€ 120,793
Safety data sheet costs	€ 1,556	€ 19,844	€ 19,844	€ 19,844

In all of the BIAs and the ExIA estimates made for each tonnage band reflected the total costs of registering the substance including registrations submitted for the lower tonnage bands. As such only the cost estimates for the 100-1,000t substances can be used to reflect the ExIA costs for the 2013 registration exercise[25]. In turn, only these can be compared with costs for the same tonnage band generated from the survey.

Table 3.3.8 provides the average statistical cost per substance from the OBS (from Table 3.3.6) and in the ExIA (from Table 3.3.7).

Table 3.3.8: Estimation of costs per substance from the OBS and comparison with ExIA estimates

	Registration	SDS	Testing/ information	Testing, registration & SDS
Projected average cost per substance from OBS	€ 82,915	€ 36,358	€ 33,922	**€ 153,195**
Cost per substance From ExIA	€ 38,487	€ 19,844	€ 135,036	**€ 193,367**

Comparison of the two sets of estimates provides a number of observations:

- the average per substance costs of registration, testing and SDS derived from the OBS data are around €153k per substance; slightly lower than the €193k predicted in the ExIA;
- Considering the uncertainties and margins of error, the OBS data does not suggest very different costs for Registration 2013 than those envisaged in the ExIA, indeed the estimates are remarkably close to one another and very much of the same order of magnitude; and

[25] And equally those for >1,000t reflect 2010 and 1-100t combined those for 2018.

- That said, estimates for the constituents of costs differ between the OBS and the ExIA. Here the OBS data suggests much higher per substance costs of liaising on and producing registration dossiers[26] compared with the ExIA. The average per substance cost of producing and translating eSDSs are also higher in the OBS that the ExIA but the magnitude of difference is not as large as for costs of registration. At the same time, the per substance testing and information costs suggested by the OBS are significantly lower than those that were predicted in the ExIA.

To recap, on an average per substance basis, then, the total cost of all elements of registration of 100-1000t substances does not appear on first inspection to have been very significantly different from what was predicted in the ExIA. On further inspection, the ExIA estimates predicted significantly higher testing costs and significantly lower registration costs than the values suggested by the OBS. SDS costs were also predicted to be lower than the OBS would suggest.

In terms of reasons for these differences, there are several possible explanations and/or effects that may be responsible for the observed differences where these include:

- ***Fewer new tests have been undertaken than was anticipated in the ExIA but the cost of purchasing data was not considered:*** The ExIA used average testing needs produced by JRC (2003) which, when compared with ECHA statistics for testing proposals for 2013 registration suggests that fewer new tests have been carried out than anticipated in the ExIA. This may be because:

  - more test information was available for more of the higher tonnage substances than was anticipated in the ExIA and so fewer tests were required (resulting in lower than anticipated costs); or, alternatively
  - there is missing information in the dossiers of some substances because required testing has not been (or is yet to be) carried out (also resulting in lower than anticipated costs). Recent evidence from a the German Federal Environment Agency screening of 1,932 >1000t dossiers for compliance[27] suggests that 58% of the dossiers showed deficiencies and were 'non-compliant' (usually for one or two endpoints but sometimes more) and for 42% it was not possible to make a firm conclusion on compliance for at least one endpoint;

- ***Legal (and associated administrative) costs of establishing SIEFs and Joint Registrations were not/not sufficiently accounted for in the ExIA:*** the ExIA predated proposals for SIEFs and, as such, the administrative and legal costs, while considered during deliberations over one substance, one registration, were not included in the estimates of registration cost in the ExIA.

[26] Comprising preparation of Registration Dossier, CSA/CSR, liaising with Downstream Users, Joint registration and SIEF administration costs.

[27] UBA (2015): **REACH Compliance: Data Availability of REACH Registration** – Texte 43/2015 https://www.umweltbundesamt.de/sites/default/files/medien/378/publikationen/texte_43_2015_reach_compliance_data_availibility_of_reach_registrations_0.pdf

Drawing from the above it is clear that the analysis of costs of the Registration 2018 exercise (Objective 12 of the study discussed in Section 4.12) should be based upon estimates that:

- better reflect the costs of testing and purchasing data from the owners of information and the impacts on, particularly, smaller companies; and
- better reflect the administrative and legal costs of consortium/joint registration and SIEF formation.

3.3.3 Availability of substances

The second part of this objective was to examine stability of supply of substances in terms of whether substances that were expected to be registered in 2013 have been registered, the prices and quantities available.

Both the CATI and OBS surveys requested information on responses to registration covering issues including the extent to which registration costs were absorbed versus prices increased to cover costs; the withdrawal of products and other responses.

Stability of Supply

Tables 3.3.9 to 3.3.11 summarise the relevant results of the two surveys across all firms responding[28]. Each survey asked questions in slightly different ways. The data suggest that withdrawal of substances from the wider market was a part of the response for 22% of respondents to the OBS and 27% of respondents to the CATI, indicating that, for the majority of respondents, withdrawal/not registering did not form a part of their response.

Table 3.3.9 What was your firm's response to the costs associated with REACH registration? (Percentage of firms indicating by firm size)

Option	Total CATI	
We decided to make the investment and covered the cost without changing the process.	48	70
We altered production so that we could register a substance in a lower tonnage band to save money on the costs or avoid registration at all	9	
We increased prices to recuperate costs	13	
We did not cover end uses of customers and only registered as an intermediate	5	27
We removed products from our portfolio because they were no longer profitable	14	
We decided not to register because the hazard profile of the substances meant that registration was not worth pursuing	8	
None of these	3	
Total	100	
n=	123	

Source: CATI

[28] Full survey results by size of company responding are provided in Section 4.3 of the Evidence Report.

Table 3.3.10 How has your firm responded – if at all - to the costs associated with the implementation of the REACH regulation? Please indicate all those that best reflect your response? (Percent indicating the specific response by firm size)

Options	All firms	
We decided to absorb the REACH related costs reducing our profit margins	51	65
We raised prices to cover REACH costs and maintain or increase profit margins	14	
We decided to withdraw specific products from the market	15	22
We decided to withdraw from specific markets	7	
Other	12	12
Total	100	100
n=	294	294

Source: OBS

Table 3.3.11 Have any of the substances that you used or placed in the market in the past been withdrawn as a result of the 2013 registration requirements? (Percentage of firms indicating)

Options	All firms
Yes	31
No	61
Don't know	9
Total	100
n=	281

Source: OBS

In terms of security of supply, the data from the surveys do not provide an indication of how many substances were withdrawn nor do they provide an indication of what other manufacturers/importers responses were for the same substances or whether substances may be registered by other manufacturers/importers in 2018. As such, one cannot draw conclusions on the extent to which REACH has affected (or will affect) stability of supply more generally. Inevitably, however, some uses and some substances may not have been registered, either because they were no longer profitable for sale on the open market (for example because the hazard profile was not consistent with uses) or because manufacturers (particularly those towards the lower threshold) have decided to register at the lower tonnage band or because the substance is not sufficiently profitable. ECHA data on pre-registrations and intended registrations for 2013 identified that 3,103 substances were intended to be registered (whether full registrations or intermediates or both). By the 31 May 2013 deadline, 933 of these substances were still not registered but 828 substances which had not been previously identified by industry in the ECHA surveys had been registered at 100-1,000 t. It is not known how many of these registrations covered all of the (former) uses of the substances or how many uses were not registered. Especially given that the majority of substances are still to be registered, it will not be until after the next deadline (in 2018) that a clear picture of the level of impact of REACH on security of supply can be established.

Prices

In terms of prices for substances registered, Table 3.3.12 provides responses from both surveys. The results of both surveys indicate that by far the dominant response to registration costs was one of absorbing costs rather than increasing them to cover costs. Altering production (it is assumed by lowering volumes rather than separating in smaller business entities) appears also to be a minority response. From this it can be concluded that REACH 2013 is unlikely to have resulted in a dramatic increase in prices across all substances. The results do suggest that an increase in prices for perhaps 20% of substances registered in 2013 is likely to have occurred (or may occur).

Table 3.3.12 Responses to registration costs

	Absorbed registration costs	We altered production so that we could register a substance in a lower tonnage band	We increased prices to recuperate costs
CATI	69%	13%	19%
OBS	78%	N/A	22%

Further remarks

It should also be noted that in the normal course of market operations substance withdrawal is a relatively common practice. The effects of a regulatory intervention may help amplify or delay these otherwise natural market economy occurrences. While this study has not dealt with this point specifically, the second case study (below) does relate instances where this has occurred. In one instance it has led to withdrawal of an ageing product which freed up production space for the supplier – although the effects on the user were not mentioned. In another instance, many substances were withdrawn with little effect on the supplier – although again, the effects on the users were not mentioned. While some of the 31% of respondents in table 3.3.11 may have been affected by such "natural" business practices, it is not possible to say, based on the data gathered in this study, how important this effect was overall.

3.3.4 Conclusion

From the OBS survey data it has been tentatively estimated that the total costs of the 2013 registration exercise were of the order of €459 million. The scope for error within this estimate is potentially large given that it is based on a combination of estimates and relatively small proportion of respondents to the survey as a whole (86/566 = 15%) provided sufficiently detailed responses to allow estimation of costs for 2013. As such the total costs may be higher or lower but still of a similar order of magnitude as the €583 million (accounting for fees) estimated in the ExIA.

In terms of the 'typical' costs of registration per substance (or per registrant), this is difficult to express as a single number. The statistical average cost per substance from the survey was calculated as being around €153k and the average cost per registrant around €66k. However, variation around these averages is wide as costs depend on a number of complex factors including the numbers of registrants, the properties identified, the further testing required/waived, the amount of test information already available, the numbers and types of uses etc.

As such, these cost estimates are only statistical averages and not 'typical' costs. They are, however, useful for making a comparison with the average statistical costs that were anticipated in the ExIA.

Such a comparison suggests that, while the total average costs across all components of registration are similar, estimates of the cost of liaising on and producing registration dossiers are much higher in the OBS than those anticipated in the ExIA. The same is also true of the costs of producing and translating eSDSs but the magnitude of difference is not as large as for costs of liaising on and producing registration dossiers. In contrast, however, the per substance testing and information costs suggested by the OBS are much lower than those that were predicted in the ExIA.

The main reason for this is thought to be a combination of the fact that legal and associated administrative) costs of establishing SIEFs and Joint Registrations were not/not sufficiently accounted for in the ExIA and fewer tests have been carried out than were anticipated in the ExIA. The latter may either be because more information was available than was anticipated for the higher tonnage substances or because a number of dossiers are non-compliant. Of the two possibilities only the latter has supporting evidence (UBA, 2015 screening of dossiers) which, if found to be the case, means that there are information costs as yet unaccounted for.

Analysis of the average costs of the different components of registration from the OBS suggests that the cost of the following activities appears to be moderately higher for SMEs compared with larger enterprises:

- Liaising with downstream users; and
- Producing eSDS.

This seems consistent with other findings from the survey in respect of good practice tools and methods for gathering information (for example, in respect of communicating with downstream users using IT tools developed for the purpose – where it is known that this has been applied by some of the larger enterprises) and perhaps learning and familiarisation with respect to producing eSDS (where it is likely that Larger enterprises will have gained more experience in doing this as part of 2010 registration compared with the SMEs).

In terms of prices for substances registered, the results of both surveys indicate that that Registration 2013 is unlikely to have resulted in a dramatic increase in prices across all substances. However, an increase in prices for perhaps 20% of substances registered in 2013 is likely to have occurred (or may occur).

In terms of security of supply, both surveys indicate that withdrawal of one or more substances from portfolios was not a part of the response for the majority of respondents, with about 30% indicating that substances used or placed in the market in the past been withdrawn as a result of the 2013 registration requirements. However, the data from the surveys do not provide an indication of how many substances were withdrawn nor of what other manufacturers/importers responses were for the same substances nor whether substances may be registered by other manufacturers/importers in 2018. Data from ECHA surveys suggests that some 933 substances that were intended to be registered in 2013 were not, but that some 828 substances not intended to be registered were registered. Especially given that the majority of substances are still to be registered, it will not be until after the next deadline (in 2018) that a clear picture of the level of impact of REACH on security of supply can be established.

CASE STUDY 1: REACH COMPLIANCE COSTS

The aim of this case study is to develop thinking for a prototype for a model with which to assess costs of compliance with the REACH legislation on an enterprise basis that could cover several roles and look at costs over a time period of a year or more – well beyond the registration deadlines The rationale for this case study is that most cost studies dealing with REACH have tended to focus at quite a high level on industry costs (e.g. "it will cost the industry" €X billion, etc) and have focused on registration costs, rather than total subsequent compliance costs that accrue over time.

In a public consultation by the Commission on the "Top 10" most burdensome legislative acts for SMEs the REACH Regulation was identified as the most burdensome individual piece of legislation with more than 50% more responses than the one that came in second place (Refund of VAT).[29] This suggests that compliance costs could be significant, especially for SMEs.

This case study is based on Interviews to identify and assess compliance costs with reference to respective information and administration requirements. Input was obtained through the surveys and additional in-depth interviews with firms.

Assessing the costs of compliance with legislation

A recent study by CEPS and Economisti Associati for the European Commission (Secretariat General) has identified the costs of regulation as including direct costs, indirect and enforcement costs. These consist of the following elements:[30]

Direct costs include:

- Compliance costs, such as:
- Charges (fees or levies, such as registration payments to ECHA).
- Substantive compliance costs (one-off, recurrent), usually calculated as a sum of capital, financial and operating costs, if for example changes have to be made to the operational set-up at a plant. These costs also include familiarisation costs (to understand the legislation and obligations).
- Administrative burdens (performed to comply with administrative obligations).
- "Hassle" or "irritation" costs that are hard to monetise or quantify and include opportunity costs related to administrative delays e.g. waiting for decisions)

[29] European Commission (2013); Results of the public consultation on the TOP10 most burdensome legislative acts for SMEs.
[30] CEPS and Economisti Associati (2013): Assessing the costs and benefits of Regulation, Study for the European Commission, Secretariat General, p.22

Indirect costs are incurred in related markets or are experienced by consumers, government agencies or other stakeholders that are not under the direct scope of the legislation, and include:

- Indirect compliance costs (transmitted through agents that comply with the legislation).
- Other indirect costs.
- Substitution effects (e.g. costs of switching to more expensive substituted substances).
- Transaction costs (e.g. increased costs of carrying out transactions with non-EU suppliers).
- Reduced competition and inefficient resource allocation (e.g. non-EU suppliers withdrawing leading to a reduced number of suppliers – based in the EU/ EEA).
- Reduced market access (e.g. for micro-firms who cannot afford letters of access).
- Reduced investment and innovation (if R&D resources are diverted to compliance).
- Uncertainty and investment (legal uncertainty may have a negative effect on expected rates of return on investment).

In addition, the *costs of enforcing the legislation* also need to be considered: "enforcement costs are an essential element to be considered in any cost-benefit analysis, as their magnitude can tilt the balance in favour of regulatory options that would not be chosen in a more partial assessment"[31].

Enforcement costs include:

- *One-off adaptation costs*: this is typically the case in which a new legal rule forces administrations to recruit or re-train their personnel or change equipment (e.g. buy personal computers, cars, etc.). In Italy for example 220 REACH inspectors have had to be trained, including in-depth training for 90 and training in Helsinki at ECHA for a small group.
- *Information costs and administrative burdens*. These are the costs of gathering and collecting information needed to effectively monitor compliance. When these activities entail the production of information to be delivered to third parties according to a legal provision, they are called "administrative burdens"; however, information costs can also be related to activities that are essential for carrying out enforcement actions, but do not entail any information obligation.
- *Monitoring costs*. The cost of monitoring compliance with the legislation, *e.g.* patrolling borders (customs and excise), collecting statistics, etc.
- *Pure enforcement costs*. These include the cost of running inspections, processing sanctions, handling complaints by the enforcing authority.
- *Adjudication/litigation costs*. These are the costs of using the legal system or an alternative dispute resolution mechanism, to solve controversies generated by the new legal rule (e.g. cases brought before the European Court of Justice). Enforcement costs are not only borne by public authorities: private actors face costs related to litigation when in need to use the legal system, as in the case of lawsuits: these are not strictly classified as administrative burdens, nor as compliance costs. They are costs that can be defined as the sum of the opportunity costs of the time spent dealing with litigation, plus the legal expenses that must be sustained (depending on the procedural rules that apply) in order to litigate a case as claimant or defendant.

[31] Ibid, p.30

Within these costs would also be included the relevant share of the costs of ECHA, DG GROW, DG ENV and other EU actors involved. *The Standard Cost Model (SCM) approach* is a way to capture these cost systematically, in terms of the Commission's *Impact Assessment Guidelines (2009), and the International Standard Cost Manual* by the SCM Network.[32]

One conceptual point with practical implications that needs to be considered is that by carrying out tests required for REACH registration, it may become apparent that a company was liable for compliance to other legislation (e.g. Health and Safety, or Environmental) that it had not earlier been aware of. In such a case, should that compliance cost be due to the REACH Regulation or the other relevant legislation? In a study on the *Cost of the cumulative effects of compliance with EU legislation for SMEs* by CSES (2015) this type of effect was described as one of *increasing marginal impact*[33]. In addition, there is the question as to whether the effect of a substance appearing on the SIN list (for example), even if not on the candidate list, should be considered as REACH-related or not.
In the course of the in-depth interviews with enterprises, and also from the open-ended responses in the surveys, it was clear that many enterprises, large and small, at all stages of the value chain and different REACH Roles, were of the view that registration costs were but an element of the costs of compliance and that other compliance costs were material.

The value chain model of the enterprise

A useful way to see where and how legislation affects costs and operations in an organisation is through the value chain model (associated with Porter). A schematic illustration of a typical value chain model is set out in table 3.3.13 below. There are two main elements to this: support activities that are felt throughout all operations and primary activities that relate to specific value adding activities.

Table 3.3.13 The enterprise value chain

Support activities	*Firm Infrastructure*					*Margin*
	Human Resource Management					
	Technology Development					
	Supply chain management					
Primary activities	*Inbound logistics*	*Operations*	*Outbound logistics*	*Marketing and sales*	*Service*	

Source: Porter, M

[32] P.6
[33] Section 2, table 2.3

REACH and the enterprise value chain

Rather than go through the different types of costs that could emerge in the course of the different support and primary activities, a few examples will be provided that indicate how and where such compliance costs arise in the enterprise (enforcement costs would have to be considered separately).

1 Support activities:

Firm infrastructure

Familiarisation: One of the first impacts of the Regulation is on senior managers and/ or technicians in the company having to take time to familiarise themselves with what is required to comply with the various obligations of the legislation. While this is generally a one-off up-front activity, in the case of REACH it is on-going and has been so since the legislation was passed (and even before) and will remain to be so for many enterprises well into the future, even if the intensity of the relevant familiarisation requirement may decline over time.

Once the implications of the regulation are grasped, companies are in a position to assess what that means for firm infrastructure: will a separate REACH unit be required, will it be integrated into HSE, for multi-plant firms – how will the activities be co-ordinated and costed? For smaller firms, how will management deal with it? Whose responsibility will it be in a small family firm or micro-enterprise where individuals already carry many "support" responsibilities without there being a formal structure of that kind in existence? All this takes time. The example of Huntsman (3.10.4) sets out what could be involved just as regards authorisation for a multinational. A small UK family firm mentioned 17 trips by the owner to Brussels in the course of 2 ½ years to understand and deal with Authorisation issues. Participation in SIEF and Consortia is another example.

Adaptation: Budgets are drawn up, discussed, negotiated; staff appointed, meetings take place, etc. as the units are set up and become operational. In large firms these are REACH Units, in others, activities are integrated into HSE operations and in small firms the owner, or scientist in the team, takes over responsibility, often on an *ad hoc* basis (see below, table 3.9.1).

In due course this part of the firm might also be involved in meetings about product lines, withdrawals, etc. that can affect the strategic direction and development of the enterprise. Intense discussions might be involved in small family businesses or firms where survival is an issue. Issues about control may also emerge as in small firms and they may become more dependent on external consultants. REACH can become a strategic issue in some firms.

Administration: Very few of these costs, often involving the time of the most senior executives in the firm, are usually captured in cost studies or company accounts where they might be listed under the heading of "meetings". They might be debited to HSE or Marketing departments.

Technology development

Familiarisation: Understanding what is involved in terms of knowledge about substances will engage the R&D resources of the company. The technical team needs to learn what is required in terms of existing substances (e.g. for dossiers or collecting data) and may also be involved in reformulations and/ or search for alternatives that exist or in finding or developing new substances that meet the requirements of customers in terms of costs and uses. In many smaller firms, the technical resources may also be those involved with

the administration of the regulation. The resources devoted to technology development could be substantial, especially if it will also involve process redesign. In the case of a small or micro firm there may be only one firm "scientist" who will have to take on this activity.

Adaptation: Adapting substances or mixtures or finding new ones can involve companies in significant R&D expenditure that they would not otherwise have incurred, much of which may be classified as administrative burden. For example, one small firm has spent over €150k on research related to authorisation. Even for non-SVHCs, if the company does not want to register a substance as it is too costly and elects to reformulate, this can involve research and development and piloting with customers who have to be persuaded that it is worthwhile. Pressure for such changes can also come from end users who might not want a certain substance to appear in their product, even if it is not in qualifying concentrations, etc.

Administration: In this instance costs will be recorded under R&D or product development although they may be purely in response to compliance, and will not necessarily lead to improved performance or innovation in the industrial sense of the term.

Supply chain management

Familiarisation: REACH imposes obligations as regards supply chain management. Companies need to familiarise themselves with these and understand what is required.

Adaptation: Suppliers need to be vetted to ensure security of deliveries in the future (both in terms of compliance and continued supply). Substances and mixtures have to be checked to ensure that they are registered, and information may have to be obtained from non-EU/ EEA suppliers. (e)Safety Data Sheets have to be developed if appropriate, or checked to ensure that uses are covered (or a separate CSR may need to be submitted). All this needs to be recorded and documented.

In the case of international supply chains this can become very complex as other companies who are involved in the supply chain need to be trained and checked to ensure that they comply. Data also needs to be recorded. This may also involve appointing or finding an Only Representative. Working through an Only Representative can also involve transaction costs in addition to financial costs. If toll manufacturers are involved they need to be checked, as do other plants in the company network that may be used for production.

One global business provided the example of appointing a person in each of its major country subsidiaries to manage substitution of SVHCs in its supply chain of over 40,000 products, supported by a costly IT system and training and project management.

For SMEs importing from outside the EU/ EEA it can be very difficult to obtain information about substances and mixtures (increased transaction costs).

Administration: In very few instances will these costs be documented separately, and in the most part they will be an administrative burden

2. Primary activities

Operations

Familiarisation: Technology development would be responsible for understanding the nature of changes required, but there may be additional requirements at operational level to ensure that obligations are met.

Adaptation: This could include process redesign, which may involve new investments in plant, machinery and related equipment. Innovation (after the research stage) requires piloting, trials (which can be costly and which may also involve customer collaboration as substances have to be tested in their machinery and systems). Instances of having to redesign the whole manufacturing process have been mentioned in the course of in-depth interviews with companies, as has the practice of having to give customers discounts in order to incentivise them to try out new products or processes.

The sums involved could be quite significant and also include retraining of employees on how to use new machinery and equipment, and learning to operate new processes, with new H&S requirements, such as having to use new protective clothing.

Administration: If changes are made in order to comply with the Regulation only, the costs involved will be mainly administrative burden.

Marketing and sales

Familiarisation: The marketing team needs to familiarise itself with obligations in question and what is required of them specifically.

Adaptation: Adaptation in this instance involves getting to know in detail what the substances, or mixtures, being sold are composed of, including if they are parts of other products or articles. This can be a substantial challenge for a micro firm with 300 substances in its portfolio, many of which may be imported from outside the EU. For distributors this can also be a major issue as they would have to gather information of uses from their customers to provide to their suppliers – there may also be language issues involved here. One company with 1700 substances explained that this requires setting up teams around substance groups to this end. Quantities of substances sold also need to be monitored closely to ensure that they are sold within tonnage bands registered, or if not registered, calculations need to be made as regards the quantities/ costs and prices to determine if they can be retained in the portfolio profitably. In addition, companies also get competitive advantages by providing a suite of products/ substances which may no longer be economic if expensive registration costs or Letter of Access need to be bought for some of those. This may require review of the marketing strategy and the company's product portfolio. Employees also need to be trained in these processes. While a good deal of this might be a one-off cost, there are also recurrent expenditures as different substances are used.

Administration: These costs can be substantial and the managers in question often have difficulty justifying them to their managers and corporate treasurers who only see costs with no corresponding benefits. In many instances the substances in question have no SVHCs and the companies involved are being affected purely because of regulatory cost.

Conclusion

While the few examples do not provide a complete picture, it does show how wide ranging and on-going the need to comply with the Regulation is in its impacts on the enterprise, and why the additional human and financial resources required go well beyond those just required for registration. There are familiarisation costs in all departments, and impacts related to all aspects of primary and support activities, some of which could be substantial e.g. related to redesign of production systems. It should also be born in mind that, as the CATI and OBS surveys have shown, most companies do not just have one REACH role to meet but there may be several. The effects will also vary in terms of the size of the business in question and the geographical scope of its operations.

In addition, due to what might be called the "increasing marginal impact" of the legislation, as a result of tests carried in the course of compliance, it may be found necessary to implement additional changes to comply with other legislation (e.g. HSE) that had not been considered necessary earlier.

The key conclusion of this case study is that although registration costs are important, in the overall compliance costs envelope involved in complying with the REACH Regulation, there is a great deal more than just registration. As such REACH – related issues have often become part of business strategy, affecting customers, product development, suppliers and stakeholders in the business.

For these reasons it is recommended that a full compliance cost study of the REACH Regulation should be carried out, so that these costs can be assessed against the projected benefits of the Regulation.

CASE STUDY 2: THE BUSINESS IMPACTS OF WITHDRAWALS

The aim of this case study is to look further into changes in the operational conditions of the chemicals industry as a result of the REACH Regulation by assessing the business impacts of withdrawals of substances. As such, it complements some of the data that was collected about withdrawals presented in the report in section 3.3.3.

The additional information presented below was obtained by contacting some 83 respondents to the CATI and OBS surveys and asking them for more detailed feedback about the effects of withdrawals. There were 31 responses, many of which indicated that there were no effects as they had not experienced withdrawals, but from those where there were some details provided the following tables have been compiled. The responses resented are meant to illustrate the type of impacts in question, related to the specific questions asked, rather than a statistically robust sample.

Three questions were asked:

- Did your company carry out any of the actions listed below as a result of REACH registration costs? (appropriate for manufacturers/ importers)
- Have any substances you used or placed in the market in the past been withdrawn?
- Do you expect to withdraw and/or experience withdrawal of any substances in the run-up to 2018?

Most respondents were large firms that had in the surveys characterised themselves as manufacturers in terms of REACH Roles in their responses. However, it needs to be born in mind that manufacturers (as is the case with other REACH Roles) in this sense often perform other REACH Roles as well (see tables 2.3 and 2.7). In the table below, the two columns on the left indicate firm size (L=large, M=medium, S=small and Mi= micro) and REACH Role (M=manufacturer, I=importer and DU-downstream user)**.**

1. Did your company carry out any of the actions listed below as a result of REACH registration costs (registrants - manufacturers/ importers)? If yes, what were the business impacts?

(a) We altered production to register a substance in a lower tonnage to save on or avoid registration costs		
L	M	Moved production of chemicals out of Europe and replaced substances to avoid registration. Currently the impact is low but a tendency to avoid production in Europe has started.
S	DU	Yes for about 30% of our portfolio
Mi	I	We reduced import below certain tonnages and/ or bought surplus through other importers
L	M	So far we reduced the tonnages for only a few substances because it takes time to find appropriate alternatives. The tremendous cost impact urges us to find out alternatives or reduce the tonnage whenever it is feasible.
L	M	Yes, we split production/importation between 2 legal entities
S	M	We kept 2 products below the 100 tons threshold in order to postpone registration cost until 2018. The impact is between 20% and 50% of the volume on these products, meaning a total impact on the company's turnover estimated 2 to 3%.

		Registration cost for these products is equivalent to several years of margin on variable cost (meaning: not affordable). It's likely that we have to take a go/no go decision by 2018.
L	M	Number of substances < 10, minor business impact regarding turnover
L	M	Ca. 10 Substances, business impact is rather low.
(b) We did not cover end uses of customers and only registered as intermediates		
L	M	This was done even for high volume products. There were high impacts for certain clients. Registration strategy has become part of business strategy.
L	M	Number of substances < 20
S	M	This is the case for 1 product. No impact in the business so far, as customers do not really care yet about receiving a product qualified as an intermediate and not fully registered (but they do mention concern about how to respect SCC, as this status is almost deterrent due to the harshness of the associated inspections).
(c) We removed products from the portfolio that were no longer profitable (due to registration costs)		
L	M	Not yet. But for deadline 2018 we expect to discontinue several substances.
S	DU	We removed some substance due to the high cost of the dossier compared to product value
S	DU	We withdrew a substance we were supplying to one customer. It was not particularly profitable but the customer was dependent on us as it is used in an ageing technology. We do not know what the customer has done as a consequence.
L	M	Yes, for one Business Unit it represents 300 k€ turnover, 150 k€ margin
L	M	Initially we had 78 substances to register in 2018. 32 (40.0 %) of them will definitely be withdrawn and for 3 (3.8 %) of them the registration status is still pending. Some of the withdrawn substances will in future be manufactured in our sister companies outside the EU, especially those whose end-uses occur in overseas countries.
L	M	Ca. 30 products. Business impact is the reduction of the portfolio (several specialities). Turnover is reduced. Full impact can only be seen in 2018.
L	M	No, however, we evaluate periodically the REACH compliance costs versus profitability. With the 2018 deadline in particular it may happen that some lower volume substances will not be registered because no longer profitable.
(d) We decided not to register a substance because the hazard profile meant it was not worth registering		
L	M	So far we have not yet withdrawn a substance because of its hazard profile. We feel that this will be the case in future, once the risk management measures to be implemented at our customers, will be communicated systematically and routinely in our extended Safety Data Sheets. For the time being only very few of our substances are listed on the

		'Candidate list' and they are used exclusively as on-site intermediates. But, we are deeply concerned about the intention of the authorities to put additional substances on this list in the future, only because they are characterized by relatively high RCRs and used for 'wide dispersive uses'. We mean the authorities underestimate by far the danger of how much a substance loses its acceptance by the downstream-users very quickly once it is placed on this list.
L	M	Yes, , for one Business Unit it represents 4900 k€ turnover, 2300 k€ margin
L	M	Several products. Some replaced. Business impact low because of alternatives, products would probably have been cancelled anyway without REACH
L	M	No, however with the 2018 deadline in mind it may happen for some lower volume substances that we decide it is not worth registering because of hazard profile.
(e) Other		
L	DU	Sometimes smaller and medium Non-EU suppliers are not familiar with registration duties when importing a substance into EU. They are not aware about the last registration deadline of May 2018. This may cause a potential danger for an existing and qualified supply chain. We have some indications that such an issue exists.
L	M	We decided to not register a number of substances that we import in order to save registration costs, meaning that we decided to purchase from the EU market rather than import from outside the EU, so we have made ourselves dependent on other companies who do have registrations. This slightly affects the profit margin.
S	M	According to our experience, REACH is clearly used by some players on the market as a barrier to competitors or newcomers. As a result, REACH has a result exactly opposite to the general purposes of the European competition policies, and a dramatic impact on the smaller companies that are excluded from the markets. It's also impacting innovation opportunities, as SMEs are in average more innovative, but have to bear higher relative registration costs (we have had to terminate some R&D projects because the impact of REACH would increase total cost-to-market beyond competitiveness limit).
L	M	In our company, registration costs of EU affiliates were paid out of the budget of the non-EU corporate headquarters. In this way, the concerned EU affiliates could absorb the cost pressure from REACH registration more easily. Nevertheless, the attractiveness (for future investments) of our EU sites did obviously not profit from the additional burden.

2. Have any substances you <u>used or placed in the market</u> in the past been withdrawn? What has the impact been on your business?

(a) Registration costs/ requirements		
L	M	One product was only registered as intermediate (Art 18) and could not be used for our customers; so it was eventually cancelled. Due to low amounts business impact was low.
L	M	Yes for one Business Unit it corresponds to 5.3 M€ of turnover and 2.5 M€ of margin
L	M	We switched to a different supplier
Mi	I	Yes, about 5 substances. We lost about 20 % of our turnover. We jeopardized our business relationship with customers
L	M	No, however, this needed sometimes quite some efforts to be achieved (compensation payment, manpower, rearrangement of supply chain), in particular in cases when the supplier only registered intermediate use.
(b) Placing on the candidate list		
S	M	Not yet but we're highly concerned by the case of cobalt salts that are on the candidate list, but are also the key for several new green technologies (e.g. biofuels and some batteries). The case of substances that can be harmful as themselves, but useful (and not always replaceable) for "green" innovations or uses, illustrates how different regulations car play against each other. In general, metals and their compounds, used in energy technologies are mainly heavy metals (and as such subject to restrictions), but have electrochemical intrinsic properties that we need to develop innovation in energy technologies (catalysis for biofuels, solar power, batteries…)
S	DU	We made the customer use another type of substance, but with repercussions on the cost of the finished product because it was formulated with more expensive raw materials.
L	M	One product, this was substituted (re-formulation). No impact
L	M	This product is used to do an analysis that is required by the European regulation. We are actually trying to find another way to do this analysis by using other products.
L	M	We stopped use of HBCDD as a flame retardant for polystyrenes
L	M	Not yet, although we still can purchase all used candidate-list substances, we have received warnings from key suppliers that in case the candidate-list substance will be placed on annex XIV, they might discontinue supply. We therefore started to preventively phase out these substances with correspondingly high efforts in R&D
(c) Authorisation (Annex XIV)		
L	M	Number of substances < 5; mitigation measure: finding other suppliers
L	M	One product which is currently substituted. Could be even a positive business impact.

Mi	I	Yes, (actually the authorization process for 3 substances are ongoing. Too early to decide)
L	M	We stopped use of HBCDD as a flame retardant for polystyrenes
(d) Other		
L	M	Many products are currently supplied on pre-registrations so the full impact can only be seen in 2018.
L	DU	A lot of chemicals still have to be registered in the future. Therefore, the management decisions especially coming from SME's regarding withdrawal for registration reasons will come in the future – near 2018. Another aspect to consider is that connected processes like authorization and restriction are still at the beginning. However, some big companies already now announced that they will not apply for authorization and sometimes will change for that reason the production site outside of Europe.
Mi	I	We believe that (after registration), the authorization process is a very costly, complex and unnecessary action. Our customers are very uncertain about the future (whether these 3 substances will be authorized or not). They DEMAND a guarantee about authorization, which we cannot give.

3. Looking ahead to 2018: Do you expect to withdraw and/or experience withdrawal of any substances in the run-up to 2018? If yes, what do you consider the business impacts will be?

L	M	We expect to replace or withdraw up to 10 substances by 2018. We are about to start communication with clients
S	DU	20% turnover reduction
S	M	If costs have not decreased by 2018, it is likely that our company will face a survival issue. Registration cost for the 20-30 remaining substances we manufacture is estimated between 1 and 3 million Euros, which is far beyond the current net result of the company. It is critical that there be changes to the rules in order to mitigate the impact on SMEs before it's too late.
L	M	We have to register about 45 substances in 2018 and for about 20 (44.4 %) we will be obliged to take over the role of Lead Registrant. Although we had issued requests to all the concerned SIEF members, less than 2 % of them have so far indicated that they may register the concerned substance as well. Based on our experience in phase II, we are deeply afraid to be obliged to register all of them not only as Lead, but as well as only registrant. As a high quality manufacturer of tailor-made chemicals, most of the endpoints in these dossiers cannot be covered by read-across approaches, i. e. most of the study costs of about 70000 or 250000 € for a 1-10 and a 10-100 tpa dossier respectively have to be carried by us! We consider the LoA cost sharing as practised so far in the whole chemical industry in the EU more than ever as deeply unfair (tonnage basis and several non-EU suppliers can register once).
L	M	In the past 30 years most of the worldwide market leaderships in textile, carpet, leather, ceramic and fibre auxiliaries have moved from multinational companies to SMEs in the EU due to innovative strategies pursued in these decades. Now, because of the considerable cost impact, we are obliged to find

		appropriate alternatives within only 2 or 3 years and we doubt that the valued benefits of the former substances will in each case be fully retained by its alternatives.
L	M	Non-withdrawals: higher prices expected, generally less chemicals on the market and less suppliers. Highest impact on low-tonnage speciality chemicals expected. EU manufacturers are at a disadvantage outside the EU. Lots of communication with suppliers about their intentions, trying to get information as early as possible to react if they want to withdraw the product
L	M	Yes, we might do due to the fact that additional requirements from REACH have arisen after the first registration of our product. The impact might be not carrying out development projects which can hinder the company product portfolio development. This will ultimately represent a guaranteed decrease of the business. How much? 5%, 10%, 20%?
L	M	The manufacturing of our main products depends on a substance which cannot be substituted. This substance is currently prioritized for inclusion in annex XIV. Since this is an imported process aid and the Non-EU supplier is not willing to apply for authorization our management has to decide whether we will apply for authorization for our own use or not. This will create additional burden and costs which cannot be compensated by prices of the products. REACH related activities do not have any positive influence on turnover, profit or quantity of sold products. Customers simply expect legal compliance of their suppliers. Therefore it is also not a marketing argument.
Mi	I	If the Commission does not review registration, especially for SMEs dealing with very complex substances with very poor literature and data, often held outside the EU/ EEA, SMEs will not buy Letters of Access. We have about 80 strategic substances (5 @ 10-100t/y, the rest 1-10 t/y) and about 40 borderline 1t/y), so it is impossible to buy Letters of Access, not even for 10% of them because it means hundreds of thousands of euros for a company with a turnover of <€3 million!
Mi	I	We will lose 50 % of our turnover and substances. We will have to sack people or perhaps close our company. The uncertainty and complexity about everything concerning REACH is a killer for further investments. We expect a shortage in certain substances in/after 2018 which will rocket prices or will cause a standstill in production.
L	M	We fear that some of the substances we purchase for our process (like catalysts) will be subject to authorisation and potentially will be withdrawn or only remain available at a higher price.
L	M	We still face situations were suppliers only registered substances as intermediates fulfilling Art 18 (SCC). We have initiated a phase out of SVHC (candidate-list) substances, among other things, because of the supply continuity risk. This involves serious efforts in F&E (note that the substitution of an SVHC ("innovation") does not necessarily improve the performance of a product nor does it lower the price). Many SIEFs for substances below 10 t/a, in which we participate, remain silent. We are afraid that we (as a company with a 100%-compliance policy) will need to carry the main burden of registration, because larger importers or manufacturers (less aware or conscientious companies) are not taking the

		necessary actions.
M	DU	The dyes business segment in our company will need to be reduced: 60 substances out of 150 will not be registered. These substances could be withdrawn without important business loss for us. There are other reasons, e.g. ecological, or they are not profitable products.

4. Further remarks

The responses presented provide an indication of the wide range of business impacts of withdrawals of substances when they occur due to, or are triggered by, REACH mechanisms. Some key points can be identified. In the first place, the overriding impression is the variety of responses, ranging from no impact (or even a possible positive impact) to cases where business survival issues might be faced if a substance is withdrawn, or if due to various costs, companies will have to withdraw substances in the future – for 2018.

It is a very small sample, but the few responses from smaller firms reflect that they are quite highly impacted as they have less cost mitigation options - they can't transfer production abroad or be funded by parent firms based outside the Union, and need to recover costs from a lower turnover. However, it may be that mainly small firms with serious survival issues responded.

Generally speaking, it would appear that the companies responding have been able to adapt, even if there have been reductions in contribution or turnover in instances, due to withdrawals by following a wide range of strategies. However, with the 2018 registration deadline, some of these responses, such as keeping tonnages below registration levels, will no longer be available. Also, concerns have been expressed as regards identifying SIEF members to work with for registration in 2018.

Several expressed the view that the 2018 registration will have a more marked impact on withdrawals than the preceding two registration deadlines because less avoidance options are available, and the resulting business impacts will therefore be greater. In order to ensure that substances are registered and not withdrawn some firms envisage having to make substantial commitments. In some cases, firms think that the resources required might threaten their continued operations and sustainability. Some respondents also aired concerns as regards the effects of withdrawals in reducing competition and disadvantaging SMEs, increasing costs and jeopardising innovation. It was pointed out that substitution ("innovation") in this sense does not necessarily lead to products with better characteristics and may be more expensive.

Although no single overall conclusion can be drawn from this case study as regard the impacts of withdrawals on business as a result of the REACH Regulation, the wide ranging impacts noted show how REACH has had an impact on the operational environment of some firms in the chemicals and downstream industry.

3.4 Objective 4 - Business opportunities

3.4.1 Introduction

The aim of this objective was to assess whether the REACH Regulation led to the opening of business opportunities for European companies within and outside the European market. In addition, examples of best practices should be described as well as the conditions in which the opportunities are more likely to arise. Objective 4 has some overlaps with several other objectives and in particular with Objective 1 "Single Market and Harmonisation" and Objective 2 "External competitiveness" as well as with Objective 6 "SMEs", Objective 7 "Downstream users", Objective 8 "Innovation", Objective 9 "Human resources and consultants" and Objective 10 "SVHCs and authorisations". Some of the information necessary for the assessment has been therefore drawn from the respective sections of the different research tools (CATI survey, online business survey, interviews with firms, industry associations and Member States).

3.4.2 The nature and examples of business opportunities

A business opportunity is the identification of a need and the development of the means to fulfil that need (that could be a new product or service) that leads to begin a business. Considering the different mechanisms of the Regulation, REACH has created the need for:

- Improved information management and information communication systems;
- Testing and analysis of substances;
- Better risk management processes;
- Development of safer alternatives to substances of very high concern.

With regard to the first two aspects, a good part of the workload created by the Regulation has been covered by companies offering specialised consultancy services and technical testing and analysis services. Indeed, all the stakeholders surveyed agree that, since REACH is a very complex piece of legislation with several requirements at multiple levels, companies that have benefited the most are the ones offering consultancy services linked to the Regulation, such as regulatory compliance, lobbying, administration of consortia or chemical risk management. This constitutes a cost that has to be absorbed by the chemical industry as a whole.

Another sector that has benefited from REACH is the technical testing and analysis sector. Eurostat data on NACE code M71.2 "Technical testing and analysis" shows that the sector has kept growing at European level even in the aftermath of the economic crisis. Although the NACE code does not capture chemical testing and analysis only[34], it can be speculated that REACH had positive impacts on these economic activities.

[34] This class includes the performance of physical, chemical and other analytical testing of all types of materials and products, such as: acoustics and vibration testing; testing of composition and purity of minerals etc.; testing activities in the field of food hygiene, including veterinary testing and control in relation to food production; testing of physical characteristics and performance of materials, such as strength, thickness, durability, radioactivity, etc.; qualification and reliability testing; performance testing of complete machinery: motors, automobiles, electronic equipment etc.; radiographic testing of welds and joints; failure analysis; testing and measuring of environmental indicators: air and water pollution etc.; certification of products, including consumer goods, motor vehicles, aircraft, pressurised containers, nuclear plants etc.; periodic road-

As in the case of the testing and analysis sector, in the chemical sector (manufacturing of chemicals and downstream sectors) it is also very difficult to use macroeconomic data to draw conclusions on the economic effects of REACH, whether these are positive or negative, especially in times of economic turbulence as the years of the entering into force of the Regulation. Also at a microeconomic level, it is very difficult for companies to judge the impacts of a single regulation. Indeed, when surveyed on the impacts of REACH on different aspects, most of the stakeholders did not blame negative effects or attribute positive effects to the sole action of the Regulation[35], but have pointed it out as a contributing factor.

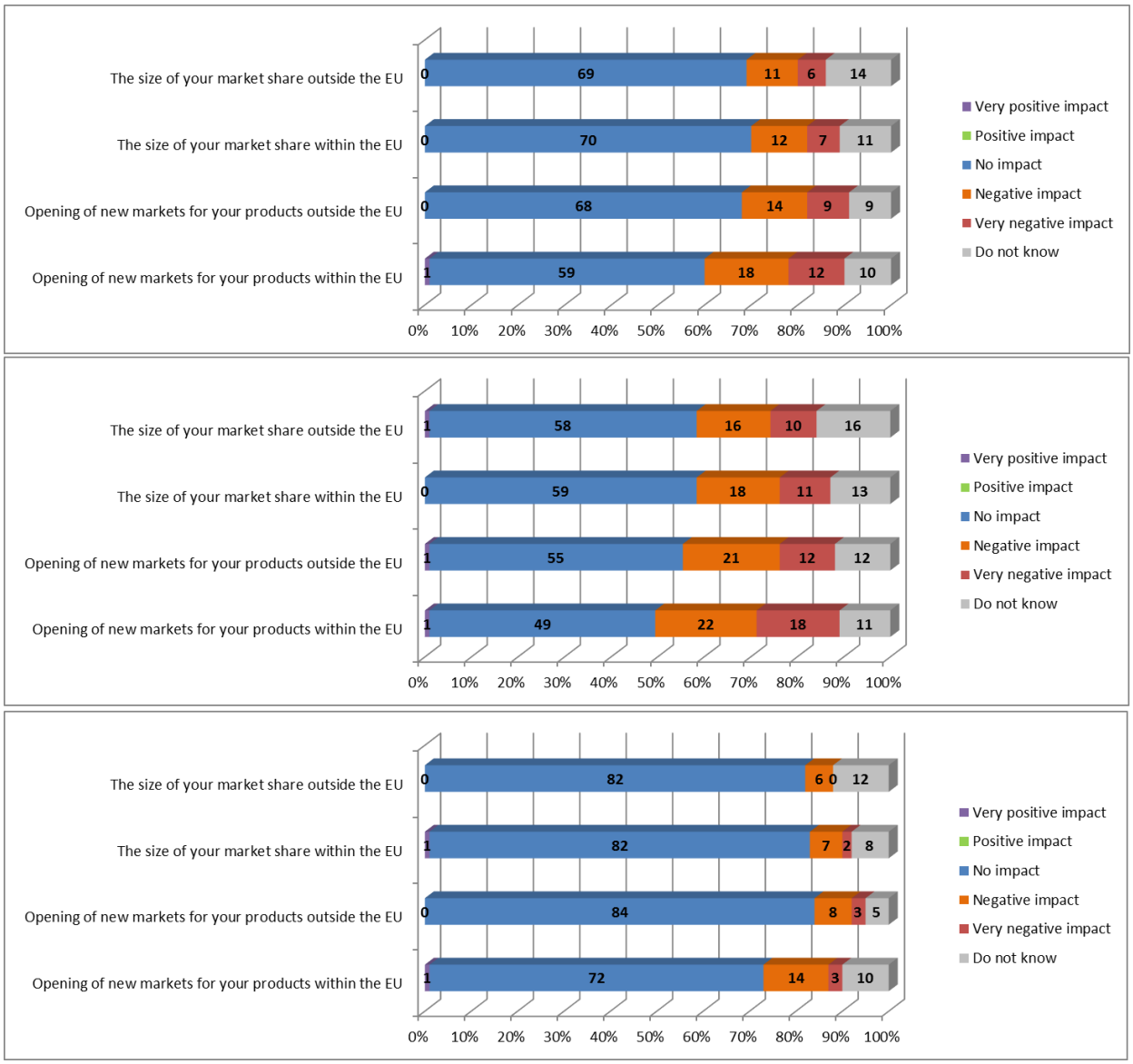
Changes in exports and imports related to the implementation of REACH have been discussed in section 3.1.

When surveyed about the opening of new markets or the REACH effects on their market share, the large majority (between 60 to 70%) observed no impact. It is important to note that a larger share of SMEs has reported negative effects in comparison with large companies: the survey results thus seem to indicate a persistent perception by SMEs of REACH as a very burdensome legislation.

safety testing of motor vehicles; testing with use of models or mock-ups (e.g. of aircraft, ships, dams etc.); operation of police laboratories.

[35] Some stakeholders have attributed specific effects to the Authorisation and Restriction process; these are discussed in the Section "Objective 10 - SVHCs and authorisations".

Chart 3.4.1 What have been the impacts, if any, of the implementation of the REACH Regulation in relation to the following aspects? (Percentage of respondents by company size: all companies, SMEs, large enterprises)[36]



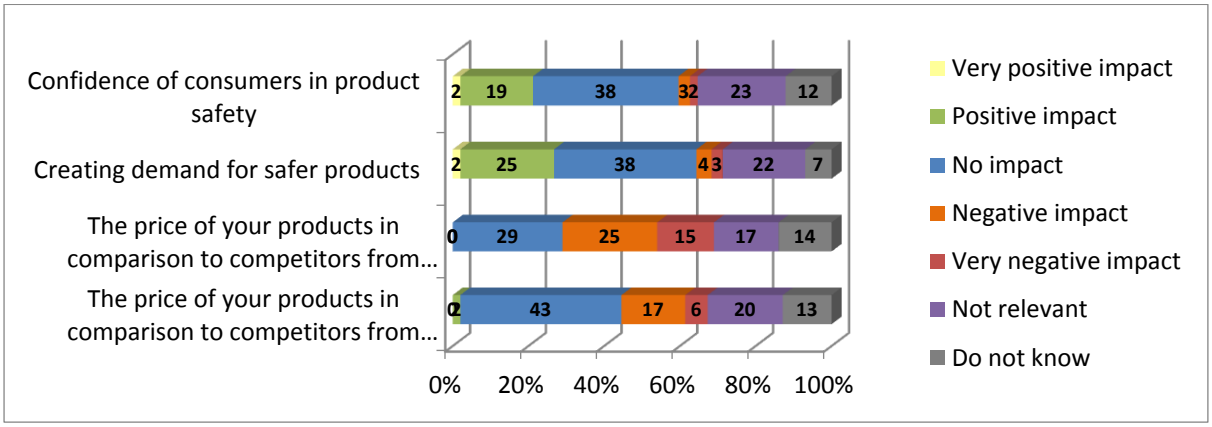
Source: OBS

[36] Between 210 and 223 respondents (depending on the response selected): 109-120 SMEs and 93-101 large companies

Between 23% and 40% of the companies indicated that REACH has a negative or very negative impact on the price of their products when compared to the European and extra-EU competitors' product prices.

Notably, between 21% and 27% of the respondents think that REACH has a positive or very positive impact on the confidence of consumers in product safety and in creating demand for safer products. This is important, as the demand for safer products can lead to the opening of business opportunities.

Chart 3.4.2 What have been the impacts, if any, of the implementation of the REACH Regulation in relation to the following aspects? Percentage of respondents[37]



Source: OBS

While in the view of the majority, REACH did not have an observable impact on the trade level or the market size and did not lead to the opening of new opportunities, between 15-25% of the companies surveyed[38] agreed that the increased harmonisation of the EU chemicals legislation brought by REACH created new opportunities for their businesses in the EU. A follow-up survey found that, except in the case of a handful of these, no concrete results had followed as yet. The creation of business opportunities by the REACH Regulation is further investigated in the case study provided.

Even though not properly fitting in the narrow sense of business opportunity, around 53% of the respondents reported to have improved risk management procedures because of REACH, with another 39% reporting to have improved the management of environmental emissions and waste. In the OBS, more information was required on health and safety aspects (Chart 3.4.4); the results broadly match with the CATI survey findings.

37 Between 320 and 327 respondents, depending on the response.
38 Depending on the research tool: 15% in the online business survey; 25% in the CATI survey.

Table 3.4.1 Contribution of REACH to the improvement of risk management measures and the management of environmental emissions and waste (Percentage of respondents by company size)

Response	SMEs		Large enterprises		All firms	
	Yes	No	Yes	No	Yes	No
Improved risk management procedures in your business	53	47	62	38	56	44
Led to improvement of the management of environmental emissions and waste.	40	60	39	61	39	61
n=	631 av.		385 av.		1,015 av.	

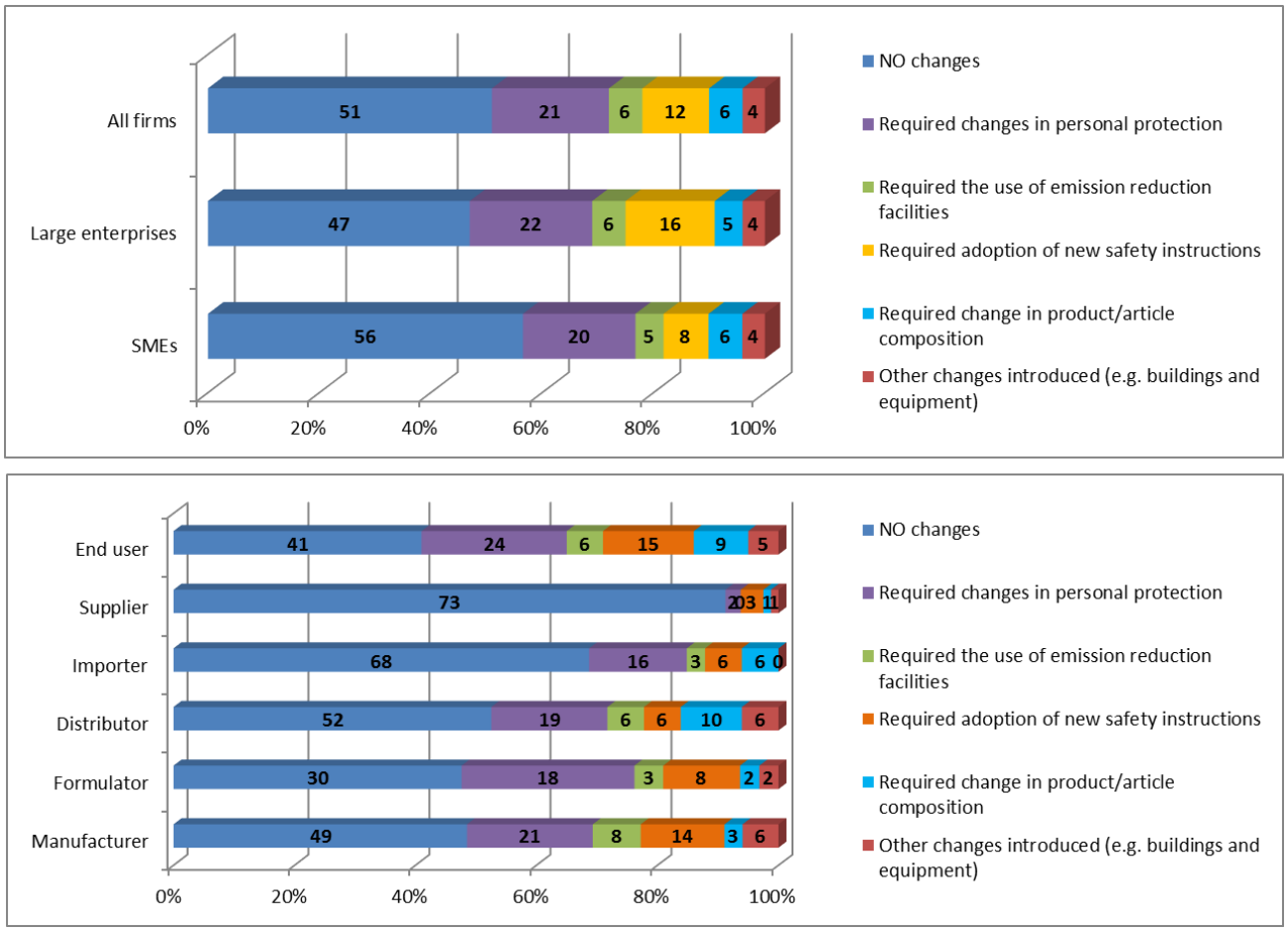
Source: CATI

Of the companies that replied to this question and declared to be SMEs, 44% had made some changes to the risk management measures in place; of the large enterprises, around 53% had to adopt some changes, with personal protection equipment and new safety instruction indicated with more frequency. This is an important finding and certainly constitutes a positive economic effect: various studies have concluded that expenditure on occupational safety and health is an investment that "pays off" and calculated the Return on Prevention (ROP) to be 2.2[39] or the Benefit-Cost Ratio to be between 1.04 and 2.70[40].

[39] Kohstall et al (2013): Calculating the international return on prevention for companies. Costs and benefits of investments on occupational safety and health. DGUV.

[40] EC (2011): Socio-economic costs of accidents at work and work-related ill health, DG for Employment, Social Affairs and Inclusion.

Chart 3.4.3 Has the information received with the eSDS so far led to any changes in your activities to protect health, safety and the environment? (Percentage by company size and REACH role)[41]



Source: OBS

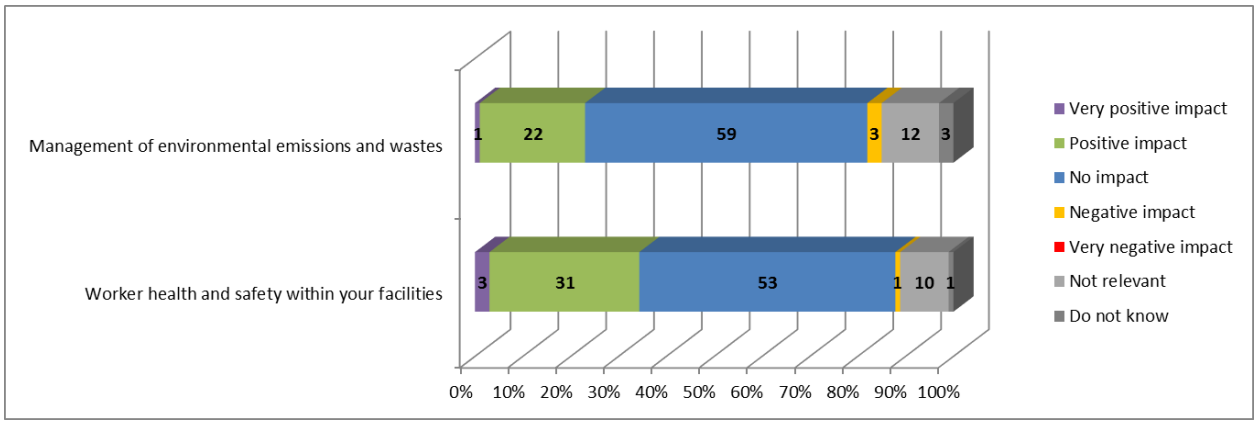
High percentages of companies declaring to be manufacturers of chemicals and formulators as their primary role had to make RMM changes (respectively, 51% and 70%); these shares decrease going down the supply chain but still remaining relatively high (from 48% for distributors to 27% for suppliers of articles), with around one on three companies having to improve their RMMs.

On top of the changes made as a result of new information received through eSDS, the European Environmental Bureau[42] highlighted that companies submitting applications for authorisation usually make improvements to their risk management measures.

[41] 307 respondents: 162 SMEs, 136 large companies and 9 not reported.

[42] Interview with Tatiana Santos (Senior Policy Officer for Chemicals & Nanotechnology at EEB) on 24/03/2015.

Chart 3.4.4 How has the introduction of REACH Regulation affected the following aspects of your firm's operation? (Percentage of respondents by company size (all firms))[43]



Source: OBS

Although overall one out of two companies declared to have had to make some improvement to RMMs, a smaller share of companies (34%) (Chart 3.4.5) reported a positive or very positive effect of the REACH Regulation over workers' health and safety: this might depend on the fact that, although companies had to improve their risk management measures to ensure compliance with the Regulation, they do not necessarily consider that these improvements had any impact on the health and safety of workers or on their environmental management systems. Indeed, during the in-depth interviews, some companies, especially in heavily regulated sectors such as oil and refinery, but also in advanced technologies such as electronics, reported that the risk management measures in place are the ones required by the occupational health and safety and environmental legislation and that REACH did not bring any added value.[44] Other companies argued that they had to change some risk management measures but only because required by worst case scenarios in the eSDS, questioning whether this results in actual exposure or emission changes.

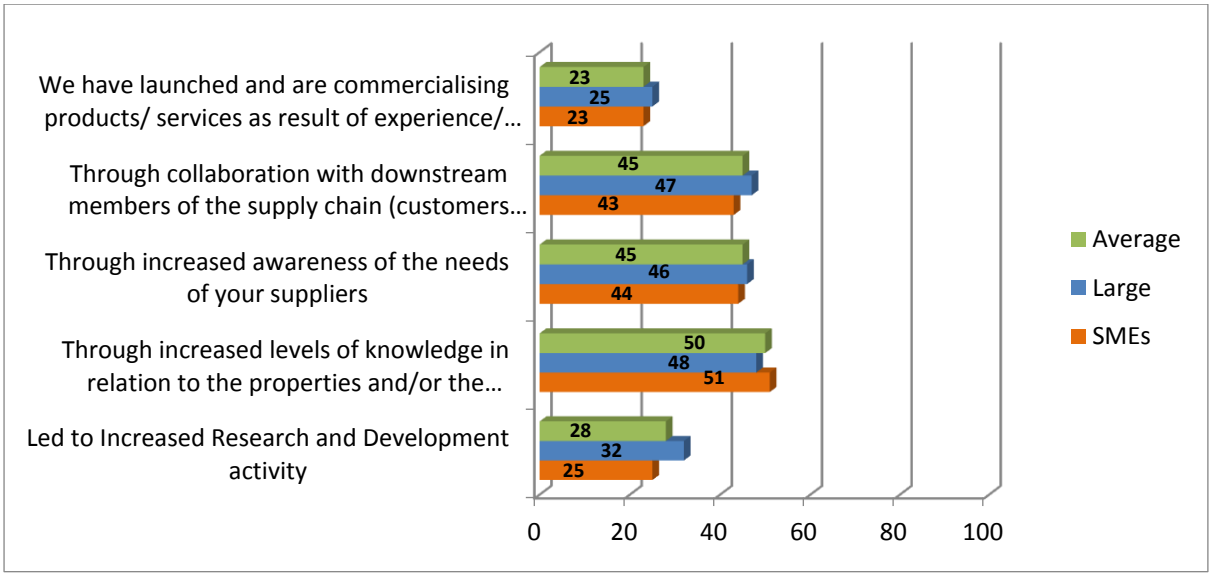
[43] 323 respondents.

[44] It has to be noted that, while this may be true from the companies' perspective, from the viewpoint of society, this information is now documented and available to the authorities to analyse whether regulatory risk management is needed, and (largely) disseminated to the general public.

CASE STUDY 3: BUSINESS OPPORTUNITIES THROUGH IMPROVED SUPPLY CHAIN COMMUNICATION

This case study investigates whether the increase of communication within the supply chain required by the REACH Regulation has strengthened the relationships between actors of the same supply chains and stimulated the creation of business opportunities. In the surveys, companies were asked whether and how REACH contributed to innovation and to the creation of business opportunities. In order to establish whether such opportunities have occurred or are likely to occur to a greater extent for large companies or SMEs or in particular roles in the chemicals' supply chain, the results are presented by company size and role (Charts below).

Chart 3.4.5: Contribution of REACH to innovation and creation of new business opportunities for your firm (Percentage of respondents by company size replying affirmatively)[45]

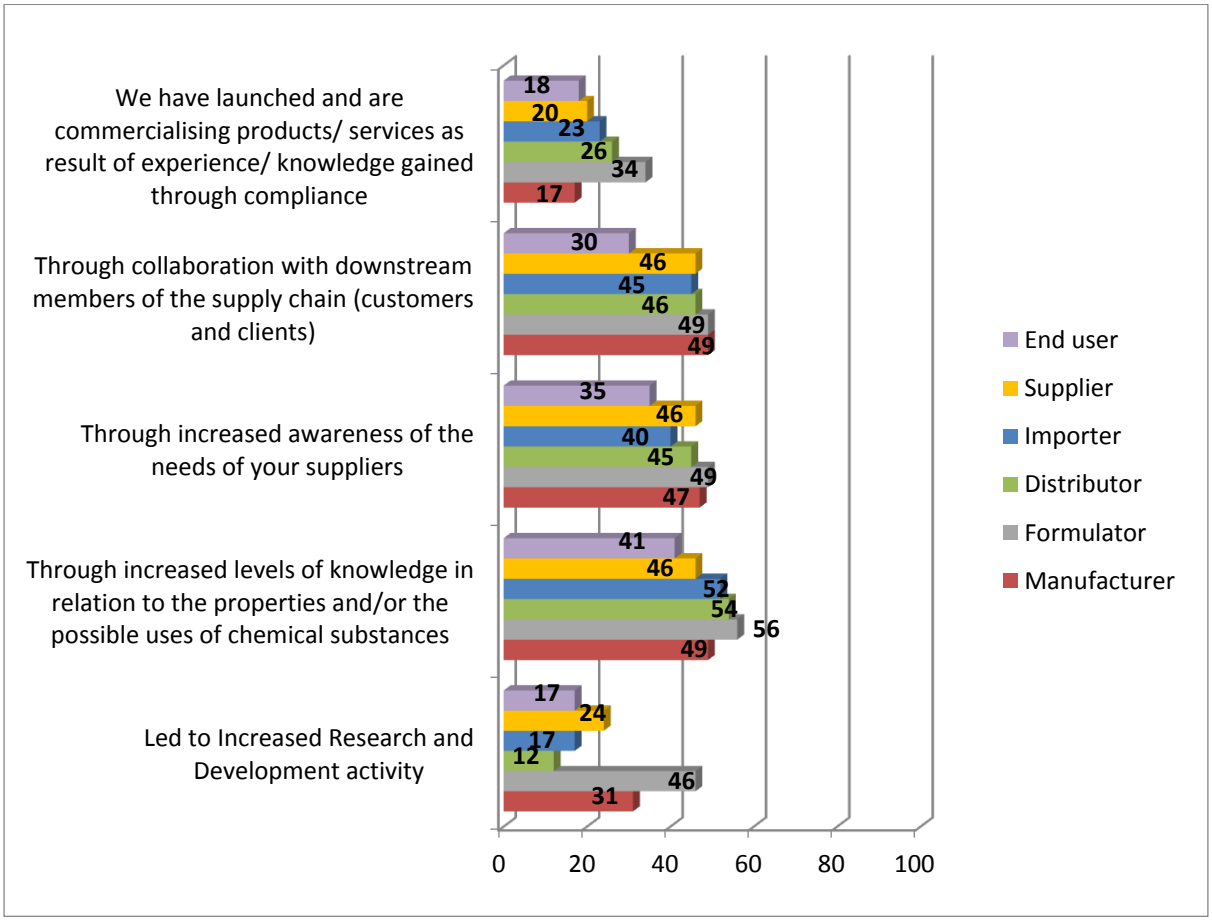


Source: CATI

Around 30% of all firms replied that the Regulation led to an increased activity in Research and Development, with a slightly higher share of large companies (32%) in comparison to SMEs (25%). Almost half of all companies (46%) declaring as their primary role to be formulators and almost one in three (31%) manufacturers of chemicals, reported that REACH led to increased R&D. Indeed, formulators and manufacturers are the categories on which most of the regulatory pressure (especially by the authorisation and restriction mechanisms) is posed. Twenty-four percent of suppliers of articles reported increased R&D as a consequence of REACH: consumers (as opposed to professional end users) are often the larger share of the customers of the suppliers of articles; therefore, these have all the incentives to find suitable alternatives to hazardous chemicals in their applications that might be targeted by regulatory initiatives or public awareness campaigns.

[45] 1,015 enterprises replied to this question, of which 631 were SMEs and 385 large enterprises.

Chart 3.4.6: Contribution of REACH to innovation and creation of new business opportunities for your firm (Percentage of respondents selecting 'Yes' by company role)[46]



Source: CATI

BEUC (the European umbrella group of national consumer organisations) highlighted that thanks to Article 33, the Regulation has provided a very important new instrument to consumers which has an important effect on the supply chain. Retailers are becoming increasingly aware that consumers can ask information on the content of SVHCs in products and these requests have positive impacts not only in terms of the right to know but also on incentives to substitute SVHCs in consumer products.[47]

In spite of the fact that one on three companies reported increased R&D as a consequence of REACH, only 8% of the companies surveyed through the OBS declared that the Regulation had a positive or very positive impact on R&D (Chart 3.4.8). However, in the view of some of the companies and industry associations interviewed, this increment in R&D is not necessarily positive: the search for alternatives to

[46] This question was answered by 1,016 companies: 195 indicated as primary role to be "manufacturers"; 238 "formulators"; 143 "distributors"; 57 "importers"; 237 "suppliers of articles"; 146 "end users".

[47] Interview with Sylvia Maurer (Head of Sustainability and Safety at BEUC) on 25/03/2015.

substances under regulatory scrutiny is seen as very time and resource intensive and as diverting resources from R&D on "real" innovations.

Some stakeholders consider that the hazardousness of some of the substances in their products does not necessarily mean that there is a risk and that the starting of the regulatory scrutiny on the mere consideration of the hazardousness creates regulatory uncertainty and divert precious resources.

Of the opposite view are the EEB and the International Chemical Secretariat (ChemSec), arguing that SVHCs-free products are safer and that hazardous chemicals should be replaced with safer alternatives. ChemSec is also of the opinion that REACH has improved the communication within the supply chain, making it easier for companies to identify new markets and opportunities. From one side, manufacturers of chemicals can get to know the needs of downstream users industries better; from the other side, DUs can work together with manufacturers for more customised products[48].

ChemSec[49] maintains the Substitution Support Portal (SUBSPORT), a project realized in the framework of the European Union's Life programme. The portal aims to provide guidelines to compare and assess alternatives and to present successful examples of substitution. A list of examples referring to SMEs developing safer alternatives has been provided by ChemSec:

- Nordic Paper has developed a technology to mechanically refining the cellulose fibres of paper used for packaging of foodstuff, enhancing its grease resistance without the use of perfluorinated compounds;
- Sustainable Cards Europe launched wood cards to substitute PVC cards used as key cards in hotel rooms;
- OrganoClick developed the Organotex® technology, a water repellent surface treatment which does not contain fluorocarbons and isocyanates, to be used on textiles and other materials;
- Sterisol focused on "active packaging" to eliminate the need for preservatives in their skin care products;
- Tärnsjö garveri is a tanning and leather goods manufacturer that refused to adopt the more time and cost-efficient chrome excel method and kept applying the traditional vegetable tanning technique of leather;
- GreenPan™ is a cookware brand that developed PTFE and PFOA-free non-stick cookware;
- Soyprint substituted petroleum-based printing toners with toner powder derived from soybeans;
- NPT developed a glue alternative to the adhesive used for wood-flooring installation containing VOCs, isocyanates or tin.

When searching for the common conditions on which these experiences of small-medium companies flourished, the *most important factor is probably that these enterprises share the same business culture, with innovation at the core of the business and strategy.* While regulatory pressure might be the initial driver for the research, most of the times companies recognise the importance to gain competitive advantages by producing safer products, saving on chemical management costs and benefiting from a green and innovative image. The exploration of the market to identify the need for greener

[48] Interview with Frida Hök (Chemicals and policy at ChemSec) on 17/02/2015.

[49] In partnership with Kooperationsstelle Hamburg IFE GmbH, The Instituto Sindical de Trabajo Ambiente y Salud (ISTAS) and Grontmij A/S.

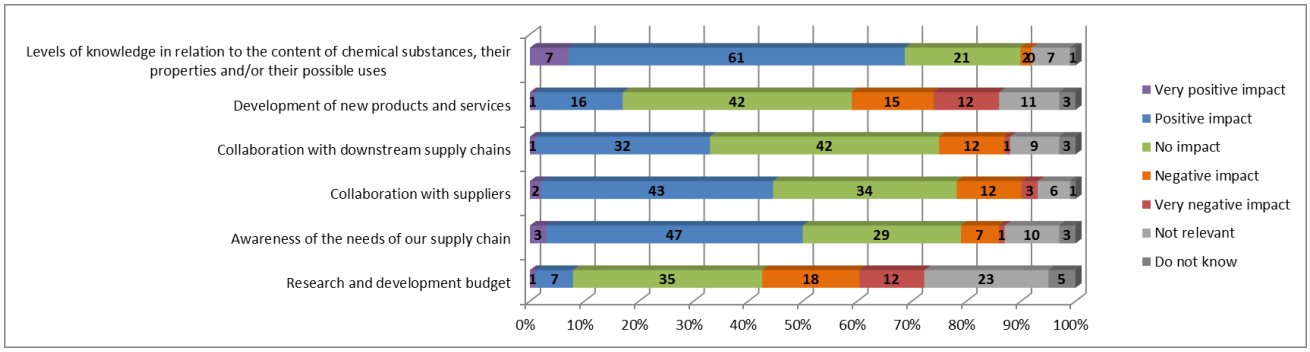
products and services is also very important and this is probably the aspect where public authorities offer most of the support and funds. Across Europe, there are indeed several initiatives focusing on providing assistance to companies (and especially SMEs) in exploring the possibility of substituting hazardous chemicals in products, for example:

- The Eco-innovation observatory funded by the European Commission[50];
- Norden – Nordic Innovation funded by the Nordic Council of Ministers[51];
- Substitution-cmr by Anses, the French Agency for Environmental and Occupational Health Safety[52].

Another crucial factor is the *availability of private funding*: in the absence of supportive private investors, innovation, and therefore substitution of hazardous chemicals with safer alternatives, is not possible. An important role for public authorities would be to bridge the gap between SMEs and private investors: regulatory pressure without adequate financial incentives and subsidies is often negatively perceived by companies and does not trigger virtuous behaviour. It should be noted that private investors have shown their interest in investing in companies researching in greener alternatives to hazardous chemicals.[53]

Beyond the authorisation and restriction mechanisms and the pressure on substituting hazardous chemicals, the Regulation has enhanced the knowledge of the companies on the properties of the chemicals used: 68% reported that the Regulation had a positive or very positive impact on the knowledge in relation to the content of chemical substances, their properties and their possible uses (Chart 3.4.8). Moreover, around 23% of the respondents (of which around 34% were formulators)[54] indicated to have launched and commercialised products/services as result of experience and knowledge gained through compliance with the Regulation.

Chart 3.4.7: How has the introduction of REACH Regulation affected the following aspects of your firm's operation? (Percentage of respondents by company size (all firms))



Source: OBS

50 http://www.eco-innovation.eu/
51 http://www.nordicinnovation.org/no/
52 www.substitution-cmr.fr
53 http://newsletter.echa.europa.eu/home/-/newsletter/entry/3_15_investor-perspective-why-reach-matters-for-your-bottom-line
54 Tables 4.4.5 and 4.4.6.

Between 45 and 50% of the companies surveyed indicated that the increased knowledge over the properties and uses of the chemical substances and the increased communication and collaboration within the supply chain led to the opening of new business opportunities. It should be noted that when asked for examples of business opportunities in the questionnaires, none of the respondents that reported positive impacts of REACH on this aspect provided examples. When further enquired during phone interviews, companies explained that the most positive aspect of REACH is that it strengthened the need for communication among the actors of the supply chains of the substances, leading to a better understanding of the needs and operations of the suppliers and downstream users. In some cases, when regulatory pressure has required investments in research and development of safer alternatives and when the economic situation and the business culture within the companies were favourable, the increased knowledge about the supply chain characteristics has led to the development of new products and thus the creation of business opportunities, as for the cases regarding SMEs reported above.

As for the negative impacts, most of the interviewees are reluctant to attribute determined positive effects or results to the sole action of legislation.

Some companies have developed sophisticated information management systems (e.g. GEMS[55]) to better handle the information flows throughout the supply chain and to collect, manage and report the presence of hazardous substances in their products. This type of system allows the systematic collection of information from suppliers and to provide information to professional users and customers or other stakeholders, in compliance with Article 33 of the REACH Regulation. Moreover, large companies include information disclosure requirements on the content of hazardous substances in the products supplied in their purchasing agreements and contracts. This certainly constitutes an incentive to the other actors in the supply chain to be REACH compliant and provide an effective co-operation. During the interviews, a similar incentive has been reported by some suppliers of articles, referring that in some Nordic countries in order to participate and gain points for public procurement bids, the authorities require "REACH compliance" certificates from the participants.

Although agreeing that the increased communication and collaboration within the supply chain has been greatly beneficial, BEUC highlighted that among retailers the management and communication of information is still very poor and the results disappointing. In a study conducted in partnership with their members, BEUC tested the "right to know" mechanism and surveyed the awareness on these obligations of different retailers[56]. The results highlighted that, at the time, retailers were still unaware of their REACH obligations and, if aware, were still confused in terms of types of information that should be provided to consumers.

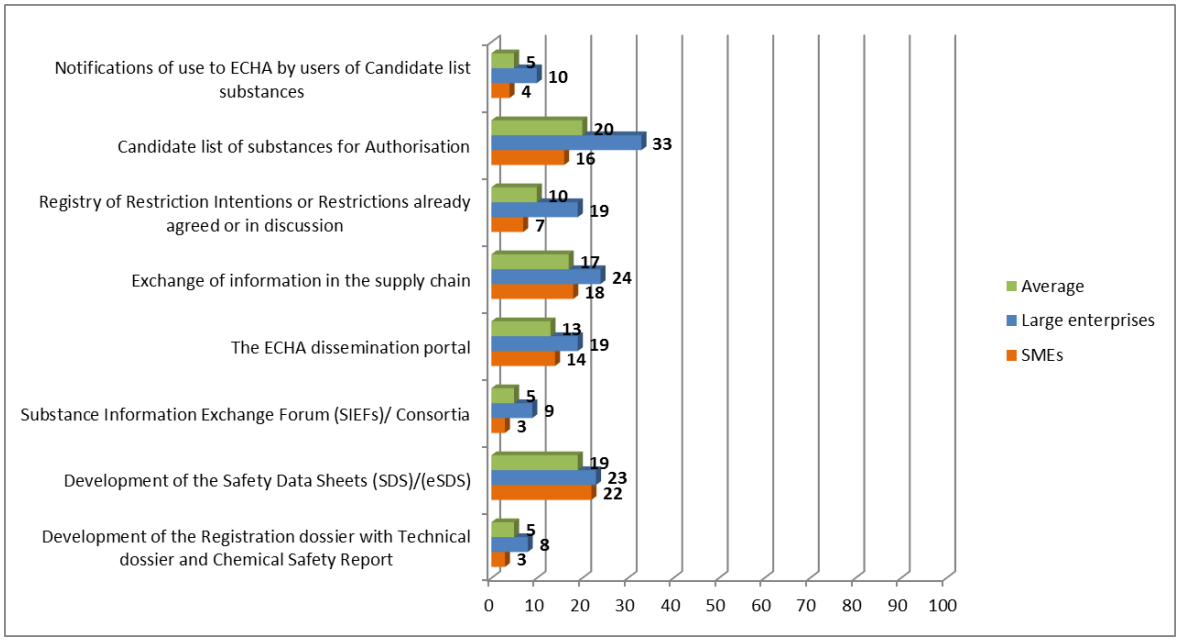
When asked about what sources of information acted as a stimulus to new product conception, development and/or commercialisation (Chart 3.4.9), although between 80 to 95% of the companies did not consider that any of the listed sources triggered business opportunities, some companies reported that the candidate list for Authorisation (20%), the development of Safety Data Sheets (19%) and the exchange of

[55] GEMS (Global Environmental Management System) by Abbott. Information available at: http://prod2.dam.abbott.com/en-us/documents/pdfs/partners/Restricted_Substances_Training.pdf

[56] More information at: http://www.chemsec.org/what-we-do/sin-list/latest-on-sin/829-consumers-qright-to-knowq-tested-companies-asked-if-they-use-any-sin-list-chemicals

information within the supply chain (17%) were useful sources of information for product conception.

Chart 3.4.8: Has the development of, or access to, any of the following sources of information generated by REACH acted as a stimulus to new product conception, development and/or commercialisation in your business? (Percentage of respondents by company size)[57]



Source: OBS

As regards best business practices, companies in the chemical sector periodically monitor the external factors that might help or harm the business, such as legislation, identifying threats and opportunities[58]: the candidate list of substances for authorisation and the exchange of information with the other actors in the supply chains are therefore valuable sources of information for the identification of threats and, potentially, for turning these into opportunities for new business, for example through the development of safer alternatives "designed" around the needs of their customers. Large enterprises seem to undertake this type of analysis and to these sources of information more frequently than SMEs, probably due to the higher availability of resources to dedicate to these tasks.

It should also be noted that any manufacturer of substances or formulator of mixtures holding an authorisation for the use(s) of a SVHC may attract new customers (downstream users) that did not apply for authorisation, as long as the downstream users respect the conditions of the use applied for.

[57] 566 respondents: 246 SMEs, 206 large companies, 114 not reported.

[58] SWOT analysis, see for example: http://ctb.ku.edu/en/table-of-contents/assessment/assessing-community-needs-and-resources/swot-analysis/main

3.4.3 Conclusions

Considering the different mechanisms of the Regulation, REACH has created the need for:

- Improved information management and information communication systems;
- Testing and analysis of substances;
- Better risk management processes;
- Development of safer alternatives to substances of very high concern.

With regard to the first two aspects, a good part of the workload created by the Regulation has been covered by companies offering specialised consultancy services and technical testing and analysis services. With regard to improved information management and information communication systems, quite a lot of work has also been carried out under the CSR/ES Roadmap umbrella, as a form of cooperation between industry associations and authorities[59].

- While the REACH Regulation put pressure on companies to invest money in research and development of safer alternatives and strengthen the communication between different actors in the supply chain, increasing knowledge on substances characteristics and uses, business opportunities arise when these factors are in combination with favourable conditions, such a supportive business culture, availability of public and private investment funds and resources to dedicate to the optimal management of the information.
- Large enterprises tend to have more resources to dedicate to information management and therefore to be in a better position in terms of identifying potential threats or spotting opportunities, beyond being able to influence the dialogue at policy making level. Although there are successful cases of SMEs, with a strong focus on innovation, developing new products in response of regulatory pressure on certain substances, SMEs with consolidated businesses require more attention by regulators. Public funding and the facilitation by the public authorities of the matching between private investors and SMEs through, e.g. substitution research programmes, are therefore recommended and of primary importance. Moreover, during the consultation with the stakeholders, it has been noted that companies active in those sectors with pro-active industry associations, tend to be well informed and had more articulated and less negative opinion of the Regulation, being able to be heard by the national and European competent authorities.

[59] http://echa.europa.eu/regulations/reach/registration/information-requirements/chemical-safety-report/csr-es-roadmap

3.5 Objective 5 - SIEF & Registration Consortia

3.5.1 Introduction

The aims of the study as regards SIEF and consortia are to: describe the pricing policies of SIEF; establish their affordability with regard to various types, sizes, sub-sectors, business models and geographic location of registrants; support the assessment of affordability through an analysis of the structure of SIEF costs and of any additional costs incurred by lead registrant and member registrants; focus on the transparency and communication practices within the SIEF; and analyse the added value of consortia, as well as the reasons for which opt-outs or 'double' registrations have been pursued by registrants. Best practices with regard to SIEF pricing policies, consortia agreements and communication should be catalogued.

3.5.2 Registration, SIEF and Consortia

The core process of REACH is the registration that has to be done by each manufacturer and importer who places a substance on the market in amounts exceeding one ton per year. Information requirements, submission formats and general rules for the registration process are laid down in the regulation itself.

The underlying principle of registration is "one substance one registration" OSOR which generally commits all potential registrants of the same substance to aim at a common registration dossier. This implies that all registrants share the available substance data and/or to generate new, commonly owned data. To support this data sharing, substance information exchange fora (SIEFs) were introduced by REACH.

As a result of the SIEF work one dossier with all hazard data on the substance is to be submitted to ECHA and all registrants can refer to this dossier and only submit a particular part of information, mainly related to the company itself, company specific substance identification and, potentially, the use and exposure information, if relevant. The central dossier is the so called lead dossier. The individual dossiers are called member dossiers (or joint dossiers). REACH also foresees sharing of costs between the members of the SIEF arising from the use of existing data, the generation of new data, and the related administrative work. How this process of data sharing and cost compensation is organised is not regulated under REACH. The approach taken must not be unfair or discriminatory for other market actors and the cost sharing should be performed in a transparent way (Article 30(1) of the REACH text).

Basically two models have been established to organise cost and data sharing:

- SIEF members directly collaborate to register a substance. This approach is frequently taken in practice if only a few businesses are involved and (most) members of a joint registration have the motivation to be active in the dossier development.
- A consortium is formed that gathers the group of active companies to elaborate the lead dossier, while the other potential registrants remain inactive. This approach is frequently taken in practice if many companies are involved and at least some of the companies want to take an active role in the development of the lead dossier. One reason for being inactive is that companies have later registration deadlines and therefore other priorities.
  Furthermore, consortia are often formed if a group of closely related substances placed on the market by similar companies are covered by a registration. This enables the consortium to make effective use of information obtained from non-testing methods (e.g. read-across) and to generate synergies across SIEF borders.

The feedback from the surveys shows some companies are not aware of the difference between a consortium and a SIEF. This is due to the fact that just Letters of Access (LoA) have often been bought from consortia in 2010/13 and no active role has been taken by member registrants. In consequence no difference could be observed by the members of a joint registration. Sometimes consortium membership was made a mandatory pre-condition for obtaining a LoA.

The trend to remain rather inactive in the upcoming 2018 registration is also reflected in the OBS. Most respondents do not see themselves in the role of a lead registrant (see below). While the general expectation is to be involved in more SIEFs in 2018, this is not reflected in a willingness to or awareness of the fact that that the lead role could also be taken, and this was the case regardless of the firm size. It was also observed that companies were not willing to take a very active role in a SIEF (core group of dossier and CSR development). Over 40 % stated they expected never – or rarely 22 % to do so.

Table 3.5.1: In how many SIEF were you (will you be) a lead registrant (percentage respondents)?

number of SIEFs with function Lead Registrant	2010	2013	2018 (expected)
0	53	52	60
1	25	19	6
2-10	29	28	18
>10-100	10	12	13
>100	1	0	0
n =	118	111	97

Source: OBS

With regard to the increasing number of substances that are expected to be registered and the smaller SIEF this could lead to a situation where all companies remain rather inactive and necessary preparatory work to ensure successful registration is either not initiated or started too late. The in-depth interviews confirm that companies who want to start work on registration for 2018 are sometimes finding it hard to identify SIEF members to work with.

According to the CATI survey a material share of the respondents that registered in 2013 were consortium members (40.2 % of the large firms and 20.6% of the SME). This appears to have led to the situation that the terms 'SIEF' and 'consortium' are used synonymously.

3.5.3 Future registration models

Despite the high share of firms that are members of a registration consortium, the OBS feedback suggests that this registration model may be of less importance for the 2018 registration deadline because the number of substances for which the firms indicate they will register in a consortium is decreasing (despite the expectation that a higher number of individual substances will be registered). This might be a consequence of more experience among the registrants that feel confident to organise a registration without

such a structure. Other reasons could be that SIEF are smaller in the low tonnages that will have to be registered and data requirements are far less ambitious (less tests and test design is easier) so that it is the expectation that organisation will be possible with a SIEF. However, the opposite could be the case. Very inexperienced registrants who underestimate the efforts that are required to realise a successful registration might be involved in the 2018 registration. Combined with the observed reluctance to take an active role in 2018 this scenario does not seem unrealistic.

Table 3.5.2: Could you please provide a number of the consortia that you joined? (absolute numbers for different Registration deadline)

No. Of consortia	Large	SME
2010 Registration		
0	7	23
1-10	49	45
11-20	6	1
21-30	2	0
31-40	1	0
> 40	4	0
2013 Registration		
0	21	31
1-10	34	28
11-20	3	0
21-30	2	0
31-40	1	0
> 40	3	0
2018 Registration		
0	21	23
1-10	35	22
11-20	0	1
21-30	0	0
31-40	1	2
> 40	3	0

Source: OBS

In the interviews individual firms expressed the view that, in contrast to the former situations, consortia might not be suitable in their SIEFs because too few registrants are in the pre-SIEFs (less than five) and therefore cost sharing is expected to be much easier than in the past (also because the registration tonnages do not spread over so many tonnage bands and hence the data needs are very similar for all registrants and, of even more importance, far less expensive and complex test data are needed to register in tonnage bands below 100 tpa).

There were several advantages perceived from being a consortium member (see table below). However, especially SMEs indicated that the main advantage is the possibility of being involved in decisions on the dossier. In principle it must be noted that this could also be achieved in a SIEF and consortium membership is not a requirement of the REACH Regulation, but in practice as stated above it was a precondition to become involved.

Table 3.5.3 Advantages from joining a consortium

	Large	SME	All firms
Main discussions were only carried out in a small core group	39,0	34,0	36,7
Contractual agreements protected intellectual property and clarified responsibilities	39,0	21,4	31,0
No specific added value but it was a precondition to be actively involved in dossier development	13,8	31,1	21,8
Other (please specify)	8,1	13,6	10,5
n =	123	103	229

Source: OBS

Several "other reasons" are mentioned in the OBS as well, related to extra work going beyond the actual registration, such as discussions on substance sameness[60], preparation of a safety data sheet, coverage of various EINECS entries, documentation of assessment approaches and deviations from standard data requirements.

These experiences with SIEF and consortia were also reflected in issues raised by industry associations and member state authorities as presented in the table below.

[60] Note: Although being mentioned in the survey, in practice this task is essential to form a SIEF and decide which substance it covers as well as to evaluate if studies apply to a substance.

Table 3.5.4: Types of issues firms have most often raised in relation to the operation of SIEFs and consortia (Industry associations, share of respondents indicating that specific issues have been raised by their members in relation to the operation of SIEFs or consortia).

Issues	SIEFs		Consortia	
	MS Authorities	Industry Associations	MS Authorities	Industry Associations
Participants demanding too much money for data	81.5%	34.6%	51.9%	57.7%
Additional/unexpected costs	51.9%	42.3%	40.7%	53.8%
Communication problems	70.4%	76.9%	29.6%	42.3%
Issues with protection of intellectual property/confidentiality	22.2%	23.1%	14.8%	34.6%
No transparency of decisions	44.4%	42.3%	33.3%	46.2%
n	27	26	27	26

Source: Industry associations' survey/ Member State authorities' survey

In general, it can again be seen that working through a small core group facilitating the work on the registration dossier in consortia leads to less complaints on communication problems. Still, there is a somewhat contrary picture on the benefits of consortia. On the one hand some companies claim that the main advantages are based on clear structures and that communication seems to be clear while on the other hand some companies see the situation as exactly the other way around. With regard to issues on cost it is also difficult to come to a clear unequivocal conclusion that firms are more satisfied in the case of SIEFs with or without a consortium. MS authorities stated that complaints on cost are raised somewhat more frequently with them when registrations were carried out by a consortium (complaint on cost: SIEF 35%, Consortia 57%). Industry association reported the opposite trend (SIEF 81% Consortia 51%). This might be due to the fact that with regard to SIEF, associations cannot clearly be identified that are active in relation to a specific substance and the MS authorities are often seen as a more neutral institution that can take up such issues. Still both reported a high level of complaints on cost for both types. This might be a bit different in the case of consortia as these often cover a segment of substance were a sector association exists (e.g. metals, refinery substances). But overall the activity of associations either in SIEFs or consortia was rather limited (26.2 % have been involved in setting up SIEFs; 19 % in consortia).

Problems that were addressed by associations with regard to SIEF/consortia management were: a lack of experienced staff, chemical experts are lacking experience in economic aspects of SIEF/consortia management and costs are not accepted (the impression was that too much money was requested for data). It was often the expectation that registration would only be a formal issue rather than being part of a business model which means that many companies only see the costs as a problem. On the other hand, it was often not explained in detail where the costs originated and how

they were composed. This lack of transparency on cost of Letters of Access has already been reported in the frame of the REACH-Review.

As a result of this ECHA and the Directors Contact Group developed Guidance on good practice of data sharing on a working level[61]. On a legislative level the EU Commission at the moment is developing an implementing regulation based on Article 27(3) and 30(1) that is meant to set a frame for fair, transparent and non-discriminatory data sharing.[62]

3.5.4 Opt-outs

Costs were the main reason for companies to opt out of a joint registration for larger firms, but also an important factor for SMEs. A reason that was more important for SMEs was their concern about sharing confidential business information (see below).

Table 3.5.5 What were the reasons for your decision to opt-out from the participation in one or more SIEFs for the substances you registered in 2013? (percentage of respondents)

Reasons for opt-out from SIEFs:	Firm size	Yes	No	n =
Concern over sharing commercially sensitive information	Large	26.1	73.9	23
	SME	**43.5**	56.5	23
	All	34.8	65.2	46
Disagreement with the lead registrant on the selection of information provided	Large	13.0	87.0	23
	SME	8.7	91.3	23
	All	10.9	89.1	46
It would be disproportionately costly to submit this information jointly	Large	**47.8**	52.2	23
	SME	26.1	73.9	23
	All	37.0	63.0	46
Other reason	Large	**60.9**	39.1	23
	SME	**56.5**	43.5	23
	All	**58.7**	41.3	46

Source: CATI Survey

Other reasons for opt-outs that were mentioned in the CATI survey showed that there still is a high degree of uncertainty related to the basic obligations, roles and processes of REACH as in fact reasons were given that do not represent opt outs as used in the REACH text. Firms stated:

- Decision of a corporate centre (alone no valid reason for an opt out)
- No registration or pre-registration yet (not an opt out)
- Costs were as high as own dossier
- Substance identity differed / Impurity profile of the SIEF did not match with the own (which is rather a SIEF split than an opt out)

[61] See paper on Fair, transparent and non-discriminatory cost sharing in SIEFs (DCG, 2014) http://echa.europa.eu/documents/10162/13559/dcg_fair_transparent_cost_sharing_en.pdf

[62] At the time this report was written draft Regulations were under discussion in the CARACAL (see Doc. CA/49/2015 18th Meeting of Competent Authorities for REACH and CLP (CARACAL), 23 – 24 June 2015 CCAB, Brussels, Belgium), assessable in CIRCABC https://circabc.europa.eu/faces/jsp/extension/wai/navigation/container.jsp?FormPrincipal:_idcl=FormPrincipal:_id3&FormPrincipal_SUBMIT=1&id=4de8ca26-4856-4ccd-abee-896ff63cb9f6&javax.faces.ViewState=rO0ABXVyABNbTGphdmEubGFuZy5PYmplY3Q7kM5YnxBzKWwCAAB4cAAAAAN0AAI3NXB0ACsvanNwL2V4dGVuc2lvbi93YWkvbmF2aWdhdGlvbi9jb250YWluZXIuanNw

- Different uses were covered (not an opt out in the meaning of the REACH text – data could have been shared and CSR sharing is not mandatory- so this could have been handled within one registration).

This shows that as regards registration, capacity building still needs to be in the center of activities to avoid unwanted developments due to a lack of understanding of the processes.

3.5.5 Conclusions

- It is not possible to make a general conclusion as to whether organising registration through a SIEF or a consortium is better. There are indications that in some situations consortia are more suitable and others where SIEFs seem sufficient and will reduce bureaucracy.
- The willingness of SMEs to play a more active role in registration is limited. This might lead to a situation in 2018 when in new SIEFs nobody becomes active with the result that registrations will not be made or have to face significant problems due to a (too) late start of the process.
- Rules for cost sharing are widely accepted by many companies, there is still a significant share of firms that claim costs are a problem.
- Cost sharing rules should be critically reviewed and if considered unacceptable changed. In such cases these changes should also be applied to existing members (with the consequence that some members of registration organisations will be reimbursed while other might need to pay once more for existing registrations). An assessment of cost sharing models could also contribute to the future Commission work to ensure transparency, non –discrimination and fairness in data sharing.
- Opt out can be justified in some cases but the principle of one substance one registration should be the guideline for all registrants and it should be critically checked if justification is sufficient for an opt out (preferably before provision of registration numbers to single registrations).
- Member states and associations should concentrate on capacity building with regard to registration in 2018 as there is still a lack of basic understanding of REACH which in practice is a source of problems both in SIEFs and consortia.

CASE STUDY 4: SIEF AGREEMENTS AND & REGISTRATION COST

Background

Approaches to facilitate successful registrations under REACH and to share data were established for the registration deadline in 2010 and were in principle also applied for the registration deadline in 2013. The survey results generated for this study show that a significant share of market actors consent to the rules developed under the approaches (Guidance on SIEF formation, questionnaires to categorise SIEF members, model SIEF agreements including cost sharing). However, another relevant share of market actors criticises the current SIEF agreement practices especially with regard to the resulting costs. According to their comments the cost implications of SIEF agreements strongly depend on the specific situation of a firm (importer or not, company size, tonnage band to be registered).

The basis of complaints on cost sharing is the REACH prerequisite for cost sharing to be: fair, transparent and non-discriminatory.

The interpretation of these three terms has been discussed very actively by many actors and the most commonly rules accepted by many firms are that *fairness* is ensured if the mechanism of cost sharing is the same for each market actor who takes part in a joint registration, and *non-discriminatory* means that everybody is allowed to take part in the registration. Consequences on market access are usually not discussed in this context which results in different assessments as to whether the approaches taken are adequate or not.

The issue of *transparency* is not discussed here in detail but only mentioned as a factor that is the cause for a high level of uncertainty as regards exactly what costs are assigned to which cost package (administrative – technical). This has consequences for how SIEF members need to pay a share of these costs.

Aim of the case study

This case study aims to demonstrate the effects that current SIEF agreement practices and in particular the respective cost compensation methods have on different market actors. Impacts of some elements of commonly used cost sharing agreements are illustrated by examples of cost calculations and other elements are qualitatively discussed. Conclusions regarding the impacts are provided in relation to the different economic situations a specific market actor is in.

The case study is based on free text survey results, interviews with firms, associations and additional interviews with services providers[63] that are active in registration support as well as the consultant's own experiences in this regard.

Basic cost sharing models

In this case study we define the "Total SIEF costs" as the sum of all expenses of all SIEF members required to prepare a joint dossier. These are broken down into *administrative costs*; which include the sum of all resources (man – days and material costs) required to manage the SIEF and prepare the registration dosser; and, *technical costs*, which include the sum of all resources (man-days, testing costs, consultant costs etc.)

[63] Input was kindly provided by Kerstin Heitmann, UMCO Consult, Hamburg in an Interview in June

necessary to technically compile the joint dossier. The borderline between technical and administrative costs is not always clear.

The OBS firms provided data on which activities needed to register a substance resulted in which share of the overall SIEF costs. Among these, there are costs that can be clearly allocated to SIEF work and costs that are (usually) not covered in SIEFs (like costs for SDS development and registration fees); the latter are not discussed here. For those costs clearly originating from work a SIEF is intended to cover, assumptions on the respective overall cost shares are derived based on the OBS data.

The following assumptions[64] are made regarding the shares of the technical costs (relative share of total SIEF costs)

- Cost for the preparation of the (joint?) registration dossier: 19 %
- Costs for gathering the information according to the Annexes[65]: 13 %
- Cost for the CSA/CSR: Hazard assessment and preparation of (basic) Chemical Safety Report: 13 %

Assumptions on the shares of the administrative costs made in the case study are:

- Costs for liaising with Downstream Users: 32 %
- Joint registration and SIEF admin costs: 23 %

In the following some general considerations on the two cost types will be discussed.

One observation from the data collected in this study is that the share of technical costs in the overall expenses for a letter of access were usually rather lower, while administrative cost were significantly higher than estimated when REACH was under development (COM 2002[66], chapter 13). Consultants reported that especially the costs for information gathering according to Annexes IX and X were often very low, as non-testing strategies were applied or only testing proposals have been provided initially. Whether or not these strategies were adequate to produce data that enable regulators to finalise risk assessments on substances remains uncertain at this phase of REACH implementation. Currently a report published by the German competent authorities[67] indicates that at least the final evaluation of endpoints with relevance for CMR and environmental hazards is difficult due to a lack of information.[68] In the latter cases the cost consequences of testing decisions was often not yet reflected in cost sharing agreements and might shift such cost towards the future if authorities demand these

[64] Assumptions were based on real life examples of cost sharing agreements. They were not questioned with regard to new developments on cost sharing that would e.g. allocate the costs for liaising with DU to technical costs as it is a mandatory requirement to describe life cycles in the CSR. With regard to demonstrate the effects of the sharing mechanisms this was found to be negligible by the author.
[65] Costs for relevant hazard information according to the REACH Annexes VII to XI and depending on waiving possibilities (testing costs, costs for interpretation of study results, developing robust study summaries etc.)
[66] COM 2002: Assessment of the Impact of New Regulations in the Chemical Sector, Final Report – June 2002 prepared for European Commission – Directorate-General Enterprise
[67] UBA 2015: REACH Compliance: Data Availability of REACH Registrations Part 1: Screening of chemicals > 1000 tpa
[68] It should be noted that the study is based on a screening method without in depth assessment. Nevertheless, there were cases observed were relevant data just were not provided or non-testing strategies were not justified.

later on. It cannot be assessed, on the basis of the data collected, to what degree resources to develop non-testing strategies and gather information were allocated to administrative or technical costs (e.g. by having meetings among active registrants where such proposals or non-testing strategies were developed). As indicated earlier, it is not always clear how the costs were and are allocated; hence this may lead to some uncertainties regarding the cost assessment.

Technical Costs

Technical costs can vary depending on the degree of complexity of the assessment required for a substance. In cases where many studies on a substance already exist, there is a need to collect available information, prepare an extensive literature review and to identify the most relevant ones (the key studies). Such efforts can be well demonstrated and are generally accepted among the co-registrants. The same is true for standard testing and/or the generation of new endpoint studies by laboratories. Costs for such services are usually well documented and can be explained within the SIEF. In general, expert work is trusted and seen a valuable. Whether or not this is always justified is difficult to judge, but often the persons that represent a member registrant are not experts in the related issues themselves so acceptance can sometimes also rely on perceived justification of a price.

The degree of acceptance is sometimes lower for evaluations of older studies that have been prepared in a non-REACH context. It was sometimes described that such studies were evaluated as if they had been prepared explicitly for a registration and consequently were priced as if they were a new study. Such practices seem to be inappropriate given the fact that 12 years after a registration data can be used in REACH registrations without compensation.

Administrative Costs

The administrative costs comprise some costs that need to be incurred to organise the SIEF. These are e.g. cost for contacting other SIEF members to agree on issues, do the contracting etc. Other costs that are included in this category are costs for meetings, etc. which will not apply to every registrant to the same extent. I can be assumed that e.g. meetings to organise data acquisition will be less relevant for registrants in smaller tonnage bands.

Sometimes it is also not completely clear how costs are treated. Here some examples:

- Cost for contracting (negotiating on the price for the study, set up a contract etc.) on the rights of a study – these costs can either be assigned to the study costs and would then contribute to technical costs or become part of the overhead.
- Meetings to discuss data waving on an endpoint – again this could be treated as meeting time (administrative) or time for technical discussion and then be assigned to the technical costs.
- The generation of the LEAD-Dossier and the often provided CSR. This also remains unclear in some cases and registrants do not benefit by this work to the same degree (a CSR is not needed by all registrants, and the same is true for specific sections of the LEAD dossier).

With regard to cost sharing two general approaches have been used in existing registrations:

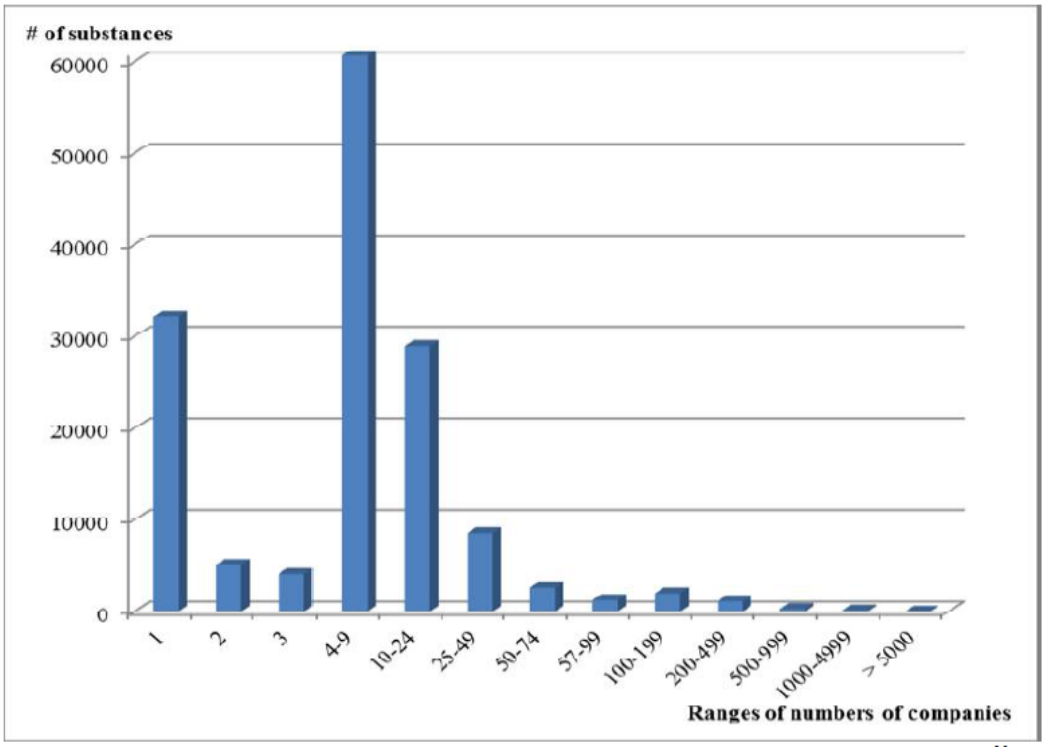
1. Cost sharing based on equal shares
2. Cost sharing based on tonnage (band)

Sometimes a part of the cost was shared as a fixed part and the other one was shared by tonnage (band). In some rare cases additional rules have been included for SME.

Examples of cost sharing models

The top 20 SIEF in terms of the number of SIEF registrants, according to data from ECHA,[69] includes SIEF with over 400 members registrants (calcium dihydroxide, ethanol) to SIEF with about 170 registrants (gasoline, styrene). The majority of SIEF are in fact much smaller. According to data presented in the REACH review 2012 and based on an ECHA analysis, most of the SIEF consisted of 4-9 companies. As it is widely assumed that in 2018 the SIEF will also be rather small, the effects of cost sharing agreements are shown for a "small" SIEF consisting of 5 registrants with different company sizes are illustrated.

Chart 3.5.1: Size distribution of SIEFs related to the number of substances (Source COM 2012)



http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/review2012/commission_report_en.htm)

[69] http://echa.europa.eu/regulations/reach/registration/registration-statistics/most-frequently-registered-substances

Methods and setting for modelling the SIEF agreement effects on registration costs

In this part of the case study the effect of different cost sharing approaches on the individual companies is demonstrated.

Overall cost setting

The overall cost situation which is applied for the examples is based on the data collected in the study and is defined as follows. Hence, it is a hypothetical illustration for a "model SIEF".

Table 3.5.6 Accumulated costs in the model SIEF for the registration of a substance

Cost category	rel. share [%]	Costs [€]
Cost for preparation of Registration Dossier	19	38,000.00
Cost for CSA/CSR	13	26,000.00
Costs for gathering the information required in the relevant Annexes (VII to XI), thereof	13	26,000.00
Annex VII	10%	2,600,00
Annex VIII	20%	5,200.00
Annex IX	35%	9,100.00
Annex X	35%	9,100.00
Technical costs total	***45%***	***90,000.00***
Costs for liaising with Downstream Users	32	64,000.00
Joint registration and SIEF admin costs	23	46,000.00
Administrative costs total	***55***	***110,000.00***
Total	**100**	**200,000.00**

Types of registrants

In order to illustrate SIEF agreement effects, including a reflection on the individual company situation, the member registrants are defined as companies of different sizes for all approaches.

Table 3.5.7 Registrant structure in the model SIEF (5 Registrants)

LR[70]	2,000 tpa
MR[71] A:	1,000 tpa
MR B:	200 tpa
MR C:	20 tpa
MR D:	2 tpa

[70] Lead Registrant
[71] Member Registrant

The three models are presented here. They differ in terms of allocation for technical and administrative costs. All three models were applied in 2010 and 2013. Other models with similar rules exist but are not further discussed here. The exact calculations are shown in Annex B.

The models were:

Cost sharing Approach 1 (basic model):

- Administrative costs are shared equally by head count
- Each registrant has to pay for the data he needs for his registration tonnage
    - Study costs are shared by tonnage band
    - CSR costs are shared from 10 tpa on

Cost sharing Approach 2 (variation of administration costs):

- Differentiation of all costs by tonnage bands (factor 10 – according to lowest tonnage in each band)
- Basic fee for administration (equal for all by head count, 5 % of overall costs)
- Note: costs for the CSR are also assigned to the lowest tonnage band

Cost sharing Approach 3 (Variation of data sharing costs):

- Differentiation of data costs by tonnage bands (factor 10 – according to lowest tonnage in each tonnage band)
- Differentiation of CSR cost by tonnage bands only for tonnage bands that need the CSR (factor 10 – according to lowest tonnage in each tonnage band)
- Administration costs equally shared (equal for all by head count)

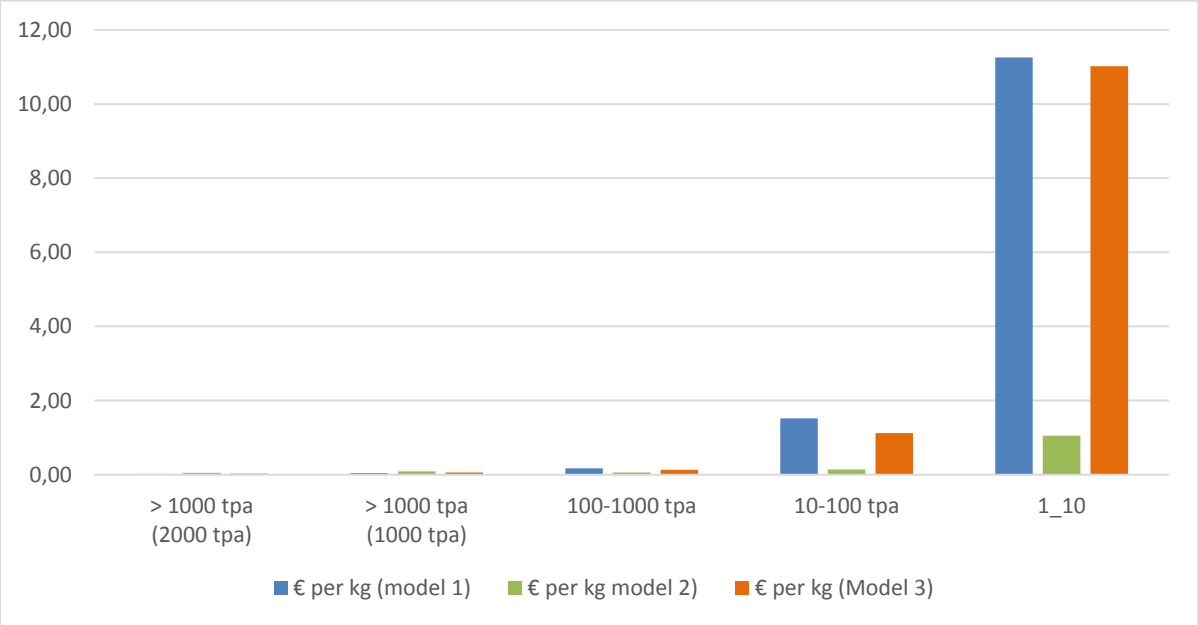
The example shows some important trends for the evaluation of fairness and non-discriminatory cost sharing of these models:

In general, and independent of the applied approach, the SIEF costs per kg substance are similar for companies registering in a similar tonnage band, regardless of the actually manufactured or imported tonnage. In other words, the cost differences resulting from different tonnage bands are higher than the differences based on the actual tonnages.

In addition, firms registering in the highest tonnage band benefit from the fact that no additional cost sharing tiers are introduced (e.g. a company that has just over 1000 tpa has to pay the same as a company with amounts 100 times as high – with higher tonnage the costs per kg decrease rapidly). This results in a competitive advantage for companies with large actual substance volumes.

If the aim of fair and non-discriminatory cost sharing is to arrive at similar costs per kg/substance a staggered cost sharing model (model 2)[72] may be the best approach (see chart 3.5.2 that compares the overall cost of the three models). It shows that although all models lead to the highest cost in low tonnage bands, the staggered approach leads to the highest level of equality.

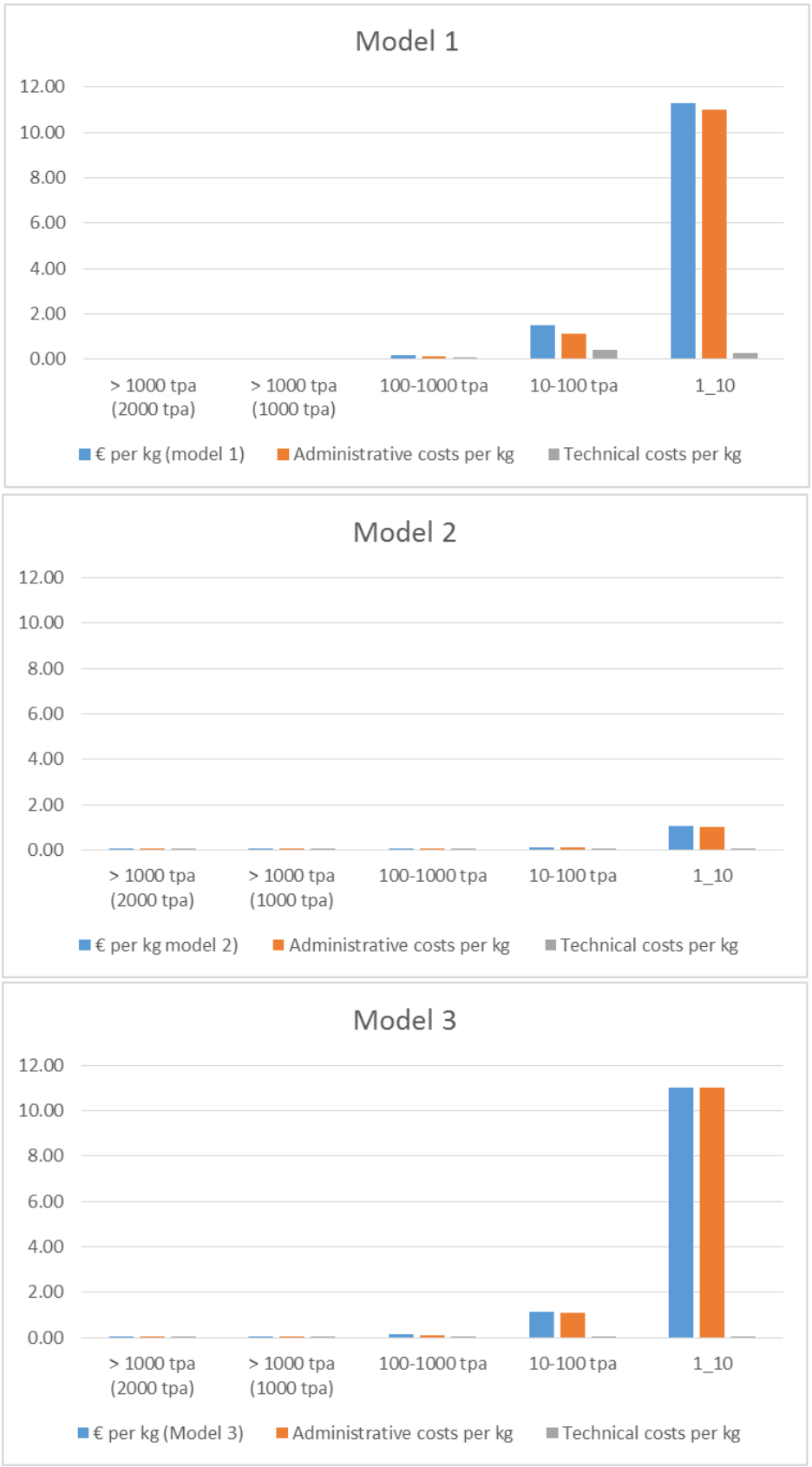
Chart 3.5.2 Overall cost per kg substance [€/kg]



A closer look at the results makes it clear that the largest impact is caused by a fixed basic cost share (usually administrative costs) that is only based on headcount and not related to tonnage.

[72] A staggered model would share all costs, technical and administrative, by tonnage band (costs are set in relation to the tonnage bands and then share by heads in the respective tonnage band).

Chart 3.5.3 Absolute Cost shares of different models to overall costs (in € per kg substance, note: all graphs scaled to the same x-axis)



Elimination of any basic fixed fee would lead to a complete elimination of difference between tonnage bands. This means, that a registrant with 5 tpa would have the same additional costs due to registration as a registrant with 50, 500 or 5000 in the example. Differences then will only be observed within a registration band due to the fact that various tonnages are covered (there will be a factor of ten between 1 tpa and 10 tpa, and the same between 10-100 and so on). Still, such an effect would lead to a higher degree of equality and is basically the same that can be observed when the registration fees are compared.

So basically two observations can be manifested from the model calculations:

- The higher the registered tonnage, the lower the extra cost from SIEFs (ratios for extra cost between highest tonnage band and lowest range from 1:21 to 1: over 500 (see tables above).
- The three cost sharing models also increase the inequality between registrants within a tonnage band with regard to extra cost (also by a factors between about 20-fold and several a 100-fold).

With regard to the ratio it can be stated that 1 kg of a registration of 1000 tpa carries about € 0.02 registration fees while a kg in the lowest tonnage band (10 tpa assumed as best case) has to carry € 0,12 (ratio 1:6) for a large firm and still € 0.064 if a micro firm benefits from reduced fees (ratio 1:3 best case).

Two additional aspects which may influence the registration costs per tonnage are discussed in the following paragraphs. These are:

1. If the LoA purchased by a market actor may cover several legal entities or only the one company actually buying it (affiliate rule).
2. If a fixed additional charge is implemented on each SIEF member per year (often this were 10 % of the initial price of the LoA)

The effects of both rules will be discussed in the following.

Affiliate rule

The model SIEF agreements provided by CEFIC[73] comprise a rule for firms with various affiliates, specifying that enterprises with more than one legal entity that need to register the same substance only have to compensate the costs for the LoA once and for the tonnage band of the affiliate with the highest tonnage band. Hence they can use the same LoA for all their member registrations. This could be the case if an enterprise is located in one member state of the EU and has other legal entities for certain business activities in other member states. In such cases enterprises often hold various firms (own legal entities) to establish clear managements structures within a unit. Depending on the degree of integration of such legal entities it can be the case that management decisions mainly come from a central division of the enterprise (this has also been reported in the surveys on REACH issues) or the individual firms (affiliates) are rather independent market actors.

[73] http://cefic.org/Files/Publications/REACH_SIEF_Agreement_02.06.09_final.doc

With regard to REACH registration obligations and payment of fees it is clear that the reference is to the legal entity even if it is part of a larger organisation. In this respect the standard SIEF agreement model mainly used in 2010 and 2013 frequently differs from this principle. This can result in a significant reduction of the number of SIEF partners (all affiliates count just as 1) who are obliged to compensate costs.

According to the database of registered substances, in the active SIEFs the number of legal entities and the number of covered enterprises[74] varied in a range of 1:3 to 1:2. In one case there were 99 legal entities with an active registration but derived from the company name they just represented 68 "enterprises" (i.e. 31 affiliates). In another case, 22 registrants were represented by 11 enterprises. If such cases are observed typically one enterprise represents 2-3 affiliates the maximum that has been found was a ratio of 1:7 and 1:6. The firm that is covering several affiliates will be called a "holding" in the context of this case study.

A ratio of 1:6 is used for the calculation in the example. The actual data and calculation are shown in Appendix B.

An obvious and simple observation of the affiliate rule is that the overall number of "heads" compensating the overall costs is reduced (in reality more registrants exist and have to pay registrations fees). The calculations show that the reduction of paying SIEF members mainly causes higher costs to the actors in the lower tonnage bands. This is due to:

- Lower tonnages by which additional costs could be compensated
- The increase of administrative cost as these are often shared by headcount (partly or completely)

At the same time, it is likely that large firms benefit more from the affiliate rule than smaller ones, because the respective business model is most frequently represented by them. This is indicated by a random analysis of the ECHA database of registered substances.

The effects become especially obvious in SIEF that are very small and comprise firms that are active in different tonnage bands (as in the example). Although the rule applies to all firms that are in the SIEF and therefore treats everybody in the same way, the rule implies a certain degree of structural unfairness by large firms over SME, as it is one specific criterion of SME to act with a certain regional limitation (which does not necessarily mean that costumers are located only in one country of the EU) and have a low degree of organisation.

Additional charges

In many SIEF it is normal to impose additional charges on the cost for obtaining a letter of access for registrants joining the registration after the initial registration date. These only depend on the effective date of obtaining the right to use the data for a registration[75]. This rule applies regardless of the actual REACH registration deadline which may be still several years in the future. It is often argued in favour of the charge that early registrants cannot use the money they spent for the registration to generate additional profit; hence they are compensated for potentially lost interest rates by late-

[74] As is assumed based on the company names published
[75] So if a company joins the registration four years after the initial registration an extra charge has to be paid on the price of the initial LoA costs.

comers to the registration, who benefit from their work (and invest). Another reason in favour of the charge is that a certain pressure on late-comers is deliberately intended to push firms with longer registration transition periods to register earlier and to reduce the administrative burden in the years after the initial registration.

In general, the basic principle of having such extra charges is accepted by most actors but there have been complaints that the additional charge is often unreasonably high, e.g. in the order of 10 % per year in comparison of the initial LoA price. Some interviewees reported that due to the charge the price of a 100-1000 tpa LoA in 2013 had almost reached the price of a > 1000 tpa LoA back in 2010. Although this practice has been already declared discriminatory[76] it has been applied frequently and is still valid for many SIEF[77].

Sometimes it is claimed that the extra fee is introduced to compensate the inflation for originally taken invests. The charge is much higher than the inflation rates, which can therefore not be used as justification: Since 2010 the inflation rate has never exceeded 3.1% (2011[78]). The European Commission recently adjusted its fees with reference to inflation by 1.5 %[79]. So it could be concluded that a similar compensation for the registration costs in a SIEF might be justified.

In the context of this discussion it is often stated that firms with later registration deadlines would be free to make early registrations to avoid additional charges. Furthermore, it is stated that additional registrants would reduce the initial cost per firm as the initial headcount will be increased. Both statements are correct indicating that there are even stronger reasons than saving money that hinder registrants from early registration and let them rely on the tiered registration approach. This is not further discussed in this case study.

Summary and conclusions

The assessment of cost sharing rules in SIEF shows that some of the conditions established in 2010 are unfair and discriminatory when comparing the registration costs / kg substance in relation to the registration tonnage. It can be concluded from the model's calculations and qualitative discussions that:

- The way costs are treated among the members of a joint registration can have a significant effect on the cost of a product and therefore lead to discriminatory conditions for small companies with low tonnages.
- The cost per ton of registered substance varies significantly between actors in different tonnage bands (up to a factor of 100).
- Equal cost sharing of administrative cost by headcount is a main driver of inequality
- Tonnage band of REACH can be insufficient to ensure equal cost sharing. These tonnage bands include a factor of 10. Above 1000 tpa there is no differentiation

[76] See decision of the board of appeal case A-017-2013 https://echa.europa.eu/documents/10162/13575/a-017-2013_boa_decision_en.pdf

[77] Service providers confirmed that this practice is still in place, also in new agreements. No refunding has been reported due to a change of such a rule.

[78] Compare Eurostat (retrieved 22.06.2015) http://ec.europa.eu/eurostat/tgm/table.do?tab=table&plugin=1&language=en&pcode=tec00118

[79] See Commission Implementing Regulation (EU) 2015/864 of 4 June 2015 amending Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (Text with EEA relevance) eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.139.01.0001.01.ENG

anymore. Therefore, very large companies (with regard to tonnage) do benefit from current practice very strongly.
- Cost effects of all models presented are limited for SIEF members registering in the same tonnage band (similar market position). With regard to 2018 one can conclude that new SIEFs will consist of market actors that all register in one or only two tonnage bands, so the differences in the cost sharing models will be lower.
- The current practice of cost sharing and allocation of costs can lead to a disproportionately high burden for registrants in the low tonnage bands.
- These practices may distort competition in the market and lead to discrimination in markets where large enterprises and SMEs are active).

For 2018 this leads to two basic economic scenarios:

- Registrants join an existing SIEF where cost sharing rules were already established in 2010/13. New firms will most likely have to accept cost-sharing rules based on similar mechanisms as the ones that have been exemplified in this case study. Past experiences have shown that newcomers in such SIEF had to accept these cost sharing agreements because often there was no willingness to negotiate by the existing registrants. The only way to deal with this was to challenge the agreements as unfair and discriminatory at the board of appeal. This approach seems too formal for many especially small firms and might lead to an opt-out which is also not in the interest of these companies (in fact they want to be part of the joint registration but at costs that are more or less the same based on the amount of product).
- New SIEF are formed for registration purposes in 2018: An assessment should be performed to what degree firms are in different positions. It can be expected that registration tonnages only vary from 1-100 tpa (in two tonnage bands). Therefore, a higher degree of similarity between market actors can be assumed. Still it would be recommendable to choose a cost sharing model that leads to a maximum degree of equality among all members regardless of the specific composition of the SIEF (for example if market shares change or tonnage bands have to be increased because the demand for a substance has increased – so the model chosen should not just consider the existing tonnage bands but also possible changes in tonnage bands that might be required by SIEF members).

Whether or not a registration is economically profitable seems to be more dependent on other factors than the SIEF agreements on cost sharing. These comprise the share of registration cost on price of product:

- For bulk products (larger 1000 tpa) the cost increase was in the range of €0.05/ kg €50.00/t) which is in the area of 5% if the substance has a market value of 1000€/t and will decrease very fast with higher tonnage.
- REACH registration costs are one time cost only and decrease over the years. A company needs to have the financial capacity to cover the investment in the year of registration.
- If markets are smaller the impact of registration will be larger. Then profitability depends very much on the end markets. If end markets are under high competitive pressures margins are already low for the substance and an increase in the price cannot be realised[80].

[80] This becomes more obvious when end markets are outside the EU and competitor products do not have to cover EU regulatory costs. Price is then deciding if market success can be achieved. Note: this is often even true for competing products that consist of other substances that have less beneficial properties for health and environment

3.6 Objective 6 - SMEs

3.6.1 Introduction

The aims of this section are to: describe and assess the roles of SMEs in relation to REACH, including additional dimensions, such as economic conditions in specific Member States; conclude on the major concerns in relation to the implementation of REACH and order those thematically according to the specific REACH related process to facilitate targeted policy response; and, establish if SMEs have specific constraints in fulfilling these roles and if these are specific to the companies fitting into the SME definition (or SME sub-categories) or are of a more general nature.

The category of "SME"[81] as defined by the European Commission encompasses a very wide range of types of enterprises. In many respects, it is a problematic way to categorise firms because it may include on the one hand a highly profitable high tech micro firm doing a global business; and at the same time a local or regional business with 245 employees that is struggling for survival. The effects of REACH on SMEs, and their responses to the Regulation, reflect this heterogeneity.

The table below sets out the distribution of (non-financial) SMEs in the EU in terms of firm size (by number and percentage), according to number of enterprises, employment and value added at factor cost. This makes explicit the importance of the role played by SMEs in the overall economy of the EU in terms of number of enterprises and employment. It also makes clear the disproportionate level of value added by large firms. This has implications as regards the resources available in SMEs as opposed to large firms for absorbing regulatory costs and burdens.

Table 3.6.1 Main indicators on SMEs in the non-financial business economy, EU28 (2013)

		Micro	Small	Medium -sized	SMEs	Large	Total
Enterprises	**Number of enterprises**	19,969,338	1,378,374	223,648	21,571,360	43,517	21,614,908
	Percentage	**92.4%**	**6.4%**	**1%**	**99.8%**	**0.2%**	**100%**
Employment	**Number of employees**	38,629,012	27,353,660	22,860,792	88,843,464	44,053,576	132,897,040
	Percentage	**29.1%**	**20.6%**	**17.2%**	**66.9%**	**33.1%**	**100%**
Value added at factor cost	**Value €**	1,362,336	1,147,885	1,156,558	3,666,779	2,643,795	6,310,557
	Percentage	**21.6%**	**18.2%**	**18.3%**	**58.1%**	**41.9%**	**100%**

Source: European Commission: *A partial and fragile recovery, Annual Report on European SMEs, 2013/2014,* p.15.

[81] As defined in EU Recommendation 2003/61

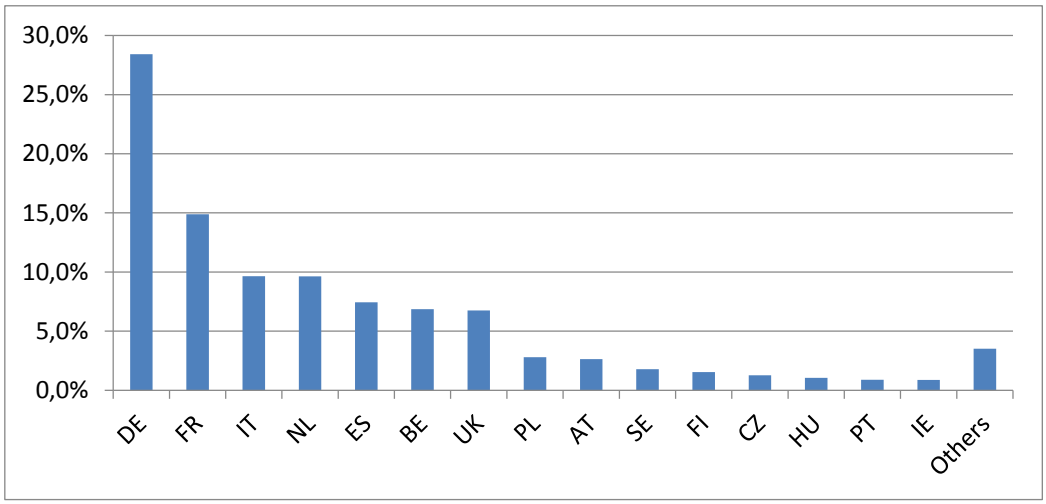
The table makes a further important point that is relevant for reading and interpreting the results that follow in this sub-section (and the rest of the report): when generalising from a percentage response in the case of large firms, e.g. "50% of large firms said …" the number of enterprises affected is very much smaller than when saying "50% of SMEs said …" because the absolute numbers underlying the percentages are widely different.

3.6.2 The roles of SMEs in Member States in relation to REACH

Table 2.10 summarises the responses by firm size of CATI and OBS surveys, and tables 2.4 and 2.7 suggest that SMEs in the chemical industry are spread throughout all REACH roles.[82] This makes clear that a small manufacturing company may also be, for example, a formulator, an importer and a distributor. However, it is less likely that smaller firms will be manufacturers due to the relatively large capital requirements compared to service activities. Generally speaking, the manufacturers are larger than the average firm in the EU. Also, there are some important differences in their distribution between Member States.

These differences can be illustrated by reference to the following three charts. The first sets out the share of sales in the chemical industry in 2014. The second presents the breakdown of firms by size in terms of percentages in the 28 Member States, and the third breakdown is in terms of number of firms by size (data underlying the second and third charts are presented in appendix C).

Chart 3.6.1 Chemical sales by Member State (% total)



Source: CEFIC/ Chemdata International (2014)

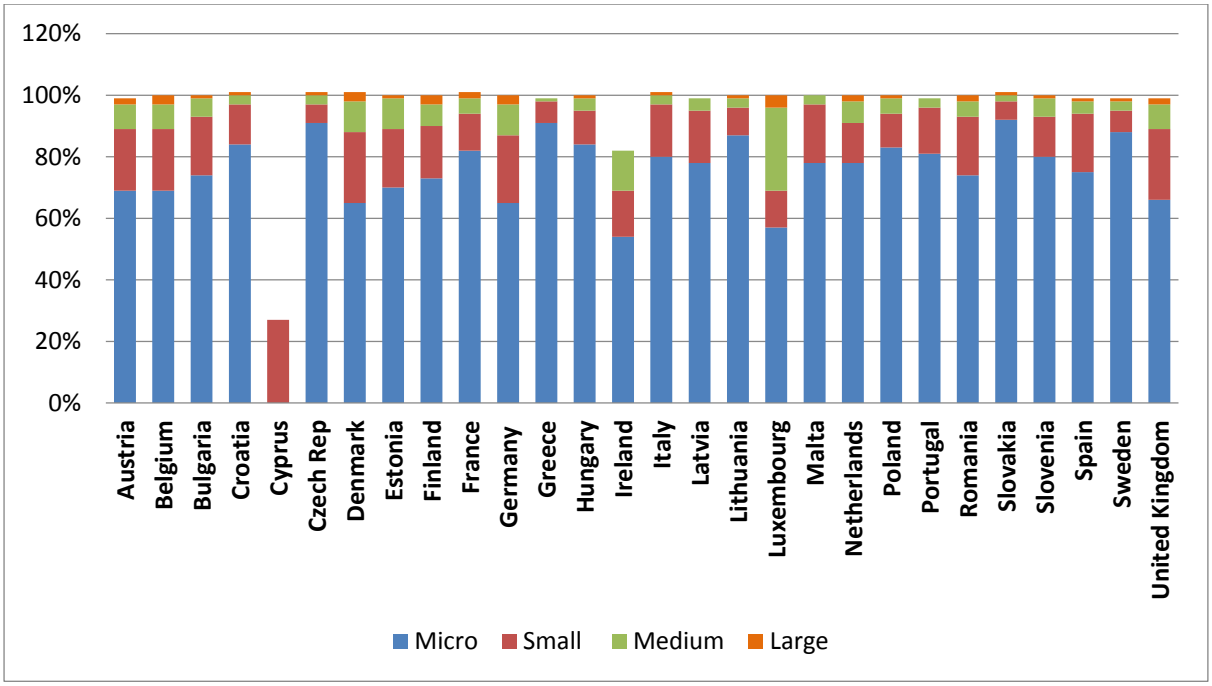
[82] It is worth repeating, at this stage, the point made in section two following table 2.10 which is that while the overall share achieved as regards SME responses from the survey is satisfactory, within the category of SMEs the largest share of responses was for medium-sized firms, with less for small and micro-firms. While this may reflect that fewer small and micro enterprises have come into contact with REACH at this stage, it does also highlight the challenges involved in obtaining feedback from small and micro firms and makes the point that while survey responses represent the broad SME category as a whole, representativeness in terms of the sub-sectors of the category in terms of, particularly small and micro firms is at a lesser level. Hence the qualitative information received in terms of in-depth interviews and follow up contact with such firms, and feedback from other stakeholders, has been of importance.

When looking at the distribution of firms in terms of firm sizes for chemical production between Member States, probably the most noticeable feature is the number of firms, and in particular micro-firms, present in Italy. Italy, with 9.6% of EU chemical sales, has 20,576 micro firms, compared to France with 14.6% of sales and 9,700 micro firms and Germany, with 28.4% and 8,564 micro firms. Italy has a similar share of EU chemicals market to the Netherlands which has 2117 micro firms. Poland, with about 2.5% of the market share, has a similar amount of firms to France and Germany.

To the extent that small and especially micro-firms are impacted differently by the REACH Regulation as compared to larger firms, there is therefore a clear difference in impact between Member States as a result of differences in the distribution of firm sizes.

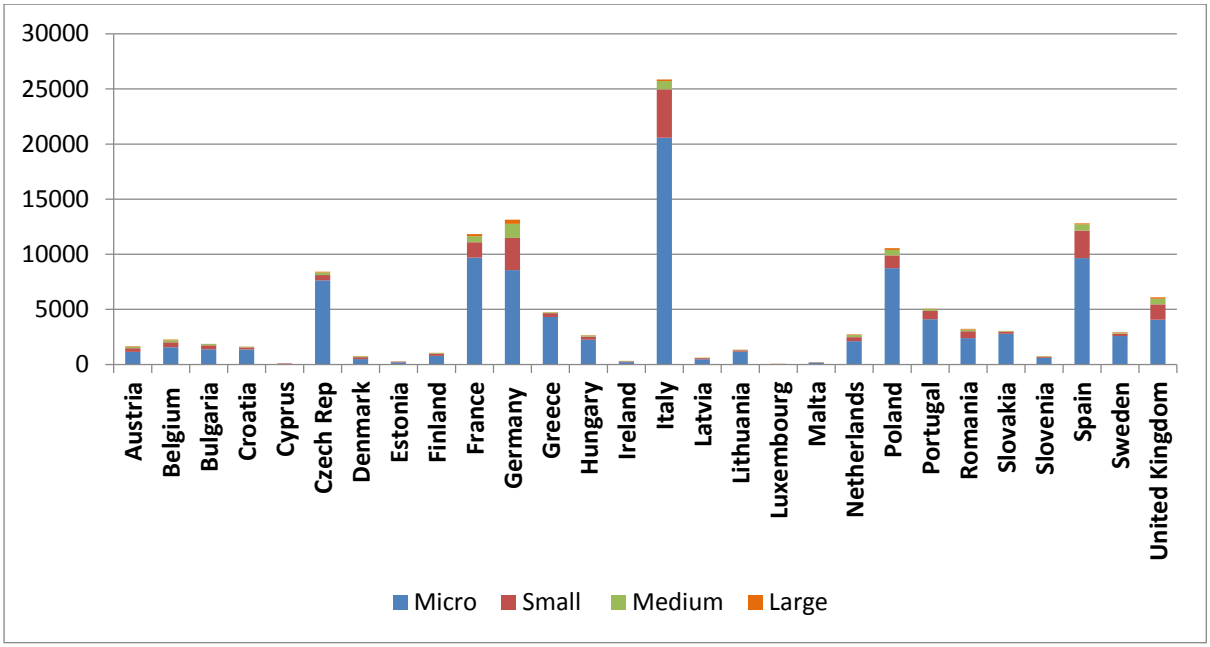
This applies across the board for all the "objectives" under consideration in this study: Single Market effects and harmonisation, international competitiveness, registration costs, business opportunities, SIEF and consortia, through to downstream users, innovation, human resources and consultants, SVHCs, support and registration in 2018.

Chart 3.6.2 Breakdown by firm size (% shares) in the Chemical Industry (NACE 20&22)



Source: Eurostat (data not available for all shares for all Member States)

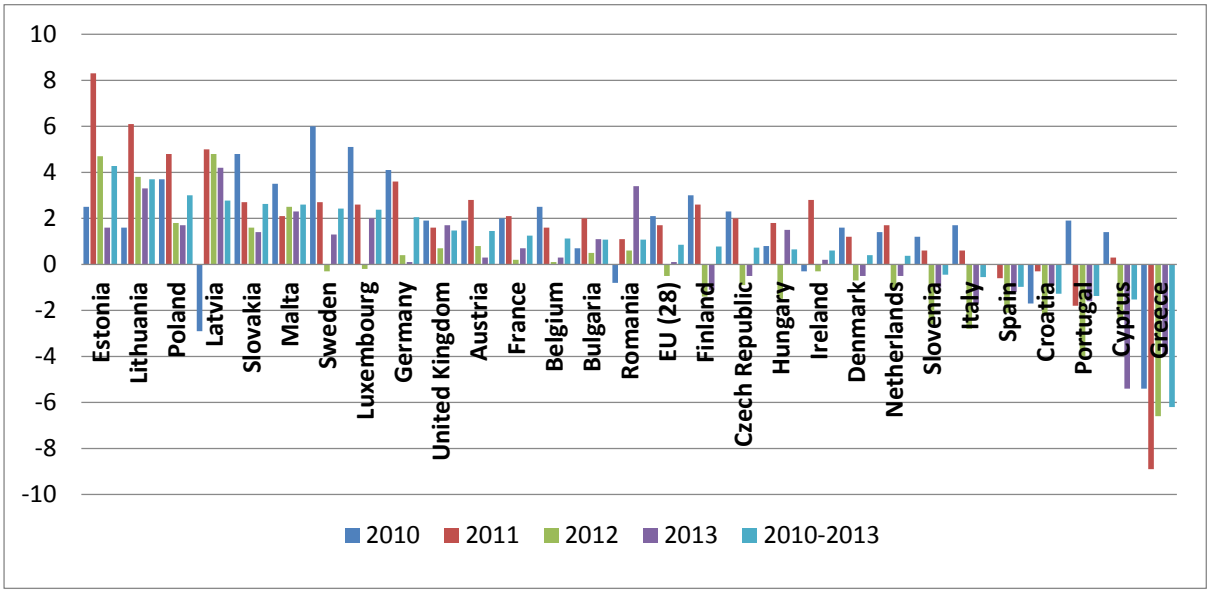
Chart 3.6.3 Breakdown by firm numbers and size in the Chemical Industry (NACE 20&22)



Source: Eurostat

The terms of reference also suggest that the economic conditions in Member States be brought into consideration. In this respect, the table below sets out annual GDP growth rates for EU Member States from between 2010-2013 and the average for the four years (from highest lowest average). The EU average over that period was 0.9%, with some countries where there are high levels of chemicals sales such as Germany, the UK, France and Belgium above average, while others such as the Netherlands, Spain and Italy were below the EU average.

Table 3.6.4 EU-28 - real GDP growth rate - percentage change on previous year 2010-2013 and average 2010-2013



Source: Eurostat

Linking the data on economic performance with that on numbers of SMEs, among major producers it is again Italy that seems to be presented with a particular challenge, although Spain as a major player has also experienced weak economic performance in recent years. But clearly other countries, especially small countries such as Portugal and Greece are also to face significant economic challenges that can affect implementation and impacts of the Regulation.

However, selection of time periods has an important influence on the data. If 2009 is included averages are significantly reduced. So the economic environment has improved compared to the 2010 registration, but on the other hand investment decisions are made over longer time periods and although prospects improved at the time of the 2013 registration compared to 2010, this does not necessarily translate into a willingness to invest. Data for the whole period 2007-2014 are provided in Appendix C.

3.6.3 The major concerns for SMEs in relation to the implementation of REACH

In the following paragraphs the main concerns of SMEs in relation to the implementation of REACH are identified in terms of their differences compared to those of large firms in other parts of this study. This is based on the evidence report and additional qualitative interviews

Comments from **Member State Authorities** about what points SMEs raised with them centred on a few key issues: **SIEF, the definition of SMEs, IT tools, and language**. SIEF (and to a lesser extent consortia) were the main issue and questions raised related to concerns about costs (registration and letters of access), data sharing, transparency, language (English), roles and responsibilities within the SIEF and communication with the Lead Registrant. The definition of what constitutes a SME in terms of REACH was also an issue that had to be explained quite often. In some Member States it was considered unfair that although, in some instances, a SME is part of a larger group, and the relationship was very much at "at arm's-length" with no support from the parent (which might be in a different business altogether or just a holding company), it would be excluded from treatment as a SME. Language issues also came up regularly due to the predominant use of English where not only a certain level of mastery but also of technical expertise in English was required.

According to **industry representatives** the points that SMEs most often raised with them also centred on **SIEF – related matters**. High up the list were costs (data, letters of access, participation), transparency, as well as matters related to having to collaborate with competitors, reliance on external advisers for matters affecting the future of the firm, lack of language capabilities (English), and the overall costs of the exercise. SMEs also had problems with the **technical matters** such as IUCLID, preparation of Exposure Scenarios, SDSs, CSRs, tracking inventory changes, etc., in many ways similar to the problems experienced by larger firms. However, SMEs had less in-house capabilities for dealing with these matters (financial, technical) and larger firms could spread costs over a larger cost base and recover those costs more easily. In SMEs the issues were more acute.

The operation of the Single Market

When considering the effects of the implementation of REACH on businesses in terms of trade inside the Single Market, by far the majority of firms (80-85%) did not identify any changes due to REACH, but among those affected the survey responses suggest there is a difference between SMEs and large firms as regards the effect on exports, where a greater reduction due to price increases related to REACH was reported for SMEs than large firms (16.7% compared to 6.3%), , and in particular for micro firms – although it should be noted that the share of micro firms responding was low (OBS). There was no real difference as regards imports.

As far as views on the effect of REACH on harmonisation of chemicals legislation and opening of new opportunities are concerned, differences between SMEs and large firms are not that significant, except in the case of the few micro firm that responded, who more often "strongly disagree" that REACH has increased harmonisation and led to new EU business opportunities (60.9%), compared to large firms (20.3%) and an average of 24.6% for all SMEs. There is also a high level of "disagree" response from small firms (39.7%)(OBS). [Again, this was based on a low number of responses].

The micro firms that responded also express a very high level (57.1%) of agreement ("strongly agree") with the statement that the level of enforcement of REACH across the EU varies and that this has a negative impact on the operation of the single market. In this instance 19.4% of SMEs as a whole "strongly agree", compared to 10.6% of large firms (OBS). Overall, 58.6% of SMEs agree or strongly agree. The majority of micro-firms in this instance and the previous paragraph had 20% or more of revenues from markets outside their domestic market.

International competitiveness

SMEs were less concerned than large firms (21.1% and 13.7% for micro firms, compared to 27.1%) about the effect of the Regulation on their competitive position vis à vis firms from outside the EU, and less SMEs (46.1%) see this in a negative light than large firms (65.8%). This may be because they compete less with such non-EU firms. However, the in-depth interviews suggest that the actual impact may be more severe for the SMEs affected, as survival, or independent survival may be at stake for them. At the same time, 46.8% of SMEs compared to 31.5% of large firms thought their position had strengthened (CATI data). This may be due to the companies in question being predominantly DUs so they are not so directly affected as manufacturers, or because EU-based suppliers would buy from them more readily rather than from suppliers from Third Countries who do not want to incur registration costs and withdraw from the EU market.

Table 3.6.2 How has the competitive position of your firm *vis à vis* firms from outside the EU been affected (percentage of respondents indicating)

Options	Micro	Small	Medium	SMEs total	Large	All firms
Strengthened substantially	7.7	2.3	2.6	2.8	0.0	1.6
Strengthened	30.8	43.2	47.4	44.0	31.5	38.5
Weakened	15.4	13.6	16.7	14.9	9.0	12.3
Weakened substantially	23.1	38.6	28.2	31.2	56.8	42.5
Don't know	23.1	2.3	5.1	7.1	2.7	5.2
Total	100.0	100.0	100.0	100.0	100.0	100.0
n	13	44	78	141	111	252

Source: CATI survey

Registration 2013

Table 3.3.3 suggests that on average cost per registrant per substance by tonnage band is not widely dissimilar between SMEs and large firms. For the >1,000 tonnes band it is a bit more; for 100-1000 tonnes it is a good deal less; for 10-100 tonnes costs are similar and for 1-10 tonnes it is some 25% more. This latter category may be important as regards registration in 2018. As a share of registration costs the cost of liaising with DUs and producing the eSDS is proportionately higher for SMEs (table 3.3.4).

SMEs tended more rarely to say they absorbed costs and reduced margins than large firms (66.7% compared to 75.9%). Table 3.6.1 suggests that SMEs have less scope for this given their lower levels of value-added. SMEs and large firms indicated that they raised prices about to the same extent (about 20%) but SMEs as a whole indicated a higher response rate than large firms to the options of "withdrawing from markets" (12.8% as opposed to 7.3%) and "withdrawing products from the market" (27.6% as compared to 14.6%) – a particularly high rate (77.8%) was recorded for micro firms for product withdrawal (however the number of responses was not high).

As regards registration in 2013, about a fifth of SMEs indicated that 81-100% of their substances are now registered, compared to two-fifths of large firms (OBS). More SMEs than large firms also indicated that 0% (20.8% compared to 9.3%) or 1-20% (25.0% compared to 14.0%) of their substances (by turnover) had been registered.

Overall, SMEs reported experiencing a higher level of substance withdrawal than large firms as a result of 2013 registration requirements (36.4% as opposed to 24.8%)(OBS). This was, again, particularly the case with micro firms (55.6%, although not many responded).

Innovation

As regards innovation, the contribution of REACH to innovation and the development of new business opportunities were not dissimilar for SMEs and large firms in the case of both surveys. SMEs generally provided lower levels of positive responses for the role of the information sources generated by REACH as a source of innovation than large firms, except in the case of the (e)SDS.

The survey responses suggest that there was not a substantial difference between SMEs and large firms in terms of reallocation of R&D resources to compliance activities. Fewer SMEs did a temporary transfer than large firms. In practice this might of course mean a high opportunity cost for a micro- or small firm if that means a manager/ owner spends time on compliance with REACH rather than running the business.

Table 3.6.3 Has the need to comply with the regulation, for example as regards preparation for registration, led to a reallocation of R&D resources?

	Micro	Small	Medium	SMEs total	Large	All firms
NO reallocation	61.5	58.8	56.9	58.2	53.7	55.6
YES, but only temporary	15.4	23.5	11.8	16.3	24.2	20.2
YES, on a permanent basis	7.7	11.8	15.7	13.3	14.7	14.1
Do not know	15.4	5.9	15.7	12.2	7.4	10.1
Total	100.0	100.0	100.0	100.0	100.0	100.0
n	13	34	51	98	95	198

Source: Online business survey

There was also not a great deal of difference as regards the effects REACH on time to market between SMEs and large firms, except where the increase was of more than 12 months, and this particularly affected micro firms.

A larger share of SMEs than large firms indicated that they had *not* been affected by the placing of substances on the candidate list (33.6% compared to 17.1%) (OBS). This is also valid for the CATI. SMEs tended less often than large firms to launch reformulation initiatives in response (24.6% compared to 41.9%). Less SMEs requested substitution of such substances by their suppliers than large firms (18.9% compared to 36.8%). In other respects, the effects of the candidate list was similar.

A lower percentage of SMEs than large firms appears affected by authorisation (29.1% compared to 37.7%), and overall, for all possible options in response to authorisation, a lower share of SMEs than large firms responded, particularly as regards request for substitution to suppliers (OBS).

When substances produced entered the registry of intended substances for restriction, substantially more SMEs than large firms withdrew the substance from the market (17.2% compared to 5.4%).

SIEF and Consortia

Feedback from SMEs as regards the value for money from participating in SIEF is mixed in comparison to the feedback from large firms. A higher percentage of SMEs thought it "very low" than large firms, but a lower percentage of SMEs than large firms saw it is "low" and "about right". A higher percentage of SMEs saw the value as "high" and "very high" than large firms (OBS).

Less SMEs (20.6%) than large firms (40.2%) joined consortia and smaller firms saw less added value than large firms in consortia as compared to SIEF (added value was defined in terms of discussions being carried out in a small core group, and in the contractual agreements that protect IP and clarified responsibilities). A substantially higher percentage of SMEs than large firms saw consortia as providing no specific value but they participated because they were a precondition for involvement in dossier development (31.1% compared to 13.8%) (OBS).

DUs Communication in the supply chain

There are not significant differences between SMEs and large firms as regards the percentages of substances used for which eSDS have been received, except possibly in the case of the 0% category (9.1% SMEs as opposed to 3.6% of large firms).

As regards information received with the eSDS leading to changes in activities to protect health, safety and the environment (HSE), the major difference between SMEs and large firms lay in the required adoption of new safety instructions. This was the case for 9.9% of SMEs and 21.7% of large firms.

SMEs are less aware than large firms of the different methods to consolidate received eSDSs into their own SDS (43.6% compared to 63.9%).

Staffing and resources

There are some significant differences in the way in which SMEs and large firms deal internally with the resources required to ensure compliance with REACH. Less SMEs report having a dedicated REACH unit (17.4% compared to 32.7%) and less have a dedicated REACH manager (28.6% compared to 48.3%). The CATI results also reflect these differences.

Both the CATI survey and the OBS indicate that there are not significant differences between SMEs and large firms as regards availability of qualified persons to deal with REACH-related activities. Interviews with companies make it clear that the key issue for SMEs is *affordability* rather than availability. This has important implications as regards the types of support to be developed for SMEs leading up to 2018.

As regards availability of appropriate educational and training programmes to deal with REACH regulation, less SMEs have designed in-house training programmes than large firms (27.3% compared to 37.0%) and more SMEs said that existing courses are not appropriate for their needs (21.2% compared to 12.6%) – especially in the case of micro firms (46.7%).

As far as working with external consultants is concerned, more SMEs say they find it very difficult to find consultants with the right level of skills and experience that they can trust and work with (22.8% of SMEs compared to 13.2% of large firms) (OBS). Several MSCAs have confirmed in the interviews that SMEs approach them asking about "approved" consultants.

2018 Registration

Less SMEs than large firms have indicated that they will be registering substances in 2018 than small firms (CATI). Some of the large firms interviewed will be registering substantial numbers of substances: 6-700 substances and even more[83], but some small

[83] Registration decisions are driven by cost and market factors. Some large companies that have many substances to register (6-700, or even more in some instances) in 2018 have advised that they adopt the following generic registration strategy: Substances are divided into three categories: those that will definitely be registered in 2018, those that probably will be registered, and those that might or might not - depending on market trends and prices closer to 2018. They usually go ahead with preparing the first category for registration, then start on the second, but decisions about the last category will only be taken much closer to the time. Hence they do not yet know with certainty how man they will register, and there may be a large potential range in the number.

and micro firms have upwards of 300 substances to register or buy letters of access for. Both the CATI and online business surveys suggest that there are some differences between SMEs and large firms as regards receiving information from suppliers of chemical substances regarding intentions for 2018, with SMEs reporting that 13.9% of suppliers indicated they will not register compared to 19.5% in the case of large firms (CATI). A lower percentage of SMEs (32.8%) indicated that they have received notification about possible withdrawal of substances in 2018 than large firms (43.8%).

A further difference between SMEs and large firms relates to suppliers informing that they intend to discontinue production/import of some of the substances (14.6% in the case of SMEs as opposed to 10.0% for large firms) (OBS).

There are also some differences between SMEs and large firms as far as main reasons to withdraw/ discontinue substances are concerned. The main difference is as regards registration costs, where 47.5% of SMEs provide this as a reason, compared to 34.7% for large firms (OBS). Also, rationalisation of the product portfolio is provided as a reason in 11.9% of instances in SMEs as compared to 18.1% of large firms. Again, it is worth recalling here, that some 97-8% of firms are SMEs, so if 47.5% of SMEs say something, it is actually representing a very much greater number than 34.7% of large firms (about a half of 97% - about 49% - compared to a third of three per cent – 1% - of the total number of firms).

Overall

As regards characterising the attitude towards the REACH Regulation based on their overall experience of working with it, a much larger percentage of SME respondents characterise it as very negative (26.9% compared to 6.5%, especially micro firms), although as regards "negative", "positive" and "very positive" the responses are similar (OBS).

SMEs and the REACH mechanisms

On the basis of the preceding comments the following table summarises the areas related to REACH implementation identified where SMEs experience particular problems.

Table 3.6.4 SMEs and REACH mechanisms

REACH mechanisms	Specific SME issues
Pre-Registration	Finding "serious" pre-registrants to collaborate with for 2018 registration – this is more of an issue for SMEs than large firms as they generally will not be able to bear costs of single registration or being Lead Registrant if required.
Registration	
	Identifying substances Understanding requirements in general
-SIEF/ consortia	Participation – time, costs (opportunity costs) Working with competitors Data sharing – confidential business information Language
- SDS/eSDS development	Technical knowledge/ expertise (to draw up and understand) Exposure scenarios Chemical safety reports
-Supply chain communication	Time and related costs and opportunity costs
-IT	Time and costs (E.g. IUCLID)
-Language	Time and costs (translations)
Candidate list	Identifying SVHCs Sharing information Identifying alternatives/ withdrawal Updating information Uncertainty
Authorisation	Cost of Authorisation (familiarisation, adaptation, administration) Registering uses/ ensuring activities are included – links with suppliers/ downstream Cost of R&D to find substitutes Uncertainty
Restriction	Covering uses – future development?
Support	Prefer individual support and being able to learn from their peers in groups However, it is difficult to raise awareness among them and make contact with

REACH mechanisms	Specific SME issues
	small and micro-firms outside the usual trade and industry association networks.

Sources: OBS, CATI, stakeholder and in-depth company interviews

Overall, the major issue for the micro or small enterprise is not willingness to comply, nor necessarily lack of technical expertise, nor having to deal with SVHCs, but the availability of resources (in terms of costs and opportunity costs) to comply with the requirements of the Regulation. The data about levels of value added in SMEs compared to larger firms (table 3.6.1) are evidence of this. Even medium-sized companies, especially at the higher end of the employment scale, tend to have a specialist Health, Safety and Environmental employee, or even a team that will tend to pick up REACH duties. For the small and micro-enterprise, it is usually the company owner/ manager or the research chemist who deals with this, in addition to this or her other duties, which can put a substantial strain on that person with important opportunity costs. Outsourcing is costly, and invariably employment of an additional person just for regulatory compliance – in addition to other REACH costs such as letters of access can have a substantial impact on return on capital.

3.6.4 SME- specific constraints in fulfilling REACH roles

It is well known that SMEs face a range of issues as compared to large firms in several fields: access to finance, access to skills and capabilities, access to markets, innovation, etc.

The above review of survey and interview suggests that there are areas where SMEs are differently impacted to larger firms as a result of compliance with REACH. There are two factors underlying these various divergences. One is related to the way in which small volume/ size interacts with the Regulation – a mechanical ratio as it were; the other is to do with the basic problem of being small, which is compounded by the specific demands of compliance.

Turning to the first factor, a small or micro firm may be more dependent on the destiny of one or a few substances than a large firm, or the cost of letters of access may be sufficient to make a SME withdraw from a business line – or it may even decide to cease operations. Large firms have much more resilience in this respect and there are already, since the 2010 registration period, instances reported during interviews of otherwise healthy businesses that have been built up over decades closing down or having to be sold to larger competitors with more financial resources due to REACH compliance costs. More of this is envisaged in the run-up to 2018.

The second factor is related to the first: larger businesses have more resources and markets from which to recover REACH compliance costs. This means that specialised staff can be recruited, trained and offered rewarding career paths to deal with REACH (and other) compliance, and they have larger capacity to absorb costs – direct and indirect, visible and invisible, captured and not captured by company accounting systems, that micro and small enterprises simply have a great deal of difficulty in absorbing. In essence, the entry barrier – fixed cost basis – for participating in the chemical industry has been raised and some micro and small firms will find it increasingly difficult to compete.

3.6.5 Conclusions

This sub-section has found that SMEs are spread throughout all the REACH roles, but probably more in the DU categories where capital requirements to operate are lower. However, the distribution of SMEs between Member States is uneven, as is the distribution between micro-, small, medium-sized and large firms. The most outstanding contrast in this respect is the difference between Germany and Italy. There have also been significant differences in the economic environment of Member States, with some experiencing on-going turmoil that affects the resources available to comply with the additional costs of legislation and administrative burdens. The level of value added in micro, and smaller firms in particular does not leave as much scope for absorbing costs of regulation as in the case of larger enterprises.

SMEs tend to see the effects of REACH on the Single Market in a less favourable light than large firms, but are less concerned, overall, than larger firms about the effects of REACH on their competitive position vis à vis firms outside the EEA. This may be because they are less involved in international trade, or more of those surveyed are DUs, who are not as strongly affected. Some SMEs also benefit from REACH when EEA-based suppliers switch their purchasing to EEA-based REACH compliant suppliers.

More SMEs have yet to register their substances than large firms, and SMEs report higher levels of substance withdrawal related to registration than large firms.

More SMEs than large firms have not had any eSDS and larger firms were more aware of the different ways in which received eSDS could be consolidated into the firm's own SDS (on-line business survey). SMEs tend to be less proactive as regards upstream communications on use mapping (CATI).

There were not great differences between large firms and SMEs as regards innovation, except when substances entered the registry of intended substances for restriction, when more SMEs than large firms withdrew the substance in question. SMEs were less positive than large firms as regards the value of SIEF and consortia.

Staffing is a key factor for SMEs, but mainly as regards cost rather than availability of suitable staff and similarly as regards consultants, although ways to assess quality in external providers was an issue. SMEs tend to outsource fully more than large firms and need more externally provided training.

Registration for 2018 remains a challenge for SMEs, as the uncertainties about supply and withdrawal are still present. Cost is the main reason provided by SMEs for not proceeding with registration (47.5%). A lower percentage of SMEs had received notification about possible withdrawal of substances in 2018 than large firms (on-line business survey). More SMEs than large firms would respond to this by not using the substance; larger firms would more often develop a substitute.

3.7 Objective 7 - Downstream Users (DUs)

3.7.1 Introduction

The aims of this section are to establish and assess the major cost drivers for downstream users with regard to REACH. Costs for major downstream sectors should be put in the context of profit margins and overall costs for safety & environment protection as required by other EU and national legislations; and to provide estimates of awareness of REACH.

As a result of REACH, downstream users have changed their roles from being passive actors regarding substance regulation to being more actively involved in generating and documenting information on the control of chemical risks. In this study the term is used for all actors in a supply chain including distributors of chemicals and article suppliers, which in the meaning of Article 3 are not Downstream Users but are market actors affected by REACH processes. The degree of involvement differs depending on the REACH process concerned. Downstream users are increasingly taking up their responsibilities and fulfilling an active role.

Besides the mandatory legal obligations, they already had to fulfil before REACH came into operation, such as having to provide safety data sheets (SDS) for substances and mixtures, a number of new tasks are to be performed due to REACH. Some of these are very challenging as they are new and partly change the DUs' understanding of how they are using chemicals. Some tasks are legally binding like the notification of SVHC in articles (Article 7), communication on SVHC in the supply chain according to Article 33 or the implementation of information on risk management received via SDSs. Other tasks such as e.g. becoming active due to non-registration of current suppliers[84] only become relevant under certain conditions and require active observation of the supply chain (mainly the suppliers) and REACH processes (e.g. the need to obtain authorisation for the use of a substance or a mixture containing a specific substance). Depending on regulatory decisions, the situation for a specific substance can change within a comparatively short period of time compared to the former legal framework before REACH and needs adequate reactions by the specific DU.

3.7.2 Overall finding - awareness

Interviews with firms, authorities and associations often indicated that a large number of DUs are still unaware of many of the main REACH processes (see following table). In the survey results it was noticed that although the questions addressed issues related to a specific DU role and/or DU tasks, the respondents' answers indicated the lack of a basic understanding of the REACH system and terminology (e.g. assignment as manufacturer but responding to the typical DU tasks like e.g. consolidation of received information for a mixture).[85]

[84] Change of supplier, review process for alternative substances or processes, consider own registration and start import activity.

[85] Although this may also have been partly because of the multiple REACH roles that businesses have and hence a misunderstanding of the questions rather than the Regulation.

Table 3.7.1 On the basis of your experience, are firms with a Downstream User role in your sector/country aware of their REACH related responsibilities?

Answer Options	Response Percent	Response Count
Do not know	10,3%	4
The majority of firms (if not all) are not aware	28,2%	11
Important part of them are aware	33,3%	13
Most (if not all of them) are aware	28,2%	11

Industry association survey

Helpdesks reported that approximately 50% of all questions are received from DUs. The questions' subjects are often related to general REACH tasks.

Although DUs are regulated as end-users of chemicals under REACH many of them, as individual companies, are not involved in REACH processes yet. The content of supporting tools and instruments as well as the overall process of registration with regard to communication in the supply chain of the first two registration phases has been mainly organised by large EU substance manufacturers and their associations (e.g. CEFIC, CONCAWE, Eurometaux) and some DU sector associations (also these involved DU organisations rather represented uses dominated by large and industrial end-users rather than uses, dominated by SME). Therefore, much work on describing uses was actually not done by individual firms. So it could be observed that many firms that responded to the survey have not been involved in use mappings in the preparation of a registration.

Table 3.7.2 Have you been involved in upstream communication during use mapping for the different registration deadlines?

	Formulator	End user	Distributor	Supplier of articles	All
Don't know	5,2	5,9	5,7	7,2	6,0
No	49,4	**73,2**	**63,9**	**66,9**	62,1
Yes	**45,4**	20,9	30,4	25,9	31,9
n =	251	153	158	251	813

Source: CATI

Feedback from interviews with member state authorities shows that it is particularly difficult to reach companies in DU sectors with little awareness of their relation to chemicals; i.e. the use of chemicals is not understood as "part of the business" a company is active in, although many chemicals may be used. An additional problem exists in sectors that are dominated by SMEs because, even if they are aware of the existence of REACH, they do not engage in identifying their obligations and understanding the processes due to high degree of complexity of the regulation itself as well as its "outputs" (e.g. exposure scenarios) and the instruments used for implementation of the obligations (e.g. XML formats for safety data sheets). In

particular, the instruments and tools do not reflect how SMEs are organised and the qualification of staff that is employed (the latter is not only true for SMEs). As a consequence, DU who are aware of REACH and have started implementation had to invest in the qualification and training of staff (about 30 %, CATI) and additionally to involve external experts (about 19 % technical and 11 % legal, CATI). A lower share of companies (about 19 %, CATI) really spent resources that contributed to the implementation of the registration process by being actively involved in use descriptions under REACH.

3.7.3 Registration

The first registrations showed that DU need to observe activities of suppliers with some attention, among other reasons because it may be questionable if all their substances are registered. Although this may not lead to the complete disappearance of a substance from the market, but with the REACH requirement that each manufacturer or importer above 1 tpa has to register, it could happen that a specific supplier stops supplying a substance, requiring the DU to identify new suppliers. The DU needs to ensure that he is part of a supply chain that is covered by a registration to continue his activities (business as usual scenario).

In the interviews the firms stated that not all substances pre-registered in 2008 will be registered. Some manufacturers and importers only make use of transition periods that enable marketing of substances after the pre-registration phase. Registration costs or even authorisation cost may make marketing unprofitable (this is due mainly for substances with small tonnages and low profit per ton). Regardless of the role, about 30 % of DUs reported that substances have already disappeared from the market due to the 2013 registration requirement. Several interviewed firms reported that they are currently reviewing their complete substance portfolio, to find out if these will be profitable if a registration is necessary. Some stated that they already have listed substances that they will definitely not market after 2018.

There are indications that importers tend to stop importing to a somewhat higher degree than manufacturers stop manufacture. This could be because their business is based on buying substances from (non-EU) manufacturers and selling them inside the EU generating profit from price differences between buying and selling. Such firms are often small entities that employ few people. Services are concentrated on logistics with low to no experience in regulatory questions and scientific issues with regard to chemicals legislation and risk assessment. They can often just cease importing and move to other business fields (substances), while EU-manufacturers seem to stop manufacture less often as their business is based on a dedicated infrastructure to manufacture a substance. It is more difficult to change the substance portfolio as their plants are often designed to produce a certain substance so that the possibilities to change manufacturing to other products are limited. Reasons for not registering were very often based on economics (investment to register all substances in the portfolio too high, single substance with too low value for company's profit, no relevance of a substance for the portfolio – low demand).

The consequence of manufacturers and importers not registering all substances of their current portfolio for the DUs is that they should monitor their own substance portfolio more carefully (including substances in mixtures and articles). In many companies, this is not yet a well-established process. It requires contacting suppliers asking for their registration intentions proactively and assessing if alternative suppliers are available. In case there are only few suppliers, companies may also consider own registrations and subsequent import. Many companies claimed in the interviews that a high additional workload is necessary for these tasks to ensure availability of raw materials.

Up to now the preferred reaction in cases where a supplier withdrew a substance from the market was either to change to an alternative substance from the supplier's portfolio (54.3 % of all responding firms in the CATI survey) or to change the supplier (51.9 %). In addition, a high number of firms replied that their own research to find alternatives was triggered (over 60 % in the group of the formulators and the article supplier group – the latter probably also in relation to the candidate listing of substances).

In many cases the consequences of a "no registration scenario" are limited. Nevertheless, as it is expected that in 2018 only few manufacturers and importers per individual substance will exist and hence will register, the possibilities for DUs to change suppliers in case a substance is not registered will be more limited. How far substitution can be realised depends a great deal on the DU process affected or the accompanying regulatory field that also applies to the DU products (a frequently discussed example in the frame of REACH is the aviation industry or the medical devices sector that need to undergo product specific approval procedures and the use of new substances could trigger the need to apply for a new permit).

It should be noted that in some cases it was reported that substance withdrawal led to a stop of the production of a certain mixture or article (in about 25 % of the cases, source CATI). The shift of production to non-EU areas was, at the moment, reported as an option of minor importance (about 7 % of the responding firms). This was confirmed in the interviews. Only companies producing mixtures for non EU-markets and hence facing global competition from non-REACH areas reported that they are considering shifting the production as an option. Other DU firms stated that the EU is their end market and that therefore a shift to non-EU countries would not be an option.

3.7.4 Communication in the supply chain

Communication between members of the supply chain of a substance is one of the key elements under REACH. Communication does not only happen via the traditional channel, the safety data sheet but also in several other contexts. Some of these communication processes are legal obligations (like several information obligations towards customers) others are in practice often interpreted as obligations that support certain implementation processes but are not legally binding (e.g. communication on uses and conditions of use in the supply chain).

Safety data sheets are still the core communication tool under REACH. Several stakeholders reported that REACH has already improved the core sections. The data basis on substances is much better in their opinion and classifications are regarded as more trustworthy. This was also an outcome of the REACH-Review 2012 where similar findings were described in the Eurostat baseline update (COM, 2012).

For hazardous substances registered in amounts exceeding 10 tpa, safety data sheets have to be supplied with an exposure scenario (eSDS) as annex. In general eSDS are known to DU although 90 % of the formulators and only 70% of the DU further down the supply chain have received eSDS up to now.

A lot of criticism has been aired as regards the eSDS and exposure scenarios. Exposure scenarios are not seen as an instrument that improves corporate health and environmental safety practices. More than 50% of the respondents answered that no changes have been made to internal practices due to the receipt of an eSDS. Changes usually only comprised the application of additional personal protection equipment (PPE, 20 % CATI) or changes in safety instructions (12 %). With regard to both measures it is doubtful if they fit in the hierarchy of measures to be applied under occupational safety legislation, as this allows the use of PPE only, if elimination of hazard or other technical measures are not possible.

Table 3.7.3 shows the share of companies with different roles that have received extended safety data sheets.

Table 3.7.3 Have you been provided with extended SDSs (Safety Data Sheets and exposure scenarios) for one or more substances that you use?

	Formulator	End user	Distributor	Supplier	All
Don't know	0,4	4,6	5,1	1,2	2,3
No	9,2	34,6	16,5	25,5	20,4
Yes	90,4	60,8	78,5	73,3	77,2
n =	251	153	158	251	813

Source: CATI

It was stated in the interviews that handling eSDS as they are currently supplied (electronically as PDF documents or physically on paper) requires a significant input of resources. Interviewees stated that the work under the CSR/ES Roadmap, which among other things aims to support standardisation and implementation of ES phrases, electronic information exchange formats and an ES format is too slow and therefore does not contribute to fulfilling the legal obligation to provide eSDS now. Furthermore, it was doubted that the instruments currently being prepared would help the broad range of firms that have to deal with eSDS. The XML standard and its implementation in ERP-IT systems is seen as a solution for "industry" but not for smaller firms which usually do not have comparable systems. Integration of a standard in smaller "stand alone" software solution seems to be the only alternative if such information should be managed by all market actors.

With regard to the SDSs, DU have to provide, only a low share of firms in the CATI believes these to be 100 % compliant. One reason might be that only about 50 % of the firms in the survey were aware of the different methods and options that are available to consolidate information for mixtures under REACH.

3.7.5 Substances of very high concern

From the perspective of formulators and end users of mixtures, the SVHC status does not cause additional problems as far as the communication in the supply chain is concerned (SDS have to be provided as for any other substance). Problems rather originate from the fact that the reaction to candidate listing at the moment is that many customers demand immediate substitution in products, as can be seen from the table below.

Table 3.7.4 Have any of your customers requested the removal of SVHCs from your products?

	Manufacturer	Importer	Formulator	End user	Distributor	Supplier of Articles	All
NO	78,7	66,7	45,5	57,6	52,0	57,7	61,2
YES	21,3	33,3	54,5	42,4	48,0	42,3	38,8
n =	61	27	44	59	25	26	242

Source: OBS

So the candidate list builds up pressure to substitute SVHC. However, the interviews showed that this substitution is often not based on an analysis of the alternatives, hazardous properties, but only on their legal status (listed on candidate list). Consequently, only in a few cases substitution pressure leads to the development of new less hazardous alternative substances or implementation of new processes at the level of the substance manufacturer. Often replacement was done from the set of other substances that were available in suppliers' portfolios that enabled the supplier to provide the product in the same (or similar) quality as before and enabled the DU to continue using their existing technology (only with smaller adaptations on the process). In some instances, DUs have reported providing lesser quality products (e.g. printing inks).

Only comparatively few substance manufacturers reported in the surveys that they started new research initiatives to develop substitutes. It is more probable that substitution is established on the level of the formulator or article producers. Innovations are frequently realised because the elimination of a SVHC in products has been on the agenda in the firms anyway and is now treated with higher priority (which also can lead to more resources being made available in the companies).

Another aspect some interviewed companies highlighted in the context of the candidate list is that communication of substitution requests in the supply chain (in particular for consumer products) has become much easier, especially in non-EU countries. The candidate list of REACH is well known and it is therefore easier to make a well-substantiated claim to request replacement of a substance with reference to REACH. This is well understood and formulations are often adapted to be SVHC free. There have been instances where companies that produce consumer products described REACH as a benchmark and a good way to present products as more environmentally and health friendly alternatives as compared to those of competitors from non-EU countries. This positive marketing effect is less obvious if products are meant to be used by commercial actors or for very complex articles.

Article suppliers also have problems in generating and monitoring information on SVHC in their articles. Although REACH Article 33 defines an obligation for each article supplier to forward information on the SVHC content (to consumers only on request), this information is often not provided. In many cases it is unclear if the lack of communication is due to the absence of SVHC in the article or due to ignorance of the supplier on the SVHC content. In practice the implementation of Article 33 consists of article recipients requesting the absence of SVHC in the articles in supply contracts. At the moment there is a high degree of uncertainty among the interviewed companies if REACH compliance can be ensured with regard to SVHC in articles.

Regardless of their REACH-role, about 55 % of firms have started to implement IT-systems to monitor SVHC in products (OBS). Over 60 % (OBS) of the firms that received articles validated the information on the SVHC content with chemical analyses for the articles they supply.

The uncertainty regarding the SVHC content in articles is reflected in several responses on related challenges. Other problem areas are raised (OBS/CATI):

- Availability of information from suppliers is problematic (either they have no information or suppliers do not understand why it is demanded).
- Lack of awareness of the obligation.
- Complex articles require a lot of communication, even more with non-EU suppliers who do not share information (not willing, not understanding).

- Relatively large administration burden to companies to track SVHC (limited human resources).
- Information needed beyond the REACH text to make the obligation work (exact concentration and location of SVHC to be able to fulfil the obligation in the next step of the supply chain).
- Uncertainty leads to additional burden by own verification of information by testing.
- Implementation of an effective and pre-emptory regulatory watch on substances of concern. Recent tools and lists published by ECHA are quite useful (CoRAP or PACT RMOA).
- Immediate effect of obligations in the supply chain and towards ECHA when SVHC appear on candidate list (non – adequate[86] - transition period to assess portfolio).
- Complex supply chain already outside the EU (loss of substance information there).
- SDS from non-EU suppliers are of bad quality.
- Due to marketing strategy substitution is the only option, but this leads to additional costs for changing production processes and sometimes for requalification of products under other regulatory frameworks and / or challenging negotiations with customers.

Although DU often request substitution of SVHC from supplied products and by this put some pressure on their suppliers, there is no defined tendency to move commercial activities outside the EU. 4.3 % of the suppliers of products with SVHC (OBS) indicated they moved away from EU-production. A slightly higher share indicated that they just stopped using the substance in commercial activities[87] (8.6 % OBS). This implies some loss of business in these sectors if not compensated by alternatives in their own portfolios or other new business development. It is not clear if this also leads to a loss for the overall EU-economy as it might be compensated by larger market shares of competitors, or for companies that use alternatives. So a potential loss of business to the EU economy can be observed for 13 % (worst case, moving activity outside EU and stopping activities) of the responding companies, but far more companies either are not affected of any withdrawal (32.4 %) and the rest is facing the problem with SVHC by either developing safer alternatives (22.1% OBS) or moving to existing ones (16 % OBS). A share of 6.3 % already has started to prepare the probable next step in the authorisation process and is preparing for an application to get an authorisation.

The withdrawal from the market of candidate list substances seems not to be the usual reaction to listing because a large share of businesses does not have any experience with this. If they can, the main reaction is to find alternatives either by procuring existing alternatives or by initiating related research for new alternatives. Moving activities to non-EU areas is selected even less frequently as an option than preparing an

[86] A notification according to Article 7 has to be made 6 months after the substance has been listed on the candidate list. No transition period is foreseen in Article 31 and 33.

[87] Formulation of mixtures, production of articles

application for authorisation. The latter seems to be especially an option for suppliers of articles.

3.7.6 Conclusions

Based on the interviews and the surveys, the following can be concluded with regard to the REACH effects on DUs:

Many companies, in particular SMEs and firms which have not been involved in chemicals legislation in the past, are still not aware of their roles, obligations and tasks under REACH.

Investments have been made to build up competence and resources to implement REACH obligations.

Most DUs compensated the loss of a substance supplier by identifying an alternative supplier, identifying alternative substances (with the help of the supplier) or by changing the design of the own products.

Complete substance withdrawal from the market due to the cease of import or manufacture is not a major issue for DUs yet, although it might be the case after the 2018 Registration.

Communication of eSDS is still not fully implemented. In particular formulators appear not yet to forward information on the safe conditions of use of mixtures.

The candidate list has several effects on DU businesses:

- listing triggers supply chain communication on the SVHC content in articles and initiates substitution activities at all supply chain levels;

- there are indications that substance replacement in some instances is drawn from existing substances that might not have been selected previously because of performance/ price issues rather than being based on the development of new alternatives. In other instances, it has been reported that safer alternatives (substances or processes) were developed or initiatives started to substitute due to candidate listing.

Article 7 and Article 33 appear not to be well implemented, in particular suffering from difficulties in supply chain communication with non-EU suppliers.

3.8 Objective 8 – Innovation

3.8.1 Introduction

The aim of this section on innovation is to consider the ways in which the REACH Regulation has been both a driver and a constraint to innovation. As regards driving innovation – drivers are identified and assessed. In particular, evidence of substitution mechanisms (e.g. Restrictions, Candidate List, Annex XIV, Authorisation conditions etc.) as well as intelligence gathered through registration and supply chain communication is described along with their potential economic impacts or benefits. As regards hindering innovation, evidence is gathered and analysed. Best practices are to be identified and assessed from the perspective of relative abilities of SMEs in capitalisation on the new opportunities created by REACH.

At the outset it should be noted that the term "innovation" can mean different things to different people, which can lead to some misunderstanding between those discussing the issue. From a *formal* point of view innovation is defined as follows: "an innovation is the implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organisational method in business practices, workplace organisation or external relations."[88] In practice, there may be different views as to whether a given change in response to regulatory demands is actually an innovation. For industry, innovation is related to and underlies *improved competitiveness* - new products or services, processes, organisational methods or messages that result in increased profitability and market share - rather than regulatory compliance (although the two might correspond, but not necessarily). Hence, if a business brings about changes that do not have those results they will not be considered "innovation", although from a regulatory or formal point of view they are.[89]

In addition to this basic source of misunderstanding in a discussion of REACH and innovation, it is worth recalling the diversity of activities and sectors involved in the chemical industry and its downstream users. It would hardly be surprising if they did not all respond in the same way to the REACH Regulation and its consequences.

3.8.2 REACH and innovation – an overview

One of the key factors underlying the Regulation has been the aim of encouraging innovation, and in particular in relation to the placing of substances on the market that are safer and less hazardous. REACH is also expected to promote other forms of innovation (process, organisational, and marketing) contributing to this overall aim.

[88] OECD/ European Commission (2005); Oslo Manual. *Guidelines for collecting and interpreting innovation data,* p.46. This definition encompasses: (i) *product innovation*: introduction of a good or service that is new or significantly improved with reference to its characteristics or intended uses. This includes significant improvements in technical specifications, components and materials, incorporated software, user friendliness or other functional characteristics; (ii) *process innovation*: implementation of a new or significantly improved production or delivery method. This includes significant changes in techniques, equipment and/ or software; (iii) *marketing innovation*: implementation of a new marketing method involving significant changes in product designs or packaging, product placements, product promotion or pricing; and,(iv) *organisational innovation*: implementation of a new organisational method in the firm's business practices, workplace organisation or external relations. This approach also underlies the Community Innovation Surveys

[89] The *Interim Evaluation: Impact of the REACH Regulation on the innovativeness of the EU chemical industry* (2012) by CSES provides contextual background on the innovative landscape in the EU chemical industry (sections 2.3 and 2.4), and also a model against which to assess for the management of innovation (section 4.2).

In general, **Member State Competent Authorities** interviewed and surveyed did not have a great deal to report as regards the relationship between REACH and innovation. Some were aware of anecdotal evidence of businesses that had had problems finding substitutes for substances, and some had taken up the general competitive challenges of particular industries, but they were generally of the view that innovative matters should be taken up with individual firms.

Industry representatives often had highly developed views. In general, they said that the effects of REACH on innovation have tended to depend on the REACH role in question. For example, distributors are not directly affected. Industry sector is also a factor, for example there might be less dyes available for the leather and textiles industries as a result of registration costs which can lead to a reduction in product range. For enterprises or sectors that use substances that have been targeted through the candidate list and authorisation it may either lead to increased R&D as enterprise search for substitutes, or it can lead to uncertainty and potentially reduced investment in R&D and innovation for several years (see below). The overall view from industry representatives is that REACH has detracted enterprises from their R&D and innovation programmes, although there might be benefits "in the future".

Many industry representatives mentioned that REACH had fostered better practices, usually with respect to improved communication in the supply chain, which has produced more transparency across industry sectors. The development of and access to some of the key REACH tools (e.g. SDS, CSR, etc.) had not had a significant impact on innovation. It was envisaged that the information shared on the SDS or eSDS might suggest new products or uses, but some considered (e)SDSs were too technical to be understood by many companies, while sometimes there were no real alternatives to substances in use, or if there were, they were not as good or substantially more expensive.

The relationship between a substance being identified as a SVHC and R&D funding and innovation is complex and depends on the substance in question. For high value added substances, such as the cobalt compounds, there might be increased expenditure on R&D. Others, such as arsenic by-products, may just be withdrawn. It also depends on whether substitutes exist or not. Where they do not, interviewees indicated that companies would be less inclined to carry out additional R&D and companies just apply for authorisation. However, no actual instances of this behaviour were identified in the study. In some industries that use substances such as lead, where there is uncertainty as to whether related possible alternative substances might not also be added to the candidate list, it may hinder investment. In cases such as industrial gases, placing a substance on the candidate list for several years before a decision is made can blight investors' interest in the sector due to the uncertainty of potential returns.

Industry representatives said that it was proving difficult, as expected, to find substitutes for some substances on the candidate list, such as those used in coatings and lubricants. Specific substances mentioned were the chromates, lead, dimethylformamide and beryllium. The processes and data generated in the course of carrying out REACH processes such as registration were not of particular use in such searches. For other substances, substitutes were more readily available.

As to the question whether REACH had, overall, provided the appropriate incentives for, or constrained, innovation, the view among industry representatives tended to be that maybe in the long term there would be positive results as regards what industry considers to be innovation that drives competitiveness, but for the time being, the compliance aspect (e.g. substituting with known substances that are less performant but with less hazardous characteristics) was predominant. However, they also often expressed the view that the existence of the REACH Regulation does provide a stimulus for companies to consider options that do not include SVHCs, and this could have a long

term effect on the direction of research and innovation in industry towards safer and more environmentally friendly technologies.

At the **enterprise level, firms** were asked to consider whether the implementation of REACH supported innovation and created new business opportunities. CATI survey responses show that the implementation of REACH is linked with increased R&D activity (around 26.3% stated this) – and in particular for 43.6% of formulators and 30.4% of manufacturers - and the launch of new products (22.4%). However, the results are substantially higher as regards the development of new knowledge and understanding in relation to the properties of substances and the better understanding of the supply chain. Furthermore, there are improved risk management procedures arising (54.5% of respondents reported this result, in particular end users and formulators).

Table 3.8.1: How has the implementation of the REACH Regulation encouraged innovation and created new business opportunities for your firm (percentage of firms responding)?

Forms of contribution to innovation	Manufacturers	Formulators	Distributors	Importers	Suppliers of articles	End users	All firms
Led to Increased Research and Development activity	30.35	43.60	11.04	16.67	23.08	16.67	26.3
Through increased levels of knowledge in relation to the properties and/or the possible uses of chemical substances	48.28	54.47	49.67	50.00	44.26	39.47	47.8
Through increased awareness of the needs of our suppliers/customers	43.84	45.93	40.76	38.33	43.95	34.21	42.2
Through collaboration with downstream members of the supply chain	47.26	47.15	43.23	41.67	44.67	28.76	43.1
We launched and are commercialising products/ services as result of knowledge gained through compliance	16.00	32.93	24.03	22.03	19.43	16.99	22.4
Improved risk management procedures in your business	51.23	62.35	45.16	51.67	51.20	62.09	54.5
Improved management of environmental	30.85	38.55	34.67	40.00	36.55	49.67	37.7

Forms of contribution to innovation	Manufacturers	Formulators	Distributors	Importers	Suppliers of articles	End users	All firms
emissions and waste.							
n	201	249	150	60	249	153	1062

Source: CATI survey

The responses from the OBS indicated a markedly lower result than the CATI in the case of R&D activity and launch and commercialisation of new products and services (8% compared to 26.3% for R&D and 17.4% compared to 22.4% for commercialisation of new products), and also as compared to other impacts. The reason for this difference is unclear, but there are indications that the group that responded to the OBS was more familiar with REACH operations than the group that responded to the CATI, so they may have had more experience as regards the matter.

A follow-up exercise to both CATI and OBS survey respondents (83) found that very few business opportunities had in fact been realised: six among the 28 that responded. Of the six, 2 have been mentioned in the section dealing with harmonisation, as they were related to harmonisation in the legislation. The four other examples are:

- Greater knowledge of substances has helped in marketing, for example of products using hazardous substances.
- Use of PPORD to carry out research to bring a product to market that had previously been considered a by-product.
- Launch of new flame-retardant products to replace HBCDD.
- An indirect contribution because the existence of the Regulation closed some research paths and supported those being followed by this specific company.

3.8.3 REACH as a driver of and barrier to innovation

In the following paragraphs the role of REACH is considered from the point of view of specific REACH processes and mechanisms: the response to registration (costs); and the substitution mechanisms within REACH – the candidate list, authorisation and restriction. Then the role of intelligence gathered through supply chain communication is assessed.

Responses to Registration Costs

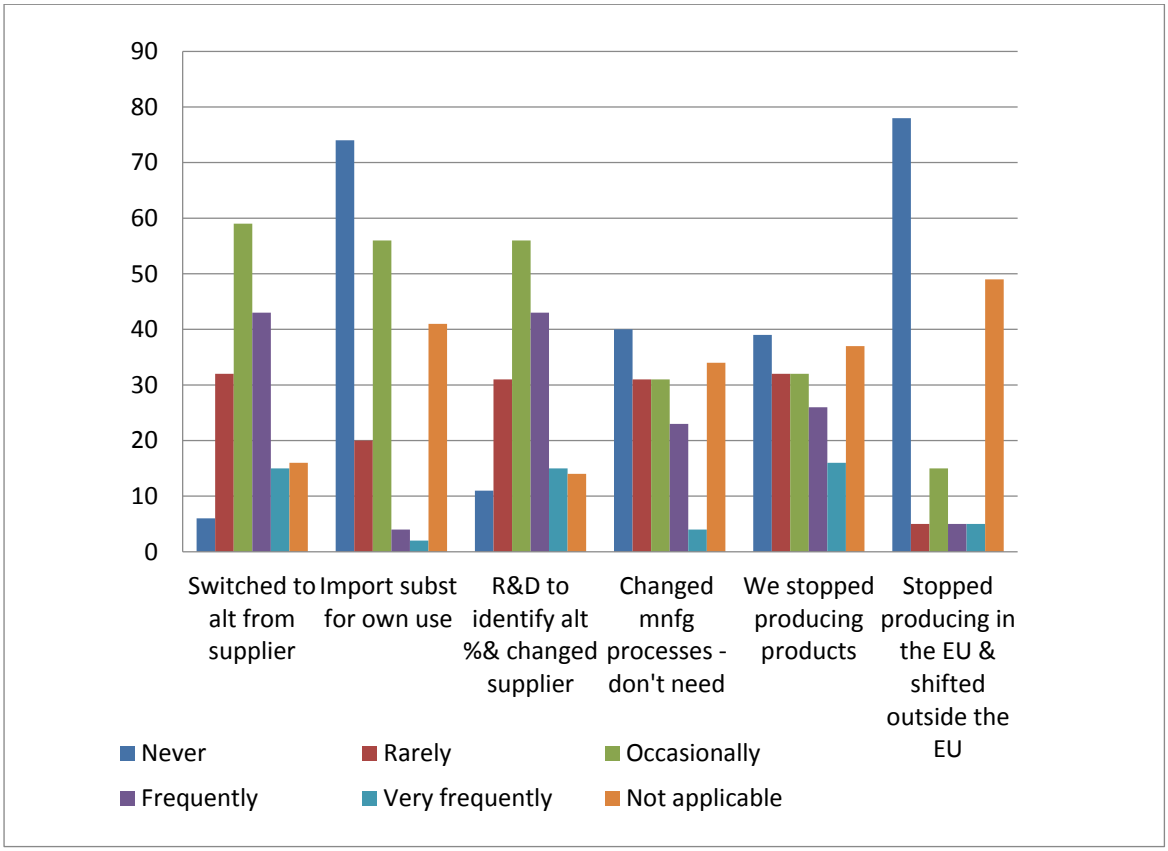
Registration can drive innovation in two ways: through the effect of registration costs and through the knowledge gained from registration processes. The first of these will be discussed here, the second below. Registration costs can lead to firms deciding to withdraw the substance if they do not want to register as it is considered uneconomic. This can lead a firm to develop substitute products that may be cheaper to register, or use alternatives already on the market (reformulating). The firm may also just buy the substance from another company that has registered, if that is cheaper. It can have the same consequences on downstream users.

Other responses to registration costs were: the removal of products, registration as an intermediate; and not registering due to the hazard profile of the substance. Between the CATI and the OBS about 30-40% of respondents indicated that they had undertaken such activities, all of which might trigger R&D activity and innovation. Some companies also opted to import the substance themselves rather than work through an intermediary if that was cheaper and provided more strategic certainty (and/ or possibly acting as a distributor to recover registration costs), or changing manufacturing processes.

Responses to withdrawal of Substances

The responses of the 31% of respondents to the OBS who said they had experienced withdrawals are set out in chart 3.8.1.

Chart 3.8.1 If any of the substances that you used or placed in the market in the past have been withdrawn as a result of the 2013 registration requirements, what was the response of your firm to the withdrawal of a substance? (Percentage of firms indicating by frequency)



Source: OBS

62.2% of firms indicated that they carried out research to identify an alternative substance, and just over a third said that they changed their manufacturing process to avoid the need to use the substance withdrawn. There were also high percentages for the formulators and the suppliers of articles in the case of research, although in the business survey other roles also evidenced high levels as compared to the CATI, namely importers and, to an extent, end users. As regards changes in manufacturing processes, there was a more even distribution of responses between roles except in the case of manufacturers where a high response was recorded.

REACH Registration withdrawal and its impact on innovation for Downstream Users

16% of downstream users indicated that they had experienced a withdrawal. However, this was 32% among formulators and much less among end users (5%) or suppliers of articles (8.4%). Nonetheless, among those firms, REACH could have important implications for the firms using those substances and could potentially operate as a driver of innovation. (CATI)

Among firms with downstream user roles that responded to the CATI survey and had experienced a substance withdrawal, 50.4% reported that they carried out research to identify an alternative substance (mainly the suppliers of articles and formulators did that). In addition, 24% indicated that they changed their manufacturing processes so that they no longer needed the substance.

Table 3.8.2 What was the response of your firm to the withdrawal of a substance by your supplier? (percentage of downstream users that experience a substance withdrawal responding)

Action taken	Formulators	Distributors	Suppliers of articles	End users	All firms
We carried out research to identify an alternative substance	60.0	14.3	61.9	14.3	50.4
We changed our manufacturing processes so that we no longer need the substance	31.3	0	28.6	0.0	24.0
n	21	7	80	21	129

Source: CATI

Evaluation

During the in-depth interviews some firms made the point that the dossier evaluation process adds some elements of uncertainty to costs over and above registration costs. This can have a negative effect on innovation.

The role of the candidate list

The candidate list is an important pre-authorisation mechanism that is expected to play a role in promoting innovation and substance substitution. Some 30% of CATI survey respondents indicated that one or more of the substances they produce or use was added to the candidate list. 9.4% of those (that is, 9.4% of 30%) indicated that they subsequently launched initiatives to develop new substances to substitute them, while 30.1% (of 30%) launched initiatives to find alternative formulations of existing substances to substitute them. In both instances the response rate among formulators was substantially higher than in other REACH roles.

In the interviews, some firms indicted that the existence of the candidate list made them speed up research programmes to substitute SVHC that were already under way, although others indicated that the time available implied by listing was insufficient to find appropriate alternatives to substances that had taken decades to develop and perfect.

Table 3.8.3 Role of the candidate list in the promotion of innovation (percentage of firms indicating specific types of actions related to innovation as a result of substances being placed in the candidate list)

Forms of contribution to innovation	Manufacturers	Formulators	Distributors	Importers	Suppliers of articles	End users	All firms
Launched initiatives to develop new substances to substitute them	7.4	15.0	4.4	7.7	9.3	4.0	9.4
Launched initiatives to find alternative formulations of existing substances to substitute them	28.4	48.0	10.9	23.1	18.5	28.0	30.1
n	81	100	46	13	54	25	319

Source: CATI

Interviews with companies indicate that the existence and updates of the candidate list (and associate lists) is generally considered not helpful for operations and planning. It also incurs high compliance costs as regards informing customers and keeping up to date. Decisions as regards product development become much more time consuming,

End users and article suppliers are also a source of pressure on upstream firms to remove such SVHC even when not strictly necessary – they are expected to substitute even if concentrations are lower than 0.1% by weight and before hazards are evaluated – which incurs additional expenditure.

Businesses do not consider such compliance driven action as innovation. Some companies have expressed the view that the growth of substances on the candidate list seems to have taken on a life of its own, unrelated to the initial logic driving it, even if many consider that initial logic to have been flawed. This may be due to insufficient awareness of firms or ineffective communication by the authorities. The intention of the SVHC Roadmap and the PACT is to provide clearer signals to the market in this respect.

Authorisation process

The introduction of substances in the list for authorisation is another intended driver for the development of new substances and innovation. Among the CATI survey respondents, 17.2% indicated that one or more of the substances they use or place on the market have been added to the list of substances subjected to authorisation. Of those, 14.8% indicated that they launched initiatives to develop new substances to substitute them. This was particularly marked with formulators and end users. A larger share (27.2%) launched initiatives to find alternative formulations of existing substances to substitute them. Again this was particularly marked in the case of formulators and end users, but a high share of manufacturers also indicated this response.

When substances produced entered the registry of intended substances for restriction, substantially more SMEs than large firms withdrew the substance from the market (17.2% compared to 5.4%). The in-depth interviews suggested that this usually led to using alternative substances where possible, and sometimes carrying out research to develop new substances, but in some instances it did lead to a loss of business in terms of turnover or profitability for individual firms. However, the overall position is complex because in some instances where a company withdrew from a business, a different company moved in.

Table 3.8.4 Role of Authorisation list in the promotion of innovation (percentage of firms indicating specific types of actions related to innovation as a result of substances being placed in the authorisation list)

Forms of contribution to innovation	Manufacturers	Formulators	Distributors	Importers	Suppliers of articles	End users	All firms
launched initiatives to develop new substances to substitute them	9.5	26.7	6.1	0.0	12.0	25.0	14.8
launched initiatives to find alternative formulations of existing substances to substitute them	26.2	37.8	15.2	0.0	28.0	33.3	27.2
n	**81**	**100**	**46**	**13**	**54**	**25**	**319**

Source: CATI

For SMEs, participation in an authorisation consortium can be extremely demanding in terms of management time and costs, especially if expensive R&D is carried out only to prove to the authorities that other avenues have been considered but in the end authorisation is granted.

Product and Process Oriented Research and Development (PPORD)

The introduction of exemptions from REACH registration obligations in the case of Product and Process Oriented Research and Development was among the mechanisms directly targeting the promotion of R&D and innovation. 9.3% of respondents indicated that they had made use of PPORDs (primarily manufacturers and formulators) (OBS).

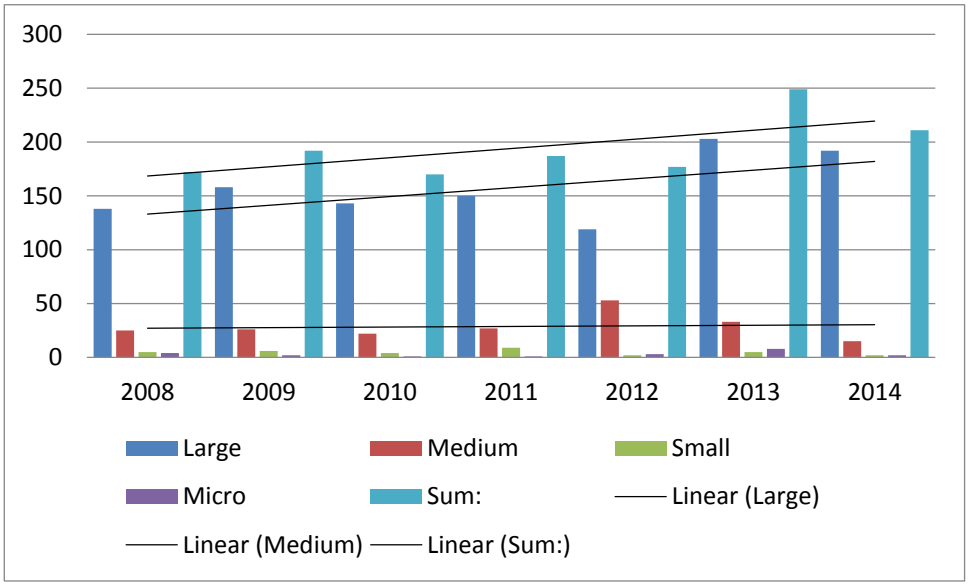
Of the total of 1498 PPORDs since 2008, 39% have been for German firms, followed by France, the UK, and Italy.

Table 3.8.5 Numbers of PPORD notifications by company size, completion year and by Country

Country Name	Number	Percentage of total
Germany	570	39
France	172	12
United Kingdom	136	9
Italy	123	8
Ireland	93	6
Belgium	73	5
Austria	58	4
Finland	52	4
Netherlands	50	3
Sweden	41	3
Spain	36	2
Czech Republic	16	1
Slovakia	15	1
Portugal	10	1
Hungary	9	1
Other	14	1
Sum:	1468	
Source: ECHA		

Large firms have been responsible for 82% of the PPORD notifications and completions between 2008-2014, medium-sized firms for 14% and small and micro firms for 2% each. A linear trend line on the data for the period 2008-2014 shows an increasing trend for the overall number of PPORDs and the participation of large firms, with that of medium-sized firms remaining level.

Chart 3.8.2 Use of PPORD by firm size, 2008-2014



The role of intelligence gathered through registration and supply chain communication

REACH has a number of processes and tools that, either directly or indirectly, can serve as important sources of intelligence that can contribute to innovation. When asked to identify those sources of intelligence generated by the REACH Regulation that acted as a stimulus to new product conception, development and/or commercialisation, the most frequently mentioned was the candidate list (19.6%) closely followed by safety data sheets (SDS and eSDS) at 19.1%. The effects of the candidate list were noted above. The role of exchange of information in the supply chain is also an important source of intelligence (17.1%) especially for distributors and manufacturers.

Table 3.8.6 Has the development of, or access to, any of the following sources of information generated by REACH acted as a stimulus to new product conception, development and/or commercialisation in your business (percentage of respondents indicating)?

Sources of information	Manufacturers	Formulators	Distributors	Importers	Suppliers of articles	End users	All firms
Development of the Registration dossier with Technical dossier and Chemical Safety Report	8.2	1.1	2.2	1.4	4.3	5.2	4.8
Development of the Safety Data Sheets (SDS)/(eSDS)	20.4	17.6	21.7	16.7	21.7	17.4	19.1

Sources of information	Manufacturers	Formulators	Distributors	Importers	Suppliers of articles	End users	All firms
Substance Information Exchange Forum (SIEFs)/ Consortia	7.1	3.3	0.0	5.6	8.7	2.6	4.9
The ECHA dissemination portal	14.8	11.0	6.5	15.3	17.4	13.0	13.4
Exchange of information in the supply chain	16.8	12.1	19.6	15.3	10.9	24.3	17.1
Registry of Restriction Intentions or Restrictions already agreed or in discussion	9.2	8.8	6.5	8.3	8.7	16.5	10.2
Candidate list of substances for Authorisation	16.3	23.1	8.7	15.3	26.1	27.0	19.6
Notifications of use to ECHA by users of Candidate list substances	5.6	4.4	2.2	2.8	4.3	7.8	5.1
n	196	91	46	72	46	115	566

Source: OBS

Impact on time to market

The length of time it takes from a product being conceived until it is available for sale (time-to market - TTM) can be a critical aspect of the overall innovation process, particularly in some of the fast moving creative sectors such as fashion, design, and ICT. Just over half of the respondents to the CATI (53.6%) indicated that there was no change (especially end users) in TTM, while 17.9% indicated an increase but less than five months (suppliers of articles – 50%; formulators - 45%; and distributors – 41% were most affected). 17.4% indicate a delay of more than 6 months.

Table 3.8.7 - Has the implementation of REACH and the various procedures involved, affected the time required to bring your products to the market?

Impact on time-to- market	Manufacturers	Formulators	Distributors	Importers	Suppliers of articles	End users	All firms
It led to a reduction of the total time required	1.8	0.0	0.0	0.0	0.0	0.0	1.0
NO change	59.6	30.0	41.7	48.5	37.5	71.4	53.6
Increased by less than 6 months	15.6	30.0	25.0	18.2	12.5	14.3	17.9
Increased by more than 6 but no more than 12 months	8.3	5.0	8.3	9.1	25.0	0.0	8.2
Increased by more than 12 months	8.3	10.0	8.3	12.1	12.5	7.1	9.2
Do not know	6.4	25.0	16.7	12.1	12.5	7.1	10.2
Total	109	20	12	33	8	14	196

Source: CATI

Implications of REACH for the allocation of R&D resources

One important point of concern linked to the procedures of REACH is the possible need for firms to reallocate resources from R&D related activities to compliance activities or to increase budgets to enable R&D activities to continue. This was a point already raised in the initial impact assessment and during the 2010 Registration.

The responses to the OBS survey suggested that about half of firms (53.4%) did not reallocate resources from R&D activities to prepare for registration. 15.8% of manufacturers and 14.3% of formulators did however indicate a permanent reallocation of R&D, as did 25% of suppliers of articles.

There was also some temporary reallocation of resources from R&D: one third of end users, close to a fifth of manufacturers and formulators, and a sixth of importers.

Companies that reallocated R&D resources were asked what percentage of total R&D resources they reallocated. The largest percentage was for <10% (36%), followed by 11-25% at 28%. Only 4% of respondents indicated that >50% of R&D resources were reallocated (temporary and permanent).

Table 3.8.8 Estimate of the level of resources (as % of the total R&D personnel) that was reallocated (percentage of firms among those indicating that they have reallocated R&D personnel)

Share of R&D personnel reallocated	Manufacturers	Formulators	Distributors	Importers	Suppliers of articles	End users	All firms
<10%	40.4	12.5	33.3	25.0	33.3	50.0	36.0
11-25%	27.7	37.5	66.7	12.5	33.3	16.7	28.0
26-50%	23.4	37.5	0.0	25.0	0.0	16.7	22.7
51-75%	2.1	0.0	0.0	12.5	0.0	0.0	2.7
76-100%	0.0	0.0	0.0	12.5	0.0	0.0	1.3
Do not know	6.4	12.5	0.0	12.5	33.3	16.7	9.3
n	47	8	3	8	3	6	75

Source: OBS

3.8.4 Best practices identified and assessed from the perspective of relative abilities of SMEs to capitalise on the new opportunities created by REACH.

Some attention has been devoted to this question in section 4.4. However, to date not many good practices have been identified for SMEs to capitalise on opportunities provided by REACH. The opportunities provided might include: export to new EU markets with an EU registration number; export outside of the EU with a REACH-compliant product; supplying an EU buyer whose non-EU supplier has not registered; buying another SME who is not able to or want to meet REACH compliance requirements and as a result wants to sell and withdraw from the business; and then there are regulatory activities to be performed in the industry which could help individuals or firms but will add costs to the operation of the industry overall.

Those SMEs that have looked further into new opportunities and developed them have often done so in collaboration with industry association initiatives, or other public sector funding support.

3.8.5 Conclusions

In general, the implementation of the REACH Regulation has led to an increase in R&D activity for about a quarter of CATI respondents. The OBS found there was an increase in R&D budgets for 8% of respondents.

However, there are different views as regards the extent to which that has led to innovation, as opposed to regulatory compliance which does not actually result in innovation in the sense of improving competitiveness.

An increase in knowledge of chemical substances and awareness of needs of upstream and downstream value chains was reported by a significant share of respondents; and about a fifth of respondents, both in the CATI and the on-line survey, indicated that they had launched new products or services as a result of knowledge gained through the compliance process. However, a follow-up exercise among these suggests that in fact only a few opportunities had actually been realised.

Among the drivers of innovation, registration (as a result of cost increases that led to withdrawals), led to an increase in R&D activity to identify alternative substances to use for about half of those affected, and a change of manufacturing processes so that those substances were no longer needed for between a quarter (CATI) and a third (on-line survey) of respondents.

A second effect of registration on innovation worked through the allocation of R&D resources to the registration process. About a third of respondents said they reallocated R&D staff to compliance activity (39% were large firms - who are responsible for most R&D), while a fifth said that any such reallocation was temporary and an eighth that it was permanent. Of those that reallocated resources, about a third said less than 10% of R&D resources were involved, a quarter between 11-25% and a fifth between 26-50%.

Among the 30% of respondents that were affected by the candidate list (CATI), about a tenth launched initiatives to develop new substances to substitute them, and a third to reformulate so that they were no longer needed. The response to substances appearing in the authorisation list was similar.

The use of PPORDs is increasing gradually. They are used primarily (82%) and increasingly by large companies and Germany alone accounts for 39% of use.

Among the various sources of intelligence for product conception, development and commercialisation generated by the REACH Regulation, the candidate list was most often mentioned, followed by development of the eSDS/ SDS and the exchange of information in the supply chain.

About half of respondents indicated that there were not any effects on time to market for their products/ services. Close to a fifth said it had increased by up to 6 months (especially formulators) and a sixth that it had increased by 6 months or more.

Overall, it can be concluded, based on the evidence of the data presented, that the Regulation has had a certain impact on innovative activity in the chemical industry, giving rise to R&D into substitutes and reformulation, and changes in manufacturing processes, but also affecting the resources allocated to R&D. There has not been a marked change in comparison to the experience with the 2010 registration, except in the sense that trends identified then have now continued. The only area where there is some difference is in that a slightly lower share of R&D resources has been allocated by firms to compliance than during the 2010 registration.

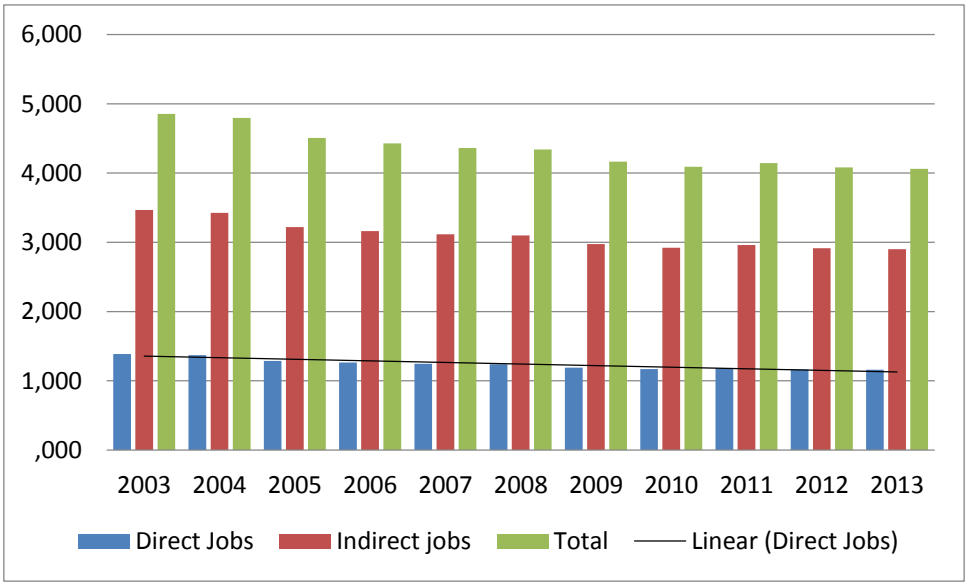
3.9 Objective 9 - Human Resources and Consultants

3.9.1 Introduction

The aims of this section are: to assess the availability of adequately qualified persons to deal with REACH at company level, including issues such as REACH jobs market saturation, level of skills as well as transparency and ease of assessing the qualification and performance of consultants and/or internal staff; to examine constraints for SMEs for both acquiring highly qualified internal human capacities and/or adequately externalizing REACH processes to consultant services should be examined; and to consider the offer of education programmes most appropriate to acquire the necessary skills and the practice of REACH professionals in documenting their skills and their trans-border.

The chart below shows that there has been a gradual reduction in employment in the chemical industry for some years. It is against this background that the aims of this sub-section are assessed.

Chart 3.9.1 Employment in the EU chemical industry 2003-2013



Source: Eurostat/ CEFIC (2014)

3.9.2 Stakeholder views on availability

Some 40% of **Member State Authorities/ Help Desks** interviewed said that that they thought there is adequate availability of appropriate human resources and 50% said that the same was true as regards appropriate external resources (primarily consultants). Among **industry representatives** over 60% thought likewise.

The slightly less positive view of Member State Authorities/ Help Desks may be because they come into contact more often with smaller firms, whereas industry representatives tend to deal with larger enterprises. This is also an area where there seems to be a good deal of variation between Member States – often smaller Member States with smaller chemical industries have more issues about supply of specialised staff, consultants and training or educational courses in the national language. They also generally point out that when good consultants are available they come at a price, which presents a cost issue for smaller firms as they can be expensive from a small firm's point of view. While

Member State Authorities are not in a position to comment on quality of local/ national consultants, several (again, mainly in smaller Member States) have said they have been approached by SMEs asking for a list of "reputable" or "accredited" consultants, which they do not have and cannot provide.

Industry representatives are also aware of the cost issue related to availability and confirm that larger companies can afford external consultants more readily, and also invest in internal training and employment of specialists, whereas in a micro-firm, the company chemist might well be in charge of both dealing with REACH obligations and R&D, and the additional cost of dealing with an external specialist is a significant financial burden. Those companies and individuals who have been working with REACH since 2007 or even earlier have developed a high level of expertise and larger firms do not experience significant issues as regards supply of suitable staff. However, this also varies by Member State and not all are immune from such problems. Quality of external consultants can be an issue (especially in smaller MS, even if there is an advanced chemical industry) depending on the specialisation required and the level of specialisation in question. SMEs do experience issues related to cost and quality - although sometimes the Industry Association can provide support (e.g. ReachReady in the UK). Availability of training varies by country, and is not always available in the national language. Industry associations (and sometimes consortia) provide training – usually in the form of workshops, webinars and short courses.

3.9.3 How companies deal with REACH obligations

Organisation of REACH compliance activities

Dealing with REACH compliance activities can be a complicated and demanding process, and firms adopt different approaches, allocate varying levels of human resources and make different use of external support. According to the CATI survey, the development of a separate REACH unit or use of a dedicated REACH manager is an approach adopted by a significant number of firms, particularly among manufacturers and formulators (see table 3.9.1). It is less common among firms with other REACH roles, especially importers or end users. As expected, it is also less common among smaller firms (14%), in comparison to large firms (35%). Much more prevalent is the allocation of REACH compliance activities and responsibilities to the Health and Safety and Environment department/unit (57.5% of the firms). Nearly half of firms indicated that they deal with REACH related material on an ad-hoc basis, when and if needed. The use of external consultants to outsource REACH compliance activities is also common, particularly among manufacturers. However, only a small share indicated that they have fully outsourced them. Among SMEs, 18% of micro firms indicated that they fully outsource their compliance activities, compared to 6.5% of small, and 2.7% of medium-sized firms. The overall percentage for SMEs fully outsourcing is 6.4% compared to 2.4% of large firms (CATI).

Table 3.9.1 - How does your firm deal with REACH compliance activities? (percentage of firms responding – multiple responses possible)

	Manufacturers	Formulators	Distributors	Importer	Suppliers of articles	End users	All firms
Dedicated REACH unit	35.0	27.1	13.3	8.3	14.7	14.4	20.8
Dedicated REACH manager	45.8	40.6	23.4	20.0	28.7	14.4	31.4
Dealt with by a team responsible for HSE compliance	57.1	62.9	51.3	56.7	51.4	66.0	57.5
Managers and technicians deal with REACH on an ad hoc basis	46.8	53.4	41.1	43.3	50.6	50.3	48.7
Partly outsourced REACH compliance activities	40.4	23.1	13.9	18.3	19.9	15.0	22.9
Fully outsourced REACH compliance activities	3.9	2.4	4.4	10.0	8.4	2.6	4.8
Other	7.9	6.4	10.8	10.0	8.4	11.8	8.7
N	203	251	158	60	251	153	1076

Source: CATI

Numbers of staff

In terms of the actual level of human resources allocated, the majority of the CATI survey respondents indicated that in 2013, they allocated between 1-2 FTE to REACH related activities. As expected, a greater share of large firms indicated more than 5 FTE, while an important share of micro firms (24%) indicated that their total FTE allocated was 0. There are small variations on the basis of the firms' REACH role. Manufacturers and formulators tend to allocate more resources than downstream users, even though there are also some article suppliers and end users which also allocate significant resources.

As illustrated in the table below there are small variations on the basis of the firms' REACH role. Manufacturers and formulators tend to allocate more resources than downstream users, even though there are also some article suppliers and end users which also allocate significant resources.

Table 3.9.2 - Total number of personnel allocated to REACH-related activities in 2013 (in FTE) – distribution by role

FTE	Manufacturers	Formulators	Distributors	Importer	Suppliers of articles	End users	All firms
0	7.9	7.6	12.0	21.7	15.1	15.7	12.0
1	39.4	45.0	38.6	35.0	34.3	30.7	37.9
2	18.7	18.3	21.5	11.7	18.3	17.6	18.4
3-4 FTE	15.3	12.4	5.1	13.3	10.8	7.2	10.8
5-10 FTE	6.9	5.6	6.3	8.3	2.8	7.2	5.7
11-20 FTE	2.0	2.4	1.9	0.0	4.0	3.3	2.6
> 20 FTE	3.9	0.0	1.3	1.7	2.4	5.9	2.4
Do not know/No answer	5.9	8.8	13.3	8.3	12.4	12.4	10.2
Total	100.0	100.0	100.0	100.0	100.0	100.0	100.0
n	203	251	158	60	251	153	1076

Source: CATI

The data from the OBS – covering the period 2011-2013 – suggest a slight increase in the number of personnel allocated to REACH-related activities among those enterprises employing 10-25 employees (from 2.3% to 3.9%), with those employing 5-10 and 2-5 remaining very similar, while an increase in those employing 1-2 occurred (22.7% to 26.1%).

In the course of the in-depth interviews distributors indicated that their REACH-related staffing had increased because of the challenges of getting data from their customers and also non-EU suppliers. It is important to note that in small and micro-firms, compliance activities can be particularly high in terms of opportunity costs for other firm activities such as innovation as often one person is responsible for R&D and compliance, and that person is also often the owner/ manager of the business as well.

In terms of evolution over time, the business survey responses provided show a small trend towards an increase of human resources allocated to REACH compliance, with more firms indicating than they have more than 2 FTE allocated. An initial analysis suggests that this is mainly driven by the increased resources allocated by downstream users, article suppliers and end users.

3.9.4 The availability of adequately qualified persons (staff and external resources).

As regards the availability of resource**s** to deal with REACH at company level, 37.4% of the CATI respondents consider that it is easy to fill REACH *staff vacancies* with the right people while 26.6% suggested that it was difficult. The analysis by firm size does not indicate any substantial differences but there are noticeable differences depending on the country where the firm operates. More than 50% of firms in the Netherlands, Spain, Sweden and Romania say that is easy while over 35% of respondents in Italy, France and Austria thought that it is difficult.

The OBS provides a more negative picture, with only a small share of firms indicating that filling REACH-related vacancies is easy or, at least, not more difficult than other positions. Also, a large majority of firms (over 65%) prefer to train existing staff rather than recruit new external staff. Furthermore, around 20% suggested that they ended up spending additional resources to train staff recruited for REACH.

According to the CATI, 45.5% of respondents do not find the availability and quality of external *consultants* (used by an important number of firms) a particular issue, and the share of positive (easy to find a consultant with the right level of skills) and negative (difficult) responses is similar (25%). The results of the OBS are also very similar. Furthermore, there appears to be no significant difference of view related to firm size (larger firms tend to say more difficult than micro or small), but there are some differences depending on the country of operation. Over 40% of Austrian and Hungarian respondents thought that access to quality consultants is difficult while over 35% of respondents from the Czech Republic, the UK and the Netherlands thought that it is easy. The survey did not ask if there were issues about costs/ affordability of consultants though, and feedback from interview programmes suggest that this is the key issue for SMEs, rather than availability.[90]

3.9.5 Specific constraints for SMEs as regards acquiring highly qualified internal human resources and/or adequately externalising REACH processes to advisory services.

There are some significant differences in the way in which SMEs and large firms deal internally with the resources required to ensure compliance with REACH. A larger share of large firms report having a dedicated REACH unit more often (32.7% compared to 17.4%) and have a dedicated REACH manager (48.3% compared to 28.6%). SMEs more often deal with REACH in an ad hoc fashion and both partly and fully outsource more often. The CATI results also reflect these differences.

Both the CATI survey and online business survey indicate that there are not significant differences between SMEs and large firms as regards *availability* of qualified staff to deal with REACH-related activities. Both seem to favour using existing members of staff and to provide them with additional training as and when needed, rather than to recruit externally. This may also be related to the economic environment in recent years, especially where there are inflexible labour markets.

As far as working with external consultants is concerned, more SMEs say they find it very difficult to find consultants with the right level of skills and experience that they can

[90] See also 3.11.6

trust and work with (22.8% of SMEs compared to 13.2% of large firms), but the overall percentages for difficult (quite plus very) are not dissimilar.

Similar shares also find it difficult to assess the value of consultants because there are no EU-wide standards to assess them against (17.5% and 16.7%) although there is a difference between small (21.1%) and micro firms (26.7%).

Interviews with SMEs suggest that the key difference between large firms and SMEs as regards staff and consultants lies in affordability.

3.9.6 The offer of education programmes

Concerning the availability of relevant education and training courses to support the firms in REACH compliance, around 50% of the OBS respondents appear to be satisfied with what is already available. Distributors and suppliers appear a bit less satisfied than firms with other REACH roles. Nonetheless, around one-third of respondents said that they complement existing training courses with internal tailor-made courses.

Less SMEs than large firms have designed in-house training programmes (27.3%compared to 37.0%) and more SMEs said that existing courses are not appropriate for their needs (21.2% compared to 12.6%) – especially in the case of micro firms (46.7%).

It should be noted that there are two different generic areas of skills in question. On the one hand there are the highly technical skills such as those required by toxicologists. On the other there is the skill level required by someone who is responsible for REACH compliance in a company, who needs to understand chemistry but may also have other company work commitments and would be involved in outsourcing work to a specialist laboratory or REACH consultant (legal or technical).

The first group is highly specialised and requires advanced university qualifications often complemented with additional diplomas and certificates.

As regards the second group, what the findings point out is that most companies have tended to adopt a learning-by doing approach to learn about what is required for compliance and then to bring about the required company changes to implement those changes. They have made use of internal resources with relevant REACH-knowledge where available, or developed such a capability by self-taught methods (often by the owner/ manager). A wide range of knowledge sources is used, including courses at industry associations, consortia, networks, ECHA websites and webinars, etc. that provide the basic information which companies then adapt to firm-specific circumstances. Some smaller MS do not always have sufficient training and consulting expertise available so it has either to be imported or company employees and managers are sent abroad which is costly. The emphasis is on the practical use of the training or education, rather than on the nature of the qualification.

A study to determine the number and type of university courses existing in the field of REACH and CLP across Europe and identify areas of opportunity for training of regulatory scientists in the field of chemicals was undertaken for ECHA and published in 2012.[91]

[91] Universita degli studi di Milano, Dipartimento di Scienze Farmacologiche e biomolecolari DiSFeB (2012) Mapping Study on Academic Courses Relevant to REACH and CLP, Final Report, December 18, 2012

The study found that many courses of various durations and content existed throughout Europe, but that there was not a 'fit for purpose' scheme that would benefit industry, students, universities and ECHA alike. This should provide a tailored and comprehensive training scheme that could be of even higher value if offered as an accredited university qualification. The following options were identified:

- To expand the experience gained during the DG SANCO European Toxicology Risk Assessment Training (TRISK) initiative, as this was a successful proof of concept focusing on human health risk assessment.

- To build on the current initiative by the Italian Ministry of Health and Research, to set up postgraduate courses in the field of REACH/CLP for the training of professionals and could be considered as an initiative to replicate across other European countries.

- The ECHA graduate scheme could be developed to work with European academic institutions to develop further education programmes, possibly linked with some form of internship or research positions for newly qualified graduates within ECHA.

According to feedback obtained during the interview programme, most of the initial universities offering masters courses in chemistry specialising in REACH have now withdrawn those programmes.

The OBS feedback suggests that companies want a practical hands-on approach tailored to their experience which cannot be readily provided by university education. For those large or specialised companies with substantial in-house laboratories and larger teams of researchers, a different approach is required to deal with issues such ecotoxicology or toxicology that is also offered in a bespoke manner appropriate for the companies in question. Small and micro-firms tend to develop the capabilities in-house (self-taught supplemented by the occasional workshop) or outsource it all (to a greater extent than larger firms).

One approach that might be worth further consideration is that of the Chemicals Office of the Republic of Slovenia. For companies that need special advice for activities in the chemicals field, staff carrying out such activities need to undergo a certain level of training and pass exams related not only to REACH but also to other regulatory areas where chemicals are involved before they are qualified to work in that area.

As regards the question of possible certification, or similar qualification that would mean that the holder has a certain level of knowledge in REACH, it was primarily SMEs that found this of interest (in countries such as Italy and Ireland). Such certificate would testify to a certain basic level of competence for the holder and could lead to the expansion of the offer of REACH consultants. There might also be a few levels within the qualification that would mean different levels of technical competency so that for basic questions it is not necessary to use over-qualified specialists. It can also be looked into whether such a qualification can be pan-European, or if there would be a pan-European basis which can then be topped-up with a national test. Furthermore, the need for such a qualification in the post 2018 registration period would have to be assessed carefully. Would there still be a sufficient on-going demand? A further issue is what will happen to demand if the EU economy recovers and starts to grow strongly in the next few years? If economic growth picks up it could lead to an increased demand for chemists that would work on product development and innovation.

3.9.7 Conclusions

The majority of firms allocate a certain level of human resources (typically 1-2 FTE) to ensure compliance with REACH regulation. Complete reliance on external consultants is

not common, although smaller firms tend to use this approach more. In most cases there is a combination of internal staff and external tailored support.

Development of specialised REACH units is the most often used approach for large firms and generally by manufacturers involved in registration activities. However, overall, most often dealing with REACH obligations is part of the responsibility of HSE departments/units or they are dealt with on an *ad hoc* basis by managers or technicians.

The research found that while overall there is acceptable availability of adequately qualified persons to deal with REACH at company level, there are variations by Member State and many firms (especially smaller ones) face some difficulties in terms of accessing adequately trained personnel in the market. It is often the case that they prefer to use existing employees rather than recruit externally, and especially larger firms organise internal tailored training.

For about half of the survey respondents, the existing external training courses are considered to be appropriate, but they do still use additional internal training which suggests that there are gaps in external supply.

In terms of the availability and quality of consultants, the picture is rather mixed. There is no indication that finding qualified consultants is particularly problematic but this may vary depending on the need and the level of expertise required. There is also a demand, again primarily among smaller firms and particularly in some countries (e.g. Italy and Ireland) for some kind of approval or quality rating so that firms can assess the technical capability of REACH-consultants. The question of consultants and specialised staff tends not to be as much an issue of availability as one of *costs*, especially as far as SMEs are concerned.

Specifically as regards smaller firms, the challenges relate to use of senior managers' or technicians' time on compliance activities, adequacy of training courses and the cost and how to assess the quality of external consultants. This also has a Member State dimension.

3.10 Objective 10 - Substances of Very High Concern (SVHCs) and Authorisations

3.10.1 Introduction

In the area of substances of very high concern and authorisations, the aim of the study is: to assess the costs of preparing an authorisation application; to verify the availability of human resources with required competences; to assess the affordability of the authorisation process, especially for SMEs; to evaluate the effects of listing substances under the SVHC roadmap, the Candidate list, Annex XIV on the availability of substances on the market and the number of suppliers; and, to assess the direct and indirect costs of the application of Article 33.

The 2012 REACH review process concluded that the authorisation and restriction mechanisms are working and are ensuring that risks from Substances of Very High Concern (SVHC) are controlled and that, where suitable alternatives are economically and technically viable, those substances are progressively replaced.

Indeed, for around 50% of the 31 substances in Annex XIV, no applications for authorisation (AfA) have been received by ECHA and the latest application dates have passed.[92] Moreover, as highlighted by ECHA during the conference "Lessons learnt on Application for Authorisation" held in Helsinki on 10-11 February 2015, half of the (31) applications received so far[93] are so-called "bridging applications", meaning that the applicants are working on phasing out the substance from their processes/products but need more time to fully develop an alternative. [94] On top of this, some of the companies involved in AfAs improve their risk management measures to have the strongest arguments for the application.

3.10.2 Costs of preparation of an authorisation application

Between 2013 and 2014 ECHA surveyed applicants with regard to the application costs: they calculated an average cost per applicant/use of around €230,000 based on 24 responses, although the trend indicates declining costs (applicants that submitted AfAs in the second half of 2014 had average costs of less than €200,000 per applicant/use). Cost component shares of an AfA are presented in Chart 4.10.1.

Companies interviewed for the purpose of this study overall confirmed these figures. Three companies that were in the process of preparing an application or that will have to in the future have estimated costs per applicant/use ranging between €250,000 and €500,000. It is important to note that when there will be more examples, the European Chemicals Agency will be in the position to calculate the cost per review period year, where an authorisation for 12 years is clearly more valuable than one for 4 years.

3.10.3 Availability of human resources

Overall, there was a certain consensus that the authorisation mechanism has been a "learning by doing" process for everybody, including the Commission and ECHA.

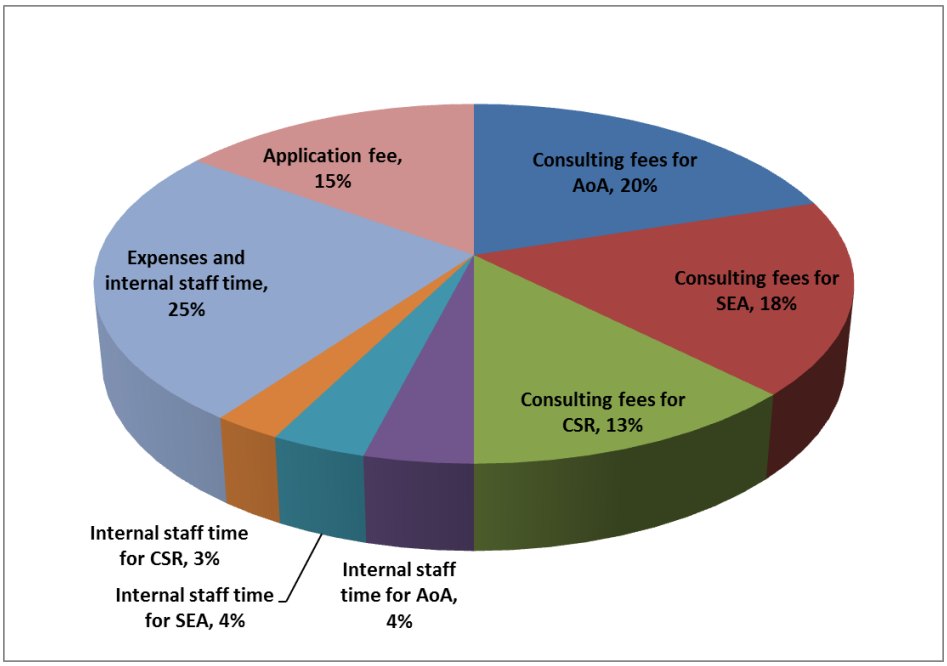
[92] It should be noted that some of the substances were already not used in the EU when they were included in Annex XIV, but they were included to prevent operators from using them as substitutes.

[93] August 2015.

[94] Presentation by Thierry Nicot of the Risk Management Implementation Unit at ECHA. Available at: http://echa.europa.eu/documents/10162/21825501/afa_201502_7_nicot_en.pdf

Availability of human resources and consultants and the verification of whether they had the right competences for following and assisting in an application for authorisation has been problematic at the beginning as there were no previous experiences and nothing to benchmark with, but the feeling is that now, although the learning process is still ongoing, human resources with the right skills for the socioeconomic analysis and the analysis of alternatives are available.

Chart 3.10.1 Cost components shares of an application for authorisation



Source: Own elaboration of ECHA data

3.10.4 Affordability of authorisation

With regard to the affordability of the authorisation process for SMEs, the costs for an application for authorisation vary depending on the number of uses, substances and applicants covered by the application. Even the application fees vary according to these factors. ECHA applies reduced fees for micro, small and medium enterprises, ranging from €5,330 to €39,975 per applicant/use (compared to an application fee of €53,300 for a large company applying for one substance/use)[95].

However, the application fee represents only a small fraction of the costs, as shown in Chart 3.10.1. As for registration of chemical substances, a way to reduce authorisation application costs is to co-operate with other applicants during the preparation of the application. However, the process remains resource and time consuming, as not every part of the application can be prepared jointly, for example to maintain confidentiality of business information. It has to be noted that any downstream user can rely on an

[95] This is more than 15% but ECHA reports 15% (slide 9, http://echa.europa.eu/documents/10162/21825501/afa_201502_7_nicot_en.pdf). The average percentage may be lower due to reduced fees for SMEs.

application that was submitted by an enterprise further up his supply chain and does not need to apply himself (thus, saving staff, time and application fees), as long as he respects the exact conditions of the use applied for. Authorisation can also create an advantageous position for those that have developed alternatives/ substitutes.

There is not enough experience yet with regard to SMEs applying for authorisation for a full assessment: only one of the companies that has already submitted an AfA is classified as a medium enterprise; some other SMEs are in the process of preparing an application. However, some argue that that with a careful and timely planning of the application, the costs are not an insurmountable obstacle even for a SME. But as noted in the section in SMEs, the term "SME" incudes a wide variety of enterprises, and the real problem is the availability (and opportunity cost) of in-house resources to follow the whole application process, which is what makes it challenging for most micro and small firms.

During the conference "Lesson learnt on Applications for Authorisation" held in Helsinki on February 2015, companies that already submitted authorisation applications described their experiences and confirmed that it is a resource intensive process: for example, Huntsman advised that for their application, for the period going from May 2011 to December 2014, a three and a half year period, a core working team of 8 people dealt with the process, having: *"18 team meetings in 7 cities and 5 countries"; monthly senior management reports; regular presentations to Board of Directors; dozens of teleconferences, hundreds of phone calls and countless email"*.[96]

It is worth noting that this was the experience of one of the first AfA, and although this reflected the experience of others interviewed, as already mentioned, subsequent applicants reported lower costs, as applications seem to require less time and fewer international meetings.

Another issue that might arise is the possibility of being the manufacturer/importer/downstream user of two or more substances in Annex XIV and of having to deal with two or more applications for authorisation at the same time or with an authorisation covering several SVHCs. In this event, even in the case of a careful planning, both availability of human resources and costs will be an issue for a small enterprise. This event is already a reality for over 30% of the large companies surveyed through the OBS (chart 3.10.2) and for 20 SMEs (of which 1 micro-enterprise) responding to have more than 1 substance they manufacture/import/use in Annex XIV (it should be noted that companies can chose not to submit an AfA). The likelihood of having companies submitting several AfAs at the same time is also confirmed by the number of companies reporting to have more than one substance in the Candidate list or that have been prioritised for inclusion in Annex XIV.

3.10.5 The effect of listing substances

With regard to the effects of listing substances in the Candidate list and in Annex XIV on the availability of substances on the market and the number of suppliers, the surveys' results offer some interesting information.

Around 40% of the respondents (Table 3.10.1) have received customers' requests to remove SVHCs from their products, with small variations between SMEs and large enterprises; around 70% of the companies declaring as their primary role to be suppliers

[96] http://echa.europa.eu/documents/10162/21825501/afa_201502_3_frazee_en.pdf

of articles received such request from their customers (Tables 3.7.4 in the Downstream user Section).

Table 3.10.1 Have any of your customers requested the removal of SVHCs from your products? (Percentage of respondents by company size)

Response	SME	Large enterprise	All firms
Yes	36	42	39
No	64	58	61
n=	124	111	242

Source: Business Survey

These results are also confirmed by the actions undertaken by companies when substances are placed in the Candidate list for authorisation or in Annex XIV (Table 3.10.2 and 3.10.3). Indeed, the most common actions are to launch initiatives to find alternative formulations or alternative technologies or processes and to request substitution to the suppliers.

Chart 3.10.2 Number of companies by size declaring to have 0, 1 or more than 1 substance in the CORAP list, in the Candidate list for inclusion on Annex XIV, that have been prioritised for inclusion in Annex XIV, in Annex XIV and in Annex XVII

Source: OBS

Table 3.10.2 What has been the response of your firm to the placing of substances relevant to your business in the Candidate list? (percentage of firms indicating)

Type of response	Manufacturer	Formulator	Distributor	Importer	Supplier	End user	All firms
Not applicable (no relevant substance placed on the list)	28.9	25.6	26.3	27.6	20.0	18.0	22.7
Launched initiatives to develop new substances to substitute them	21.7	20.5	15.8	13.8	12.0	28.0	18.7
Launched initiatives to find alternative formulations of existing substances to substitute them	28.9	46.2	21.1	24.1	28.0	44.0	29.9
Withdrew them from our product portfolio	9.6	28.2	15.8	24.1	8.0	12.0	14.0
Requested substitution of those substances by our suppliers	14.5	30.8	26.3	17.2	40.0	42.0	23.7
No special action taken	25.3	7.7	26.3	24.1	32.0	14.0	18.7
We are applying for Authorisation	7.2	2.6	0.0	0.0	12.0	6.0	5.0
Total	100.0	100.0	100.0	100.0	100.0	100.0	100.0
n=	83	39	19	29	25	50	278

Source: OBS

Table 3.10.3: What has been the response of your firm to the placing of substances relevant to your business in Annex XIV? (percentage of firms indicating)

	Manufacturer	Formulator	Distributor	Importer	Supplier	End user	All firms
Not applicable (no relevant substance placed on the list)	41.0	43.6	21.1	31.0	24.0	22.0	29.5
Launched initiatives to develop new substances to substitute them	14.5	5.1	5.3	3.4	12.0	20.0	11.2
Launched initiatives to find alternative formulations of existing substances to substitute them	7.2	17.9	10.5	17.2	20.0	28.0	14.0
Withdrew them from our product portfolio	8.4	15.4	36.8	13.8	8.0	16.0	12.6
Requested substitution of those substances by our suppliers	7.2	7.7	10.5	13.8	36.0	26.0	13.3
No special action taken	10.8	5.1	10.5	3.4	16.0	6.0	7.6
We are applying for Authorisation	13.3	10.3	0.0	6.9	20.0	30.0	13.7
Total	100.0	100.0	100.0	100.0	100.0	100.0	100.0
n=	83	39	19	29	25	50	278

Source: OBS

Similar actions were taken when substances have been withdrawn from the market (Table 4.10.4). Over 50% of the (243) companies replying to this question initiated research on available alternatives or moved to existing alternative substances. Notably, around 12%of the companies indicated that they have ceased the activities that relied on the substance withdrawn while 6% indicated to have moved their operations outside the EU. As already noted, REACH is often the trigger for the rationalisation of the product portfolios of companies, inducing them to reflect on the costs and thus on the opportunity of registering substances at the end of their product life cycle or substances with hazard profiles that make them eligible for regulatory scrutiny. It should also be noted that some of the 46.5% of the companies indicating not to have had experience

with the withdrawal of substances may have switched or moved to alternative substances or technologies before.

Table 3.10.4 What has been the response of your firm to the withdrawal of a substance from the market due to its being entered onto the Candidate List or the Authorisation List?

Type of response	Manufacturer	Formulator	Distributor	Importer	Supplier	End user	All firms
Have had no experience of any withdrawal	61.5	45.5	44.0	33.3	50.0	32.1	46.5
Identified a new supplier of the substance	1.5	2.3	4.0	8.3	3.8	10.7	4.9
Initiated research on available alternatives	15.4	36.4	36.0	33.3	23.1	46.4	31.7
Moved to an existing alternative substance	13.8	25.0	16.0	29.2	26.9	32.1	23.0
Registered and/or imported the substance yourself	1.5	0.0	0.0	4.2	3.8	1.8	1.6
Ceased production activities that relied on the substance	6.2	13.6	36.0	16.7	3.8	8.9	12.3
Moved operations outside the EU	1.5	9.1	4.0	12.5	3.8	7.1	6.2
Started working on an application for authorisation	7.7	2.3	4.0	4.2	19.2	16.1	9.1
Other	9.2	6.8	4.0	4.2	7.7	12.5	8.2
Total	100.0	100.0	100.0	100.0	100.0	100.0	100.0
n=	65	44	25	24	26	56	243

Source: OBS

With regard to the effects of the inclusion of substances in the Candidate list on their availability on the market, some industry representatives reported on some specific cases.[97] Accounts of the experience of the authorisation process by industry suggest that, in some cases at least, it can result in the need to make substantial adjustments in the market. [98]

In general, industry representatives and companies agree that authorisation does have an impact on competitiveness and innovation and especially on investment decisions: the existence of the authorisation mechanism might be a contributing factor in the decision making process when considering the pros and cons of producing in the European Union or outside. If a company wants to make a multimillion investment for expanding its capacity and the machinery or any part of the production process have substances that are included or might be included in the future in Annex XIV for their hazardous profile, the following questions may be considered by investors: how can the authorities guarantee that the company will be able to use those production lines for e.g. 30 years? Will the company have to invest new money to change the process after 12, 7 or even 4 years? On the other hand, as already mentioned in Section 3.4, it is important to note that investors have shown interests in greener business models and that these may result in business benefits considering a longer time horizon.

The inclusion of substances in the candidate list triggers considerations of reformulation for some products and of withdrawal for some others: in particular, the continuous inclusion of new substances might imply the reformulation of a high number of products with associated high costs and the inevitable dropping out of some products from the companies' portfolios. Some industry associations highlighted that this process is slowing down product development and diverting resources from what they consider "real" innovation – which improves competitiveness.

The withdrawing from some markets and the possible relocation of activities outside Europe depend on the criticality of the substance going through Authorisation/Restriction and on the feasibility of substitution. In the case of a complete ban on the use of a critical substance with no feasible substitutes, or the need for submission of a costly and in any case time limited authorisation, industry would have no choice but to contemplate non-EU solutions.[99] At the same time over 95% of the companies in the chemical sector and its downstream users sectors are SMEs: it is unlikely to be economically feasible for SMEs to relocate to extra-EU countries. Companies with manufacturing facilities outside Europe might consider relocation or shifting production a straight-forward solution, being able to import the articles without having to deal with the Authorisation procedure.[100] Another possible solution would be the outsourcing of the manufacturing process; however, difficulties could be foreseen in terms of extra costs, logistical issues and ensuring batch to batch integrity.

[97] Eurometaux provided the example of arsenic trioxide: this substance is recovered as a by-product from copper smelting streams and, after its inclusion, there has been a reduction of 50% in the manufacturing, with arsenic trioxide quantities that before were processed now being sent to landfills. Eucomed and EDMA reported the case of medical grade DEHP.

[98] http://www.federchimica.it/docs/default-source/eventi_092015_13aconferenzasicurezzaprodotti/6-colombo-a.pdf?sfvrsn=2

[99] It is important to note that the review period for an authorisation is linked with what the authorities consider the feasibility of substitution and if and when warranted, review periods can also be relatively long.

[100] The import of articles containing an Annex XIV substance is examined after the sunset date for the substance in order to determine whether a restriction is warranted applying to those articles (via article 69(2) of REACH).

Many of the different stakeholders interviewed, from NGOs to industry associations, have stressed that the fact that imported articles do not have to go through authorisation is unfair and a competitiveness issue.

Another issue that has been pointed out is that chemicals suppliers may choose not to apply for Authorisation for small volume uses as the costs of doing so are too high, meaning that the cost of application would fall entirely on downstream users. An example is the in-vitro diagnostic industry that typically tends to use smaller amounts of critical substances relative to quantities used by other sectors. The costs for AfAs are likely to be passed to the end-user clinical laboratories. The interviewed stakeholders have also voiced concern that, although Article 56(3) exempts the use of substances in scientific research and development from authorisation, the supply of substances used by the non-commercial laboratory-based sector and included in the Candidate list or listed in Annex XIV could be threatened. This may happen for example when the supplier of a substance manufactured in low volumes and used in in-vitro diagnostic and in other applications decides not to apply for authorisation for the other applications due to the low margins and consequently ceases manufacture of the substance, even if authorisation would not be required for the quantity of the substance used in in-vitro diagnostic. This may impact the delivery of laboratory medicine to European healthcare, as new substances would need to be found across the portfolio of tests requiring such substitution. Due to constraints on human resources and costs, substitution could not be undertaken across all tests at once and priorities would have to be set. The result will be assigning a low priority to low volume or low margin tests, e.g. for rare diseases.

Some stakeholders have suggested that inclusion in the Candidate list should be based on actual risk consideration instead of being hazard-based. Right now, risk is considered too far down the process, meaning that substances in the candidate list are already "black-listed" even if there is no risk, with all the repercussions over reputation and availability of the substance on the market. Moreover, some stakeholders claimed that the Candidate listing started even before the first Registration process was finished, leading to targeting the same hazardous substances for which most of the data were already available, for which substitution had already been considered and for which very strict RMMs were already in place.

In order to further assess the effects of the identification and listing of SVHCs, a case study on the PACT list is presented at the conclusion of this Section.

The Commission and ECHA are aware of industry concerns and started to reflect on how to streamline and simplify the authorisation process for specific areas where authorisation requirement might impose disproportionate administrative burden on operators and authorities[101]. On the basis of the discussion with the Member States Competent Authorities and industry stakeholders, the Commission and the Agency are looking in particular to four areas:

- Uses in low volumes;
- Uses in legacy spare parts;
- Uses in products subject to type-approval; and
- Uses as biological essential elements.

[101] Announced in the Communication of 18 June 2014 on "Regulatory Fitness and Performance Programme (REFIT): State of Play and Outlook".

The use of Annex XIV substances in *low volumes* has been considered because the costs of a full-scale AfA in comparison with the potential benefits for the human health and the environment in terms of reduced risks related to their substitution are likely to be disproportionate.

Legacy spare parts are spare parts intended for articles produced and placed on the market before the sunset date: they have been considered as an area for simplification because, given the limited and decreasing volume of spare parts intended for articles that are no longer produced, the costs for an AfA are likely to be disproportionate and because research on alternatives for such uses is technically and economically difficult. Another reason is to avoid premature obsolescence and disposal of articles and extend their useful life.

Certain uses of Annex XIV substances might be subject to *type approval* or authorisation requirement under other pieces of legislation and the use of an alternative would require a re-approval or re-authorisation (for example in the aerospace or automotive sectors). This is therefore another area where a simplification of the AfA might benefit companies without hindering the objectives of REACH. However, different conditions apply to type approval/authorisation in different sectors and it is difficult to define a general framework. The Commission will consider different aspects for the simplification of this area, such as the need for re-approval or re-authorisation, the high socio-economic values of certain uses in certain sectors with regard to the Socio-Economic Analysis and the setting of the review periods in line with the length of the review periods for re-approval/re-authorisation.

Uses as *biological essential elements* will be considered for simplification in the future, after the consideration of the uses in low volumes and the uses in legacy spare parts, as are not yet a concern for the currently listed Annex XIV substances.

It should be noted that the NGOs interviewed have voiced their concern over the streamlining process of the authorisation mechanism and have called the Commission to lift the *de facto* moratorium on the inclusion of SVHC into Annex XIV[102].

3.10.6 Assessment of compliance with Article 33 of REACH

With regard to the assessment of the direct and indirect costs of the application of Article 33, usually information management systems are integrated and they help companies to comply with several pieces of legislation[103] as well as to better manage information. It is therefore very difficult to attribute direct costs to the need of companies to comply with Article 33 only.

During the interviews, NGOs and trade unions[104] have stressed the importance of Article 33 (establishing the so-called "right to know") that has provided a very important new instrument to consumers which has an important effect on the supply chain. Retailers are becoming increasingly aware that consumers can ask information on the content of SVHCs in products (as confirmed by the results of the surveys presented in Table 3.10.5) and these requests have positive impacts not only in terms of the right to know but also on incentives to substitute SVHCs in consumer products.

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[102] http://www.eeb.org/?LinkServID=6E866A31-5056-B741-DBC7F95AB907572B&showMeta=0&aa

[103] See for example the Global Environmental Management System developed by Abbott: http://prod2.dam.abbott.com/en-us/documents/pdfs/partners/Restricted_Substances_Training.pdf

[104] BEUC, EEB, ChemSec, ETUC and Client Earth.

Moreover, consumer organisations can now communicate easily with the Agency and the Commission, notify concerns over certain substances and contribute to the public consultations launched by ECHA during the authorisation and restriction processes.

Through the OBS, companies were asked whether they had been required to communicate information on SVHCs to downstream users under Article 33 of REACH. Table 3.10.5 provides the responses for different roles. These would suggest that a potentially significant proportion have had to do so, with this proportion broadly increasing as one progresses down the supply chain.

Table 3.10.5 Have you had to communicate information to industrial or professional users and distributors on the presence of a substance on the candidate list being included in an article at above 0.1% (w/w) (under Article 33 of REACH)? (percentage of firms responding)

	Manufacturer	Formulator	Distributor	Importer	Supplier	End user	All firms
Yes	*26.7*	*42.9*	*62.5*	*33.3*	*54.2*	*53.6*	*45.5*
No	*73.3*	*57.1*	*37.5*	*66.7*	*45.8*	*46.4*	*54.5*
Total	*100.0*	*100.0*	*100.0*	*100.0*	*100.0*	*100.0*	*100.0*
n=	*30*	*14*	*8*	*12*	*24*	*28*	*121*

Source: OBS

This is confirmed by the companies that reported to have installed specific IT systems for answering customers' questions regarding to SVHC content in articles (around 57% of the respondents), with suppliers of articles and end users having the highest percentages (Table 3.10.6 and 3.10.7). These results are encouraging and indicate that awareness or Article 33 among companies is increasing and that the call from NGOs to implement dedicated management systems in order to ensure coherence in the answers provided in different countries is being progressively accepted by companies across the EU. In order to verify whether there is effectively a positive trend, during the interview BEUC's representative suggested the Commission to launch a study to update and expand the survey conducted in 2011 by BEUC and its national members investigating the functioning of article 33[105].

[105] More information at: http://www.chemsec.org/what-we-do/sin-list/latest-on-sin/829-consumers-qright-to-knowq-tested-companies-asked-if-they-use-any-sin-list-chemicals

Table 3.10.6 Have you installed specific internal (IT) systems and/or routines for answering customer/consumer questions regarding the SVHC content in the articles you place on the market? (Percentage of respondents by company size)

Response	SME	Large enterprise	All firms
Yes	40	70	57
No	60	30	43
n=	40	54	97

Source: OBS

Table 3.10.7 Have you installed specific internal (IT) systems and/or routines for answering customer/consumer questions regarding the SVHC content in the articles you place on the market? (Percentage of respondents by company role)

Response	Manufacturer	Formulator	Distributor	Importer	Supplier	End user
Yes	55	44	56	30	68	63
No	45	56	44	70	32	38
n=	20	9	9	10	25	24

Source: OBS

It should be noted that also private investors have highlighted the importance to strengthen chemicals companies' reporting of product stewardship, substitution and management of substances of concern.[106]

3.10.7 Conclusions

The authorisation mechanism has begun to work: for around 50% of the 31 substances in Annex XIV, no applications for authorisation (AfA) have been received by ECHA and the latest application dates have passed, and half of the 31 applications received so far are "bridging applications". However, some of the substances were already not used in the EU when they were included in Annex XIV, but they were included to prevent operators from using them as substitutes.

The costs for the development of the first AfAs have been estimated by ECHA at around €230,000 per applicant per use, with the latest AfAs being less costly (around €200,000). With regard to SMEs applying for authorisation for a full assessment, there is the concern that the availability (and opportunity cost) of in-house resources to follow the whole application process could pose a major barrier to SMEs. In this respect, it will be important to monitor the experience of the SMEs that are currently preparing for an application for authorisation. However, downstream users can refer to upstream

[106] http://newsletter.echa.europa.eu/home/-/newsletter/entry/3_15_investor-perspective-why-reach-matters-for-your-bottom-line

applicants within their supply chains, and do not necessarily have to apply themselves. How the upstream applicant deals with that is of course a commercial matter.

In general, industry representatives and companies agree that authorisation does have an impact on competitiveness, innovation and investment decisions. Investors need regulatory certainty over the use of substances critical to some industrial processes or applications that might be included in Annex XIV.

The inclusion of substances in the candidate list triggers considerations of reformulation for some products and of withdrawal for some others. The continuous inclusion of new substances might imply the reformulation of a high number of products with associated high costs and the inevitable dropping out of some products from the companies' portfolios. Some industry associations highlighted that this process is slowing down product development and diverting resources from what they consider innovation that improves the competitiveness of firms. However, according to the OECD definition of innovation, the substitution of a SVHC can be regarded as innovative.

The withdrawing from some markets and the possible relocation of activities outside Europe depend on the criticality of the substance going through Authorisation and on the feasibility of substitution. Companies needing to submit a costly and in any case time limited application for authorisation may have to contemplate non-EU solutions. Companies with manufacturing facilities outside Europe might consider relocation a straight-forward solution, being able to import the articles without having to deal with the authorisation procedure. Another possible solution would be the outsourcing of the manufacturing process; however, difficulties could be foreseen in terms of extra costs, logistical issues and ensuring batch to batch integrity. Moreover, for many SMEs, relocation to extra-EU countries may not be economically feasible.

Many of the stakeholders interviewed have stressed that the fact that imported articles do not have to go through authorisation is unfair and a competitiveness issue.

Another issue that has been pointed out is that chemicals suppliers may choose not to apply for Authorisation for small volume uses as the costs of doing so are too high, meaning that the cost of application would fall entirely on downstream users.

The Commission and ECHA are aware of industry concerns and started a reflection on how to streamline and simplify the authorisation process for specific areas. Initiatives aiming to increase transparency and predictability, such as the PACT, have been welcomed by the stakeholders.

CASE STUDY 5: THE PUBLIC ACTIVITIES COORDINATION TOOL (PACT)

The aim of this case study is to assess industry awareness of the PACT and to verify whether the listing triggers earlier actions in response of potential regulatory risk management measures in the future.

Since September 2014, the PACT has been available online.[107] Its main purpose is to give advance notice of the substances that are being scrutinised by the authorities to determine whether there is a potential need for regulatory risk management.

The PACT is part of the implementation of the SVHC Roadmap commenced in February 2013. Through the PACT list, the European Commission, ECHA and the Member States Competent Authorities want to comply with their commitment to increase transparency and predictability towards the general public and the stakeholders. The communication of information about the substances under regulatory scrutiny should enable stakeholders to better predict the adoption of formal risk management routes in the future and should also give them the opportunity to:

- In case of being registrants, ensure that their registration data are up-to-date;
- Consider the best business strategy to address substances of potential concern;
- To get prepared for the public consultation that could be launched to inform any regulatory process;
- To have easy access to the contact details of the authorities carrying out the risk management option analysis (RMOA) in case they would like to contribute to the development process[108].

As of 1 June 2015, the PACT contained 274 chemical substances[109] for which a risk management option analysis (RMOA) or an informal PBT/vPvB properties hazard assessment or endocrine disruptor properties hazard assessment is being carried out or has been completed.

The PACT presents information on:

- Substance identification (name, EC and CAS number);
- Date of inclusion in the list;
- The national authority carrying out the RMOA/hazard assessment for PBT/vPvB or endocrine properties;
- Whether the national authority is carrying out a RMOA or a hazard assessment for PBT/vPvB or endocrine properties;
- The scope of the activity (the suspected hazard or concern considered);
- The outcome with any document available.

[107] http://echa.europa.eu/documents/10162/19126370/svhc_roadmap_2015_en.pdf
[108] Although it is the decision of the authority on how to take into account any input provided by stakeholders.
[109] The PACT list is updated monthly. More information can be found at: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/pact

The information and views presented as well as the outcome of the RMOA and of the hazard assessment are those of the evaluating authority only and do not preclude other Member States and the Commission to initiate other regulatory measures if deem appropriate, for example in consideration of new available information or further assessment.[110]

In the framework of this case study, the Commission suggested investigation of the PACT list effects on the supply chain actors of diisocyanates.

Diisocyanates are manufactured in high volumes: according to Eurostat data, in 2013 there was a total production of 2,155,000 tonnes in the EU28[111]. Main applications are:

- In the production of polyurethanes (reacted with polyols);
- In coatings, adhesives, sealants, elastomers and binders.

Many of the isomers of diisocyanates (and in particular the most diffuse mixes of monomeric MDI and TDI) are subject to harmonised classification, with MDI and TDI isomers classified as suspected to cause cancer (H351), as skin, eye and respiratory irritants (H315, H319 and H335), as acute toxic if inhaled (H330) and as skin and respiratory sensitisers (H317 and H334). MDI is classified also as potentially toxic to kidney and liver (H373), while TDI as harmful to aquatic life with long lasting effects (H412).

Some of the diisocyanates have been included in the Community Rolling Action Plan (CORAP) for substance evaluation (table 3.10.8).

[110] Disclaimer on ECHA's website.

[111] According to the Danish Environmental Protection Agency (Survey of certain isocyanates (MDI and TDI), Part of the LOUS-review, Environmental Project No. 1537, 2014), the isomers of Methylene diphenyl diisocyanate (MDI) and Toluene diisocyanate (TDI) are commercially the most important, making up about 95% of the market volume-wise.

Table 3.10.8 Diisocyanates in CORAP

Name	EC Number	CAS Number	Year	Member State	Initial Grounds for Concern	Status
3,3'-dimethylbiphenyl-4,4'-diyl diisocyanate	202-112-7	91-97-4	2013	France	Human health/Suspected CMR; Sensitiser; Environment/Suspected PBT; Exposure/Consumer use	Ongoing
4,4'-methylenediphenyl diisocyanate	202-966-0	101-68-8	2013	Estonia	Human health/CMR; Sensitiser; Environment/Suspected PBT; Exposure/Wide dispersive use; Consumer use; Aggregated tonnage	Ongoing
m-tolylidene diisocyanate	247-722-4	26471-62-5	2012	Poland	Human health/CMR and sensitiser; Environment/ Suspected PBT (hydrolisis products); Exposure/Wide dispersive use, high aggregated tonnage	Concluded
4,4'-methylenediphenyl diisocyanate, oligomeric reaction products with butane-1,3-diol, 2,4'-diisocyanatodiphenyl methane, [(methylethylene)bis(oxy)]dipropanol and propane-1,2-diol	500-312-1	123714-19-2	2016	Estonia	Human health/CMR; Sensitiser; Environment/Suspected PBT; Exposure/Wide dispersive use; Consumer use; Aggregated tonnage	Not started
4,4'-methylenediphenyl diisocyanate, oligomeric reaction products with butane-1,3-diol, 2,4'-diisocyanato-diphenyl methane, 2,2'-oxydiethanol and propane-	500-415-1	158885-29-1	2016	Estonia	Human health/CMR; Sensitiser; Environment/Suspected PBT; Exposure/Wide dispersive use; Consumer use; Aggregated tonnage	Not started

Name	EC Number	CAS Number	Year	Member State	Initial Grounds for Concern	Status
1,2-diol						
Reaction mass of 4,4'-methylenediphenyl diisocyanate and o-(p-isocyanatobenzyl)phenyl isocyanate / methylene diphenyl diisocyanate	905-806-4		2015	Estonia	Human health/CMR; Sensitiser; Environment/ Suspected PBT; Exposure/Wide dispersive use; Consumer use; Aggregated tonnage	Ongoing

Moreover, the use of MDI-containing consumers' products is restricted in the European Union[112], coupled with a European Commission Recommendation on the professional use of MDI. There are several other sector regulations addressing MDI and TDI (e.g. cosmetics, food contact material, waste, industrial emissions) and some Member States have National Occupational Limit Values for MDI, TDI and other diisocyanates.

It is evident that diisocyanates have been under regulatory scrutiny for many years, so it is not a surprise they were included in the PACT. Currently, there are four Member States looking at different suspected hazard:

- Denmark was carrying out a RMOA on diisocyanates as CMR but the analysis has been put on hold;
- Estonia and France are carrying out a hazard assessment for PBT properties;

Germany has concluded a RMOA on diisocyanates as sensitisers and deemed appropriate to initiate regulatory risk management action.

More precisely, Germany will propose *"to integrate a certification scheme defining minimum handling conditions into a REACH restriction"* on the use of substances which contain more than 0.1wt% of free diisocyanates, *"unless a company can prove convincingly that they have an internal system in place that ensures the procedures to handle diisocyanates are strictly followed"* [113]. The details however are still to be defined.

For the purpose of this case study, the project team held phone interviews with three industry associations of manufacturers and downstream sectors:

- The European Diisocyanate & Polyol Producers Associations (ISOPA) and the European Aliphatic Isocyanates Producers Association (ALIPA) represented by Jörg Palmersheim (Secretary General);
- The European Association of paint, printing ink and artists' colours companies (CEPE) represented by Didier Leroy (Technical Director);

[112] Entry 56 of Annex XVII to REACH.
[113] Risk Management Options Analysis Conclusion document for Diisocyanates by Baua.

- The European Association of flexible polyurethane foam blocks manufacturers (Europur) represented by Michel Baumgartner (Secretary General).

All the interviewees were well aware of the PACT and actually welcomed it, agreeing that increases the transparency of the regulatory process. However, they noted that some improvements can be made, for example clarifying the terminology and increasing awareness among stakeholders that "restriction" does not automatically mean "ban", especially in this case where the German initiative is targeted on workers' protection. This would allow avoidance of a "black list" effect and to trigger questions and concerns on product availability among customers.

Interviewees were also very satisfied by the collaboration with the German authorities and that they could feed information in the process. However, they noted that the involvement of the whole supply chain is very difficult to achieve and public authorities should think on how to actively engage the third or fourth level down the supply chain[114]. For example, only in the EU end users' sectors of aliphatic diisocyanates, there are around 150,000 companies with around 800,000 workers. This is also very important, given that already at the level of the formulators for the different applications, 95% of the companies are SMEs and around 100% among the end-use applicators and in the indirect industry[115].

From their side, the main producers of diisocyanates have, through ISOPA, developed the product stewardship programme "Walk the talk", aiming to improve health and safety across the polyurethanes industry. Producers provide regular training to their employees on how to handle diisocyanates and offer training and guidelines to their customers too. All employees that could be potentially exposed to diisocyanates are screened through health surveillance programmes once a year and are encouraged to have a lung function test at least another time in one year.

Although some alternatives are available for some applications (see for example the OrganoTex® water repellent technology developed by OrganoClick and listed in the Subsport portal about substitution of hazardous chemicals maintained by ChemSec[116]), economically suitable alternatives to diisocyanates for their wide range of applications are not readily available on the market; there is ongoing research for developing isocyanate-free polyurethane adhesives, sealants and coatings[117].

In conclusion, the main challenge will be the involvement of all the end users' sectors: one of the findings of this study is that in those sectors where there is a pro-active industry association dealing with all aspects of the Regulation and actively engaging with the public authorities, problems and conflicts are minimised, companies are more likely to be better prepared and to better answer to regulatory pressure. Not surprisingly, chemicals manufacturers and formulators, both at company and industry association level, are better equipped to deal with REACH; going down the supply chain, the size of the companies decreases and chemicals regulation becomes just one of the aspect that sectorial industry associations have to deal with.

[114] Also referred as "indirect industry", including service providers such as the logistics and maintenance companies.
[115] http://www.alipa.org/index.php?page=end-use-sectors-summary
[116] www.subsport.eu
[117] http://www.turi.org/content/download/9523/165782/file/Toluene%20Diisocyanate%20Policy%20Analysis.%202014..pdf

3.11 Objective 11 - Support and assistance instruments

3.11.1 Introduction

The aims of this section are to characterise and provide feedback on the available support and assistance instruments to the industry provided by ECHA, Member States and industry associations; to provide feedback on the services most valued and demanded; and to provide feedback to Member States and business organisations on the best practices and areas for further investment. The feedback from SMEs should be considered as a priority.

This study objective concerns the level of support and assistance instruments available to industry and SMEs provided by ECHA, Member State authorities (including the role of REACH helpdesks) and industry associations. There are important links between this objective, which relates to the broader question of the availability of support for firms[118], and Objective 9 (Human Resources & Consultants), which relates to the extent to which firms have sufficient internal human capacities and/or are adequately externalising REACH compliance processes to consultants. For both objectives, there is a particular interest in establishing how far external support is sufficient to meet the needs of SMEs in achieving REACH compliance, and in maximising the potential benefits, whilst reducing the potential administrative burdens for smaller firms.

3.11.2 Overall observations

As pointed out in the section on methodology, the feedback from the OBS and the CATI survey does sometimes differ due to the different audiences and delivery methods in question. The CATI survey is designed to be a representative picture of the sector as a whole. A random sampling method was used. Responses to this survey provide no indication how deep the specific firm is really involved in REACH activities. The OBS was an internet based open survey. Everybody who was willing to contribute and became aware of the survey could take part. This can be assumed to be more likely firms that are involved in REACH issues and already performed some activities to implement REACH.

Generally, it could be observed that companies contributing to the CATI survey used support structures significantly less than companies that contributed to the OBS. Even the most common support instrument was used by only 50% of the respondents. This could be an indication that the individual users prefer different instruments (and therefore no instrument is used by a large majority) or that many companies did not use any of the instruments, yet. As all instruments addressed in the online survey have been used by a high percentage of the respondents the former explanation (market actors use various information and support instruments) seems more likely.

Another observation supporting the assumption that CATI respondents are relatively less involved in the REACH implementation is that a high share of the contacted industry associations believes a large share of downstream users is unaware of their REACH obligations (and consequently have not used the supporting instruments extensively).

[118] In the following when text we refer to "support structures" these include all kind of tools (documents, IT-Tools, Helpdesks, websites, information events etc.), that have been developed in the past to support market actors to Implement REACH.

Table 3.11.1 On the basis of your experience, are firms with a Downstream User role in your sector/country aware of their REACH related responsibilities?

Answer Options	Response Percent
Do not know	10,3%
The majority of firms (if not all) are not aware	28,2%
Important part of them are aware	33,3%
Most (if not all of them) are aware	28,2%
Total	100%
N	39

Source: industry association survey

Many organisations have developed support structures. The most common support instruments are the guidance documents that have been developed for different REACH processes (e.g. registration, downstream user obligations etc.) or on more specific issues with practical use (e.g. standard SIEF agreements and cost sharing models[119], comments on safety data sheet documents[120] or the specific Environmental Release Categories that can be used in risk assessments and support registrants in this activity[121]).

Further supporting instruments are still under development in the frame of the CSR/ES Roadmap as a shared activity between ECHA, member states and industry[122], e.g. the standards for an electronic exchange format for extended safety data sheets or methods for the consolidation of information for the safe use of mixtures by downstream users. Especially the outcome of the work on a ready-to-use electronic exchange format and a related IT-tool was often mentioned in interviews as "long awaited". This is due to the challenge of managing the large amount of new information generated and received from registration.

Overall it was observed that all institutions provide similar "sets" of instruments/support often consisting of guidance documents, training events/network/conference and formats/standards.

In those cases where practical implementation of REACH-tasks is supported, the respective instruments are actually industry-specific. Examples are associations developing registration dossiers or preparing authorisation dossiers for their members or taking over the administration of SIEF/Consortium processes.

[119] See e.g. CEFIC website: Implementing REACH Guidance and tools http://www.cefic.org/Industry-support/Implementing-reach/Guidances-and-Tools1/

[120] E.g. on the website of the Federal Institute for Occupational Safety and Health (BAuA) http://www.baua.de/de/Themen-von-A-Z/Gefahrstoffe/SDB/Muster/Muster.html;jsessionid=460FC4D3B25F38CA367D9FFDB7E91397.1_cid333

[121] For an overview on this instrument see Report on the ECHA project: "ASSESSMENT OF RELIABILITY OF SPERCS"FRAMEWORK CONTRACT NO ECHA/2011/01; SERVICE REQUEST SR16" (Ökopol, 2014) http://echa.europa.eu/documents/10162/13628/assessment_of_reliability_of_spercs_final_report_en.pdf

[122] http://echa.europa.eu/de/csr-es-roadmap

3.11.3`ECHA support structures

REACH was designed as a system that from the start contained elements that aimed to support the stakeholders during implementation. Article 77 defines a list of supporting instruments that the ECHA had to generate. An overview on the status of the implementation activities by ECHA is given every year in the general reports of the Agency[123]. In a report to the Commission in the frame of the REACH Review 2012[124] it was concluded that ECHA achieved most of its support obligations. However, it was also stated that some instruments or activities would need further improvement. This can also be seen in the stakeholder answers in the online business survey of the current study. While over 90 % of the respondents across all REACH roles[125] answered that ECHA supporting instruments have been used, which was the maximum value, the degree of usefulness varied between 9.1 % and 29.8 % that found the ECHA support extremely or very useful. Another 7.3% to 20.4 % evaluated it only slightly useful or not useful at all.

Stakeholders often highlighted that the supporting documents are too extensive and often too scientific which makes it difficult for some stakeholders to use them. It was further highlighted that the availability of supporting structures in national languages is core to improve understanding of REACH among the stakeholders.

Many comments have been received in the surveys that qualified the ECHA Website as a very useful instrument on its own. Another instrument that has been mentioned to be helpful is the registration database.[126]

Many stakeholders stated that the further development of existing supporting instruments, in particular regarding their accessibility for SME with regard to 2018 is important. However, over 50% of the respondents across all stakeholder groups welcomed that tool updates are limited to only twice a year (65 % of manufacturers).

With regard to the next registration phase, ECHA started to reorganise their website structure and to develop dedicated shorter guidance for SMEs[127]. When conducting the survey, no responses were provided on these tools particularly developed for SMEs. Support structures are developed with regard to the following expectations by ECHA[128]:

- The number of registration dossiers and substances will be about three times the number of the ones registered up to now.
- New SIEF will be smaller.
- It is expected that more importers and more SMEs will be involved.
- The last registration phase will be the one with the largest number of substances - also for large enterprises who will register more substances than they have up to now.

[123] http://echa.europa.eu/web/guest/about-us/the-way-we-work/plans-and-reports
[124] PriceWaterhouseCoopers (2012) on behalf of the EU-COM DG ENT (now Growth), The Review of the European Chemicals Agency Main report http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/review2012/echa_en.htm
[125] Manufacturer and Importer, Formulators of mixtures, Distributors, Supplier of articles and End user of chemicals
[126] Portal on registered substances: http://echa.europa.eu/information-on-chemicals/registered-substances.
[127] see http://echa.europa.eu/reach-2018
[128] Interview with ECHA after data generation in the frame of this study.

- There will be more registrations in the tonnage band 1 – 10 tpa than in the 10 -100 tpa band (which means there will only be the need to provide a basic data set according to Annex VII and no CSR). As a result, it is expected that costs for such registrations should range between € 5,000 and 50,000.

Based on these assumptions, new support instruments are being developed. They do not target the large firms that will register a large number of substances but are already experienced. New instruments aim for reduction of complexity of information materials and instruments that are needed to perform registrations. These are:

IT-Systems: IUCLID 6 will be provided as a basic version with less functionalities that only covers registration requirements needed for the lower tonnage bands and single substances. Installation will be optimised. As a result, the IUCLID 6 software will be provided self-installing. Additionally, a web interface will be developed to enable member registrants to generate their joint dossier online. Help texts will be directly integrated into the tool. The aim is to avoid the use of additional external guidance documents as far as possible. The help texts will be translated in different languages.

Dossier submission support team: A dedicated team of ECHA staff is providing help on ECHA´s own initiative when it is noticed that problems occur with registration (e.g. repeated submission failures from the same legal entity). Pragmatic support is offered via the telephone in a direct discussion.

Partner for development of specific guidance: Industry associations and consortia for specific substance groups often develop dedicated guidance to ensure successful registration for a specific sector of substance group. These often cover clarifications on substance identity (e.g. in case of UVCB-substances, or substances with similar chemical structures)[129]. ECHA served as discussion partner and checked the approaches in a critical review. Through such a process, market actors gain feedback on acceptability of a specific approach and predictability on the outcome of the registration process.

Capacity building: One challenge for 2018 will be to inform new registrants on the registration process. The focus of ECHA activities in this respect is:

- ECHA has set up a network of "networkers" whose aim is to facilitate information campaigns in member states and dedicated target groups. Members of this network come from the member states and other ECHA associated organisations. The network is open to any organisation that wants to contribute and refers also to existing structures (e.g. the directors contact group). ECHA provide information material, initiates campaigns via social media and short movies to target various information channels. Local events in MS are intended to be initiated by members of the network. ECHA will support such activities either by providing information material or if reasonable with dedicated staff for presentations in events.

- ECHA developed dedicated support websites for the registration phase 2018. The basic concept of this site is the division of the registration process in 7 phases[130]. Phases will be complemented with information material (see above) and support will be organised in a time line until 2018. Each phase will be announced with a press release and accompanied by a webinar that explains the content of each phase (first

[129] Examples in the past have been essential oils form plant extracts or pigments and dyes.
[130] In principle these have to be performed in a row but it can be that some have to undergo an iterative process.

phase started in June 2015). Press work will be organised in a coordinated campaign with member states (press release at the same time in MS, ECHA).

Further support is developed on a case by case basis where gaps are identified. The Directors' Contact Group has developed a document with recommendations for co-registrants [131] on cost sharing principles and what is seen as transparent, fair and non-discriminatory. The development of an implementing regulation by the Commission (see chapter on SIEF and Consortia) suggests that this document might need revisions in the future.

ECHA is also providing DU support (developed partly under the industry/authorities joint platform CSR/ES Roadmap) published via the DU hub of ECHA website.[132]

3.11.4 Industry association tools

Industry associations provide assistance in REACH implementation on various levels. Assistance ranges from the development of general guidance documents that explain REACH and that are aimed at dedicated industry sectors (e.g. for cars[133], metals[134] and others) to very specific instruments to be used in REACH processes which are based on specific sector knowledge (e.g. use maps, emission factors and risk management measures for risk assessments, standard phrases for descriptions in safety data sheets). As these kinds of instruments are often dedicated to a specific audience, they seem to meet the needs of the users better than the general instruments, so that the respondents of the online business survey rated them slightly higher with regard to their usefulness.

[131] DIRECTORS' CONTACT GROUP, DCG3/7/AP3a,1 October 2014, FIRST EDITION, FAIR, TRANSPARENT AND NON-DISCRIMINATORY COST SHARING IN SIEFS, http://echa.europa.eu/documents/10162/13559/dcg_fair_transparent_cost_sharing_en.pdf

[132] http://echa.europa.eu/web/guest/regulations/reach/downstream-users

[133] ACEA 2012 REACH: Automotive Industry Guideline, http://www.acea.be/publications/article/reach-automotive-industry-guideline) available in six languages, three non EU (Chinese, Korean, Japanese)

[134] Eurometaux and other industry associations: Industry REACH Authorisation Guidance for Downstream Users http://www.reach-metals.eu/index.php?option=com_content&task=view&id=171&Itemid=270

Table 3.11.2 How helpful were the support structures for the implementation of REACH in your firm? (Percentage of firms)

	Extremely useful	Very useful	Quite useful	Slightly useful	Not useful at all	n =
European Chemicals Agency (ECHA)?	9,1	29,8	33,5	20,4	7,3	275
National Helpdesk (in your country)?	3,8	16,7	38,0	26,1	15,4	234
National Competent Authority	2,4	11,3	31,1	34,4	20,8	212
National/ local trade or industry association	**19,9**	**34,1**	30,5	10,6	4,9	246
European industry association	**23,2**	**27,5**	27,1	15,9	6,3	207

Source: OBS

Besides very positive evaluations of many activities initiated by industry associations in interviews it was sometimes criticised that many of the instruments are either not suited for SMEs or even discriminate such market actors, as solutions often do not reflect the situation of such companies. Mentioned examples are instruments which make reference to extensive ERP[135] systems or descriptions which are too scientific to be handled by SMEs. In the context of support with regard to SIEF organisation, consortium management and particularly cost sharing, it was stated by some that standards are in favour of large enterprises. On the other hand, others evaluated the established practice as in principle working very well (with some exceptions).

Another point of criticism is the fact that support by industry associations is often not available to all companies (as it is sometime for exclusive use by members).

With regard to the upcoming registration deadline 2018, over 50 % of the contacted associations already have plans to develop new instruments to support market actors. Some associations are already now involved in registration activities. Some take up the role of an administrative body of a consortium or a SIEF, others also provide technical support if resources allow (this depends on the associations' understanding of their work either as solely political representation or also as technical supporter).

Associations also received questions on specific REACH subjects. In such cases they were often the first contact for a company regarding its REACH obligations (56.7 % "we have heard about REACH, what do we have to do?"). Besides guidance documents, training events and experience exchange workshops were most frequent used by market actors (see table below).

[135] Enterprise resource planning (ERP), IT systems to support collection, storage, management and interpretation of, data from many business activities. More likely to be used by complex large enterprises. Examples are SAP, Oracle, Infor, Sage, Microsoft and others.

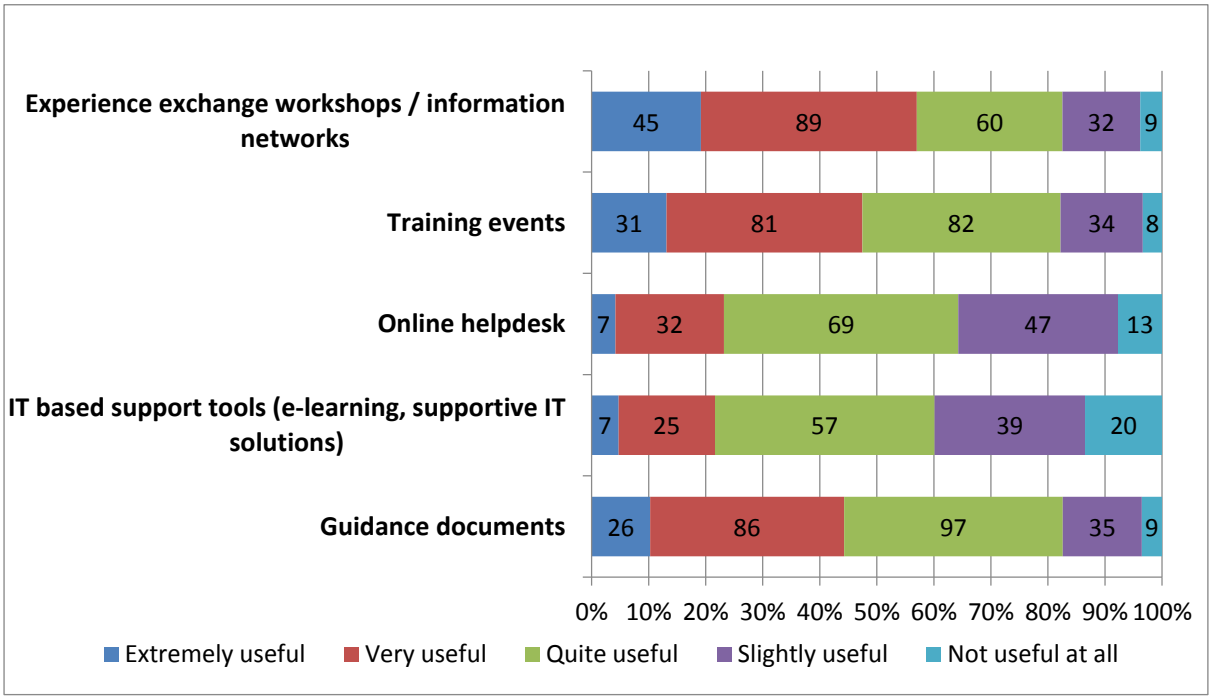
Table 3.11.3: Use of Industry association tools during REACH implementation in your firm? (percentage of firms)

	Manufacturer	Formulator	Distributor	Importer	Supplier	End user	All firms
Guidance documents	86,7	95,3	88,0	78,9	81,5	85,5	86,3
IT based support tools (e-learning, supportive IT solutions)	61,8	45,2	48,0	47,2	29,6	54,7	51,9
Online helpdesk	64,4	66,7	56,0	55,3	38,5	55,6	58,7
Training events	87,1	90,7	88,0	76,3	66,7	74,1	81,9
Experience exchange workshops / information networks	86,3	83,7	84,0	73,0	74,1	79,6	81,6
n	105	43	25	38	27	55	293

Source: OBS

These two instruments both have a high degree of acceptance as regards usefulness (approximately 50 % considered either as extremely or very useful and a very low share of market actors (app. 20%) found these tools not useful at all or only slightly useful). Several interviewed SMEs said that they found the type of experience exchange program that was run by Essencia particularly useful. EEF also said these were most appreciated by SMEs but there were challenges in funding such programmes. This high evaluation of usefulness differed from the evaluation of such events organised by member state public bodies (only about 30 % extremely or very useful).

Chart 3.11.1 How useful was the specific industry association tool (if used)?



Source: OBS

3.11.5 Member state support structures

The report on the operation of REACH (RPA, Ökopol 2012[136]) stated that helpdesks have been established in all member states. With regard to the effectiveness and diversity of the support structures it was reported that some variance existed among the different helpdesks. Member state authorities and the national helpdesks in parts mirrored the support structures of ECHA. Core elements are the website of the helpdesk (sometimes integrated in websites of national authorities or commissioned institutions), written guidance documents in national languages and often some information material for certain sectors (often those where SMEs prevail).

In some countries dedicated information events have been organised to inform industry on their REACH obligations. In an interview, it was stated that a roadshow on REACH was established initiating workshops throughout the country to provide basic information on REACH. Sometime these events were combined with other issues of interest for companies in order to reach firms that are not aware of the own involvement in REACH. Some of these countries made use of a mandatory organisation of companies in national structures (e.g. some countries have mandatory memberships in chambers).

The helpdesks are evaluated by the stakeholders as very important with regard to answering specific questions, but it was often criticised in the interviews and the surveys that answers are often too general or just making a link to the specific Article in the REACH text instead of going a step further and providing legally robust interpretations of the REACH text or pragmatic advice how to proceed. Another criticism was that some

[136] http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/review2012/commission_report_en.htm

helpdesks often had rather long reaction times, which often do not fit with the timing of problems to be dealt with in firms or among stakeholders. Nevertheless, it was acknowledged that at least harmonised Q&A documents are available and that the ECHA helpnet now shares best practice among the national helpdesks and defines shared approaches.

A key challenge for the future is how to identify and connect with companies that are not aware of their REACH obligations and the 2018 registration, particularly in countries where membership of the relevant industry body is not mandatory. In Italy, for example, the plan is to work through the Enterprise Europe Network.

3.11.6 Consultants[137]

Consultants provide a wide range of services with regard to REACH. Some are more technical while others provide strategic consultancy or serve as administrative support for REACH activities.

In interviews especially smaller firms stated that the use of a consultant during registrations is almost unavoidable, as the wide range of tasks cannot be covered by own staff, which in many cases is not even organised in a dedicated REACH unit but is fulfilling REACH tasks alongside other activities.

With regard to registration services the interviewees often stated that there was a problem of finding the right consultant that could be

a. Trusted, and
b. Had the right level of knowledge

It was reported that the cost of the consultant is not an indication of quality and cannot be judged from the start. There are cases reported, when the most expensive consultants partly did not deliver the best quality and the consultant with lowest rates may turn out to be rather costly as they work inefficiently (and spend many hours).

All actors were very clear that completion of the whole REACH process would not be possible without the help of external support.

3.11.7 Conclusions

The assessment showed that there is no lack of support structures at all levels although some issues as regards quality have been reported. For companies that already have well developed REACH structures, the existing information seems to be very well suited. As regards the 2018 registration deadline, improvements can already be observed in terms of developing support structures suited to SMEs, e.g. the dedicated parts of the ECHA Website (this was an outcome of the REACH review 2013 and is now being implemented).

[137] See also 3.9.3&4

The question that still needs serious consideration is how to engage firms that have (or will have) REACH obligations but are still not aware of REACH or REACH-related processes? Some promising approaches are:

- Linking REACH to other relevant networks (e.g. the eEnterprise Europe Network) and issues in information events (e.g. "green innovation"),
- using senior management to address the issue,
- intensifying public events with close connections to companies – e.g. roadshows (low efforts are required by firms to participate),
- simplifying content (at least in the beginning) to keep firms involved (wrong level of information demotivates involved people as they can´t follow the debate).

Some processes that have been implemented to provide new (scientific) instruments lack a pragmatic breakdown on a level suited for SME (e.g. activities on (e)SDS by content and by technical implementation).

3.12 Objective 12 – Registration 2018

3.12.1 Introduction

The key study objectives in respect of Registration 2018 are as follows:

- Based on the findings in other subject areas, update the estimates with regard to the costs of the 2018 registration deadline if no changes are made in the implementation of REACH as compared to the current practice; and
- Establish specific cost categories with a highest room for achieving cost-efficiencies, as well as suggesting specific implementation measures to achieve them, while maintaining the capacity to deliver the expected health and environmental benefits.

Approach to assessment

RPA recently updated the Excel® based Monte Carlo simulation model that was used by the Commission in its final assessment of revisions to REACH requirements for 1-10ts (in November 2006). The model was updated as part of a study to assess options for changing the information requirements for 1-10t substances[138] (for DG Environment). A detailed description of how the model works is provided in the Annex to the Final Report of that study and this section provides only a brief overview of the approach and how the model has been adjusted so that it applies to substances to be registered only at 1-10t and also:

- Substances to be registered only at 10-100t; and
- 10-100t substances also registered at 1-10t.

The assessment considers only substances that have not already been registered and so does not consider those already registered in higher tonnage bands. An unknown (but probably quite small) percentage of substances already registered in higher tonnage bands may not have submitted lower tonnage registrations and may be submitted in 2018.

Overview of the Monte Carlo approach

The Monte Carlo simulation uses a probabilistic model to consider the registration of individual substances. It considers one substance at a time, using probabilities to generate a profile of each substance in respect of the key determinants of cost variation. The costs of registering any given substance depend on a number of factors including:

- Whether there is already toxicological or ecotoxicological information on that substance or whether there is some or none;
- Whether that substance is identified by QSARs or other evidence as meeting one or more of the criteria in Annex III and, hence, must generate the toxicological and ecotoxicological information in Annex VII (only applies to 1-10t substances);
- The outcome of screening tests and, in particular, those for mutagenicity (where a positive result will require that further testing is undertaken);

[138] Technical assistance related to the review of REACH with regard to the obligations for substances manufactured/imported in the range 1-10t tonnes per year. Contract: 070307/2013/668917/SER/ENV.A.3

- For Chemical Safety Assessment (CSA), whether an exposure assessment and risk characterisation is required in addition to hazard assessments (applies only to 10-100t substances);
- The number of companies registering that substance (which influences both the sharing of information costs in a SIEF and also the cost of administering a SIEF);
- Whether the registrants of that substance will all support a joint registration or whether one or more individual registrations will be submitted also; and
- The size of the companies registering that substance (which determines the registration fees due and also allows exploration of the impacts on SMEs versus larger companies).

Clearly, different permutations of the above have different results in terms of the cost of registering different substances. In addition, the number of possible permutations is very large (a few thousand possibilities). Some permutations may result in higher costs of registration and some lower costs. The Monte Carlo simulation model explores the different permutations, calculating and recording the costs associated with each. In this way, the multiple rows of data produced by the simulation (numbered in their hundreds of thousands) provide a predicted cost distribution similar to that observed in the results of the cost estimation for REACH 2013.

In the Monte Carlo simulation, the probability and values attached to each permutation is governed by the model inputs. These inputs have been based on a combination of data on registrations (including in 2010 and 2013), statistical data on the structure of the industry as well as previous assessments (principally the Commission's ExIA and the BIAs from which it drew most of its data) and data that underpinned them (including surveys). Many of the inputs are identical to those used in the past or are broadly consistent with them. However, in the light of findings under Objective 3 of the study we have considered the need to make alterations in the model inputs to reflect new information.

Here, Objective 3 of this study (discussed in Section 3.3) provided an updated assessment of the costs of Registration for 2013 using data from the CATI and OBS, comparing the resulting costs with those presented in the Commission's Extended Impact Assessment (EIA). Conclusions were drawn on areas where adjustments might be made such that estimates of the 2018 costs better reflect:

- the costs of purchasing data from the owners of information; and
- the administrative and legal costs of consortium/joint registration and SIEF formation (as the ExIA pre-dated REACH provisions on SIEFs).

In relation to the first, the model includes decision rules applied to distribute costs between SIEFs. These include payments made for existing data on substances (where such data exist).

Costs of SIEFs and Joint Registration

The issue of SIEFs and joint registration is more complicated. Elsewhere in this report it has been identified that costs of SIEF formation and joint registration may have been higher than was anticipated. Further analysis of registration data provided to the study by ECHA has been carried out to reveal the possible reasons for this and to identify whether there is a need for adjustments to be made in the estimations for registration costs 2018.

The analysis of the ECHA data reveals that the higher than might have been anticipated costs of SIEFs and consortium/joint registrations may (in large part) be due to the

relatively large numbers of M/Is of the higher tonnage substances (>1000t and 100-1000t) compared with the predictions that were made at the time of the ExIA. Table 3.12.1 provides an overview of the predicted/actual percentage of substances with only one registrant (M/I) versus more than one M/I registering substances in each tonnage band and the actual average number of M/Is registering each substance in each tonnage band. Substances are divided into those registered only in one tonnage band versus those also registered in lower tonnages bands (which adds to the total number of M/Is involved in SIEFs and also in consortia). Also provided in the table are the values used for prediction in the revised BIA/ExIA.

Table 3.12.1 Overview of the predicted versus actual percentage of substances with only one registrant (M/I) versus more than one M/I for the higher tonnage substances

Source	Type of registration/ substance	Only one M/I	More than one M/I	Average number of M/Is
Based on ECHA registration data (2015)	>1000t only	52%	48%	4.06
	>1000t and also lower tonnages	0%	100%	18.41
	>1000t Overall	19%	81%	13.08
Revised BIA/ExIA	>1000t	20%	80%	3.3 (predicted)
Based on ECHA registration data (2015)	100-1000t only	65%	35%	1.73
	100-1000t and also lower tonnages	0%	100%	4.44
	100-1000t Overall	51%	49%	2.31
Revised BIA/ExIA	>1000t	20%	80%	3.3 (predicted)

As can be seen from the data in the table:

- For the >1000t substances: comparison of the data would suggest that the Revised BIA/ExIA assumption was broadly correct concerning the overall percentage of substances registered by more than one M/I (80%). However, it significantly underestimated the actual numbers of M/Is registering these substances, particularly those substances also registered in lower tonnage bands (for which no estimate was ever made).
- For the 100-1000t substances: the Revised BIA/ExIA assumption on the overall average number of M/Is was closer to the actual (2.3 versus 3.3 M/S predicted) but significantly overestimated the number of substances for which is more than one M/Is (49% actual versus 80% predicted).

The net effect of this is that:

- For the >1000t substances: the numbers of substances for which there would be a SIEF and potentially a consortium/joint registration was broadly correct but the numbers of M/Is that would be a part of each SIEF was significantly underestimated;
- For the 100-1000t substances: the numbers of substances for which there would be a SIEF and potentially a consortium/joint registration was overestimated but at the same time the numbers of M/Is that would be a part of each SIEF was underestimated; and
- The ExIA estimates would underestimate the number of M/Is that would be in each SIEF/consortia for the higher tonnage substances and, hence, the complexity of the arrangements in terms of the numbers of participants.

In addition to the unforeseen complexities in relation to the numbers of participants listed above, there is an additional complexity that was not considered in the ExIA or the revised BIA. Here, neither the BIA nor the ExIA considered registration of substances in lower as well as higher tonnage bands.

In practice, a significant number of the substances registered in higher tonnage bands have also been registered at lower tonnages (mostly in the next lowest but many also spanning lower still)[139]. This means that, not only were there more members of SIEFs/consortia than would have been anticipated but also that the majority of the SIEFs/consortia also had to incorporate differences in information required for different registrants at different tonnages. All of these factors combine to create a situation of increased complexity, associated cost and larger number of M/S than anticipated facing those costs. In other words, higher costs for SIEF and consortium formation than anticipated.

In relation to the 10-100t and 1-10t substances, however, the potential for such factors to have such a significant effect is much lower owing to factors including the following:

- There is only one tonnage band lower than the 10-100t band and none lower than 1-10t – thus, over all of the substances to be registered in 2018 there is much less potential for complexity compared with those registered in 2013 (or first in 2010); and
- What evidence there is suggests that a significant proportion of the substances registered at 1-10t only are likely to be speciality chemicals manufactured by one or a relatively small number of M/Is – thus there may be relatively fewer SIEFs and the number of participants much smaller.

That said, the way in which costs are calculated has been improved upon in the Monte Carlo simulation[140] since calculations were originally been made for the revised BIA/ExIA. Where previously a flat rate of cost was used to differentiate between a joint/consortium registration and an individual registration (i.e. it did not change according to the number of M/Is), the model calculates costs based on the number of M/Is and also the size of the lead registrant. The costs applied also capture the setting up of SIEFs, engaging on

[139] Analysis of the registration data provided to the study suggests that around 63% of >1000t substances and 21% of 100-1000t were also registered in lower tonnages.
[140] These changes were already incorporated into the model produced for DG Environment for 1-10t and have been extended to cover 10-100t for this study.

information and on preparation of the registration dossier and are applied on a per M/I registering rather than on a flat rate.

Testing and Information Costs – Availability of Existing Information

In terms of adjustments to the testing and information costs for 2018, as discussed under Objective 3 (on Registration 2013), both the survey and ECHA data on testing proposals suggest that fewer new tests may have been carried out for the 100-1,000t substances than were anticipated in the revised BIA/ExIA. As noted there, this may be because:

- more test information was available for more of the higher tonnage substances than was anticipated in the ExIA and so fewer tests were required; or
- there is missing information in the dossiers of some substances because required testing has not been (or is yet to be) carried out.

Of the two there is currently only evidence for the latter. Here, recent evidence from a the German Federal Environment Agency screening of 1,932 >1000t dossiers for compliance suggests that 58% of the dossiers showed deficiencies and were 'non-compliant' (usually for one or two endpoints but sometimes more) and for 42% it was not possible to make a firm conclusion on compliance for at least one endpoint. As such, whilst the data may suggest that fewer tests may have been carried out than anticipated in the ExIA this is not the same as fewer tests being required under REACH because, as noted by UBA (2015), the indication is that further improvement of data in registration dossiers is required.

Given this, as with the ExIA (and the BIA/JRC estimates that underpin them), there is no evidence to suggest that a significant proportion of the 1-10t and 10-100t substances already have the information required in Annexes VII and VIII (as appropriate) and the modelled simulation applies data and assumptions used in previous analyses (including the BIA and ExIA).

Testing and Information Costs – Costs of Individual Tests and Use of Alternative (non-testing) Methods

The estimates for the costs of testing and information contained within the ExIA were themselves drawn from JRC (2003)[141]. Further inspection of the assumptions and costs underpinning the original JRC (2003) estimates reveals that:

- estimates were ambitious concerning the extent to which QSARs and other non-testing methods would be developed and would fully satisfy information requirements without the need for testing. This is particularly important regarding the most expensive tests in Annex VIII (8.7.1 – Screening for reproductive/developmental toxicity and 8.6.1 – Short-term repeated dose toxicity) which, together, represent around 64% of the total cost of full tests for Annex VIII (considering updated estimates of the cost of individual tests); and
- according to more recent data from the CEFIC testing catalogue (as well as other sources), the cost of undertaking some of the tests is expected to be higher (and occasionally lower) than that assumed in JRC (2003) estimates. Generally, the costs

[141]JRC (2003): Assessment of additional testing needs under REACH Effects of (Q)SARS, risk based testing and voluntary industry initiatives http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/testing_needs-2003_10_29_en.pdf.

of individual tests are close to more recent estimates. Importantly, however, the JRC (2003) analysis estimates that the cost of undertaking screening for reproductive/ developmental toxicity (8.7.1 - OECD 421 or 422) is € 24,093 (updated to the present day) where more recent data suggests that the cost is around € 97,000 (with some estimates from testing labs being slightly above and other estimates slightly below).

The combination of underestimated testing costs for the most expensive test in Annex VIII and assumptions on the use of QSARs and read across for this (and other) endpoints means that there is a risk that costs for 10-100t substances may be higher than the average per substance cost of all tests of €59,699 estimated in JRC/ExIA (2003). This is illustrated in Table 3.12.2 showing the original JRC estimates for the two most expensive tests, the original estimates updated to reflect current estimates of the unit cost each of the tests and the effect of removing assumptions on the use of QSARs and other non-testing methods applied in JRC (2003).

As can be seen from the table, in the JRC (2003) analysis applying QSARs, tests for repeated dose toxicity and screening for reproductive/developmental toxicity comprise €13,070 of the average total per substance cost of €59,699 predicted. Updating the unit costs of tests to more recent estimates of the costs but retaining the JRC assumption that, for 58% of substances QSARs are accepted as a substitute for full tests for both endpoints, results in a doubling in the cost of the two tests to €26,479 per substance on average. If the above mentioned QSAR assumptions are removed, the cost increases to €113,505 per substance on average, i.e. potentially more than eight times the original estimate of €13,070 for these tests and nearly double the average statistical cost of €59,699 per substance predicted by JRC (2003) for all tests.

Table 3.12.2: Effect of Test Cost underestimation and QSAR Assumptions on Test costs for 10-100t substances

	With QSARs		Without QSARs
	JRC statistical average cost per substance - old test costs	**JRC statistical average cost per substance – updated test costs**	**JRC statistical average cost per substance without QSARs**
Annex VIII 8.6.1. Repeat dose toxicity - Short term (1 route only)	€ 8,733	€ 8,997	€ 39,694
8.7.1.Screening for reproductive/ developmental toxicity, one species (OECD 421 or 422)	€ 4,337	€ 17,482	€ 73,811
Total	**€ 13,070**	**€ 26,479**	**€ 113,505**

Clearly, as can be seen from this, of the two factors assumptions regarding the use of QSARs have the greatest impact on overall costs and, within this, the QSAR assumptions applied to the more expensive tests have the greatest impact. The sensitivity of cost

estimates to assumptions on the use of QSARs, read across and other non-testing methods is illustrated in the range of costs produced by JRC(2003) for the ExIA shown in Table 3.12.3. Each set of estimates (minimum, average and maximum) is based on different assumptions concerning QSAR/read across acceptance. As can be seen from the table, the impact on the costs was significant, particularly on the cost estimates for the 10-100t substance. Here, the 'maximum' estimate is nearly four times that of the minimum.

Table 3.12.3 JRC and ExIA estimated total testing costs (€million)

	1-10t/y	10-100t/y
JRC Minimum	€164 million	€201 million
JRC 'Average	€233 million	€364 million
JRC 'Maximum'	€316 million	€755 million
ExIA estimate	€150 million	€300 million

The estimates that were eventually used in the ExIA were less than half of those identified as the 'maximum' testing needs by JRC and the importance of assumptions on QSARs, read across and other non-testing methods across were acknowledged in the ExIA by the caveat that costs "*assume validation and acceptance of (Q)SARs can be applied within the timeframe envisaged*".

Regarding the level of validation and acceptance assumed by JRC(2003) and the ExIA, as noted above, it was assumed that QSARs and read across would be widely applicable and that negative as well as positive results would be an acceptable substitute for test information. Regarding the current level of validation and acceptance of QSARs/Read Across generally:

- certain toxicological effects based on more complex processes are not yet or not fully covered by alternative methods, these include repeated-dose toxicity, skin sensitisation, carcinogenicity and reproductive toxicity;
- for developmental and reproductive toxicity endpoints there are relatively few models available and those have limited applicability domains;
- it has previously been identified (in 2011) that work to replace animal testing for this endpoint would take more than 10 years to achieve[142].

Regarding QSARs and read across for reproductive/developmental toxicity screening specifically, Annex VIII identifies that testing must be carried "*if there is no evidence from available information on structurally related substances, from (Q)SAR estimates or from in vitro methods that the substance may be a developmental toxicant*". In other

[142] See for example, http://ec.europa.eu/consumers/sectors/cosmetics/files/pdf/animal_testing/final_report_at_en.pdf

words, according to Annex VIII of the regulation, a negative QSAR result for a reproductive/developmental toxicity screening study would have to be followed by a test. This is does not seem consistent with the assumption in JRC(2003) and the ExIA that 58% of substances would be able to use information from QSARs as a substitute for the test (and would imply 58% of substances self-classifying for this endpoint).

In the light of the sensitivity of any cost analysis to assumptions on the application of QSARs and read across and the fact that no assessment has been made of available information and QSAR applicability/validity since JRC(2003) the cost estimates in this study are based on a worst case approach to provide a maximum expected cost for further exploration of cost savings in future studies. Here, **for all costs presented for Registration 2018, QSAR and read across results are assumed not to provide a substitute to full testing for the purposes of Annexes VII to X of the regulation.** Information from QSARs and read across is, however, assumed to be applied to 1-10t substances in respect of the criteria in Annex III and the need to submit the toxicological and ecotoxicological information in Annex VII.

This worst case approach has been applied because, within a short study such as this, it is not possible to establish the extent to which QSARs, read across and other non-testing methods will eventually provide a substitute for full testing or the extent to which existing information may already be available.

However, ECHA have provided some comment on these issues noting that:

- for Annex VII/VIII environmental endpoints in case of organic monoconstituent substances, QSARs are a good alternative, and ECHA is intensifying its support to registrants to promote this. ECHA expect that higher fraction of dossiers will be successfully covered by QSARs in last registration deadline than in previous rounds of registration; and
- ECHA is intensifying its support on the alternative methods as part of Phase 4 of the REACH 2018 Roadmap.

As such, it can be hoped that work in this area may produce a reduction in the maximum test costs provided here. The extent of that reduction requires more detailed examination than is possible in this short study.

3.12.2 Costs of Registration 2018

Overview

The Monte Carlo simulation produces estimates of the cost of registering each **individual substance** for each **individual M/I** registering that substance. As such it provides the potential to provide:

- An estimate of the overall total costs across all substances and M/Is (i.e. the predicted total cost in 2018);
- Statistical description of likely costs per substance and per tonne of substance for the different tonnage bands (including averages, max/min and frequency distribution of different cost levels); and
- Statistical description of likely costs to M/Is of different size to examine variation in costs between SMEs versus larger enterprises.

In terms of a breakdown of costs into the different cost categories, the complexity of the model and the vast volume of data it produces is such that it is not possible to provide a

breakdown of each and every component. However, a division has been made between the following two cost categories so that costs can be explored in more detail:

- ***'Registration costs' comprising the total of:***
    - The administrative cost of liaising with other M/Is in producing the registration dossier (for joint registrations);
    - The cost of preparing and submitting the dossier (for individual and/or joint registrations); and
    - Fees.
- ***'Information costs' comprising the total of:***
    - Cost of obtaining information (including testing costs and purchase of data based on the 2012 CEFIC testing catalogue);
    - Administrative cost of engaging on information with other M/Is within SIEFs;
    - Cost of submitting proposals for animal tests;
    - Cost of producing study summaries/robust study summaries; and
    - Costs of updating SDS and undertaking CSA/CSR (for 10-100t substances).

As with the revised BIA and ExIA, the cost assessment for Registration 2018 considers only the cost for substances registered and not those withdrawn from the market. The revised BIA/ExIA assumed that 15% of the 20,000 1-10t substances and 10% of the 10-100t substances would not be registered but would be removed from production.

Clearly, the decision to withdraw a substance depends on a number of factors of which the most important are likely to be the potential cost of registration, the value of the product to each of the MIs and, hence, the ratio between both. When considering withdrawal, it has been assumed that the most costly substances to register on a cost per tonne across all M/Is will be withdrawn. Analysing the dataset produced by the Monte Carlo simulation, substances with average total registration costs of in excess of €2,600 per tonne for 1-10t substances and €3,250 per tonne for 10-100t substances are assumed to be withdrawn. Consistent with the previous assessments, this represents 3,037 (~15%) of the 20,000 1-10t substances and 504 (~10.1%) of the 5,000 10-100t substances. These substances and associated costs have been deleted from the dataset. The remainder are assumed to be registered and the costs associated with the registration of these substances represent the costs of the Registration 2018 exercise. These costs are set out in the sections below.

Total costs of Registration 2018 and Comparison with previous Assessments

The resulting total costs of registering all substances at 1-10t and 10-100t are provided in Table 3.12.4 and are broken down by registration costs and information costs as well as totals. As noted earlier, these costs are calculated on the basis that QSARs, read across and other non-testing methods are assumed not to act as a substitute for full test information. Also provided in the table are the estimated costs that appeared in the ExIA which *"assumed validation and acceptance of (Q)SARs can be applied within the timeframe envisaged"*.

Table 3.12.4 Comparison of estimates of the total costs of registration (€ millions)

	Total Registration Costs plus Fees	Total Information and SDS Costs	Total Costs of registering
1-10t*	**€ 77.4**	**€ 150.4**	**€ 227.8**
1-10t Ex EIA	€ 116	€ 179	€ 295
10-100t*	**€ 123.0**	**€ 1,012.7**	**€ 1,135.7**
10-100t Ex EIA	€ 116	€ 465	€ 581
*estimates assume that validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods does not occur within the time frame first envisaged.			

For the 1-10t substances the following can be concluded:

- The total cost of registering all 1-10t substances in 2018 is estimated to be up to around €228 million, of which around a third of the cost is associated with the information elements of registration. As with other estimates for Registration 2018, costs assume that validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods does not occur within the time frame first envisaged; and
- This is of a similar order of magnitude to the €295 million originally estimated in the ExIA but, clearly, lower. This difference is as a result of the criteria applied to 1-10t substances in Annex III in combination with Article 12 (where this article did not exist at the time of the ExIA).

For the 10-100t substances the following can be concluded:

- Costs of liaising on, producing and submitting dossiers and fees are of the order of €123 million;
- This is comparable with the €116 million estimated for similar cost elements in the ExIA;
- In contrast with this, the cost of the information related elements of registration of 10-100t substances may be up to around €1,013 million if validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods does not occur within the time frame first envisaged. This is far in excess of the €465 million estimated in the ExIA (which assumed QSAR validation and acceptance);
- Owing to this, the resulting total cost of registering 10-100t substances is estimated to be potentially as high as €1,136 million if validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods does not occur within the time frame first envisaged.

Clearly, from the above a key conclusion from this assessment is that, owing to costs of the information elements, if validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods does not occur within the time period envisaged then the total cost of registering 10-100t substances may be significantly

higher than was previously estimated in the ExIA, underpinning the need to increase the applicability and acceptability of QSARs and other non-testing methods.

Estimated cost of registering individual substances estimates (assuming no validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods)

Whilst useful for considering and comparing different costs, statistical average values such as those in Table 3.12.4 are less useful for considering the impact of those costs on the receptors. Here, averages are not necessarily representative of the 'typical costs' to those receptors because there is significant variation between estimates for different substances (and different receptors).

To provide some insight into the distribution, Table 3.12.5 provides average, median, min and max values for overall registration costs across all of the substances and Chart 3.12.1 provides a plot of the distribution of cost estimates in terms of the percentage of estimates falling between each cost range.

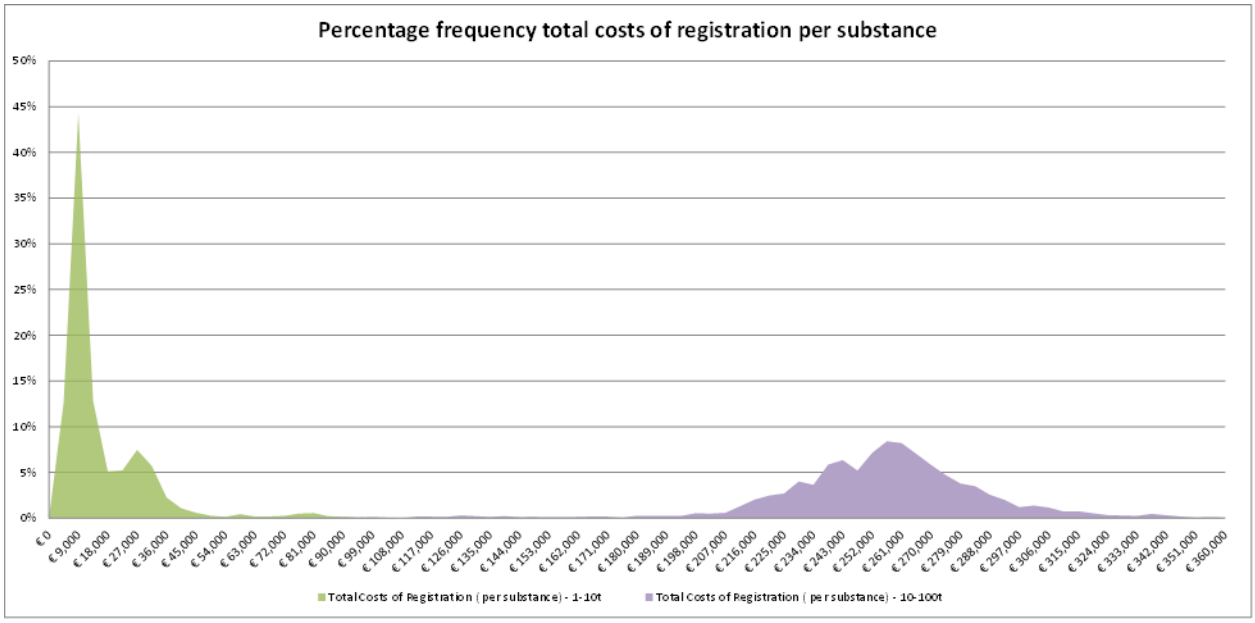
As can be seen from both these, for the 1-10t substances costs for 50% of the substances (the median) were less than half of the average across all substances suggesting that 'typical' costs are less than average. This is mostly because there are two types of registration for the 1-10t substances: registrations requiring the physico-chemical information in Annex VII only and registrations also requiring toxicological and ecotoxicological information in Annex VIII as dictated by the application of the criteria in Annex III of REACH. As a result, despite the fee waiving that is applied to substances providing full information, the cost distributions in Chart 3.12.1 show two overlapping peaks.

In contrast to the 1-10t substances, for the 10-100t substances, median and average are very similar and the cost distribution is much more normal.

Table 3.12.5 Total Costs of Registration (€ per substance)

	1-10t	10-100t
Average	€ 13,427	€ 252,605
Median	€ 7,447	€ 254,818
Min	€ 2,982	€ 67,800
Max	€ 95,910	€ 393,805

Chart 3.12.1 Percentage frequency of the total costs of registration per substance (€ per substance registered)



Information costs as a percentage of total per substance registration costs (assuming no validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods)

As noted above, the total registration costs have been divided into:

- ***'Registration costs' comprising the total of:***
    - The administrative cost of liaising with other M/Is in producing the registration dossier (for joint registrations);
    - The cost of preparing and submitting the dossier (for individual and/or joint registrations); and
    - Fees.
- ***'Information costs' assuming no validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods and comprising the total of:***
    - Cost of obtaining information (including testing costs drawn from the 2012 CEFIC testing catalogue and purchase of data);
    - Administrative cost of engaging on information with other M/Is within SIEFs;
    - Cost of submitting proposals for animal tests;
    - Cost of producing study summaries/robust study summaries; and
    - Costs of updating SDS and undertaking CSA/CSR (for 10-100t substances).

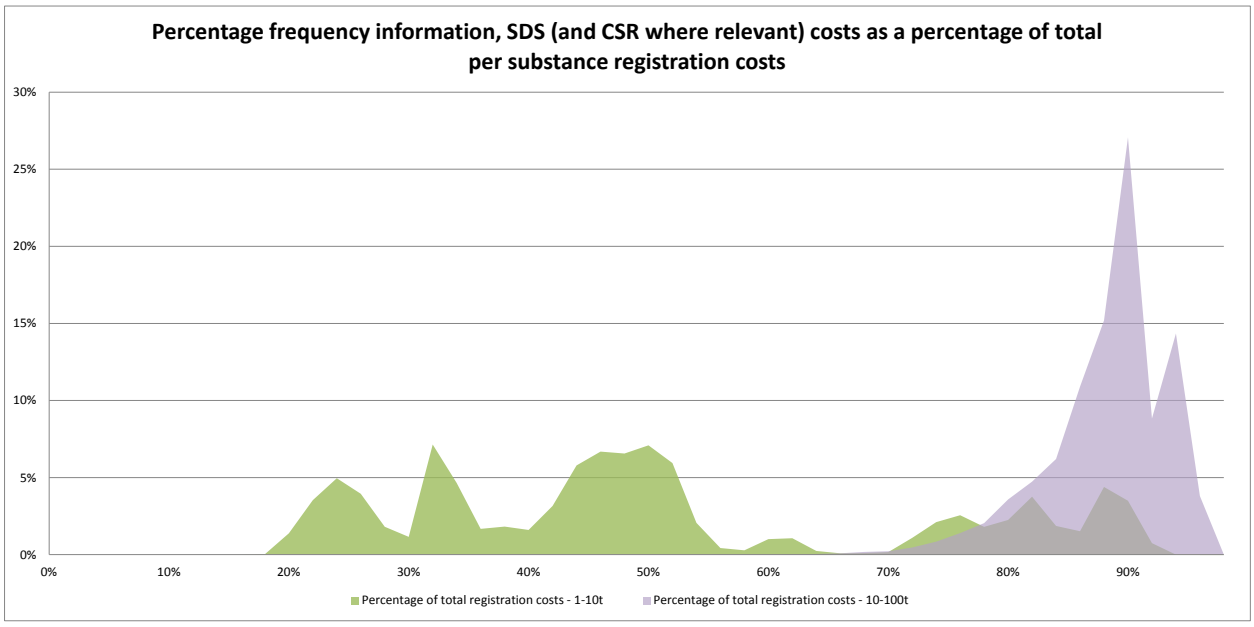
Table 3.12.6 and Chart 3.12.2 provide the share of the total registration costs that are attributable to the information components with results describing the average and distribution for different substances. The impact of the information elements on the registration costs for 10-100t substances is obvious from both the Table and the Chart with these suggesting that typically the information elements account for around 90% of the total costs for these substances.

For the 1-10t substances, the information costs and the registration dossier costs are more equal but, as might be expected, the distribution falls into two categories reflecting those substances that must provide full Annex VII information versus those that do not.

Table 3.12.6 Information costs as a percentage of total per substance registration costs

	1-10t	10-100t
Average	52%	89%
Median	48%	90%
Min	20%	58%
Max	94%	97%

Chart 3.12.2 Percentage frequency information costs as a percentage of total per substance registration costs (assuming no validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods)



Costs of Registration per tonne of substance (assuming no validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods)

In terms of the scale and affordability of registration costs compared with production and production value for substances registered in each tonnage band, no information is available on the value of substances. The closest indication one can get is from calculating costs on the basis of the cost per unit of production. As the Monte Carlo simulation also generates substance specific estimates on the volumes produced by each M/I, this can be calculated for each of the virtual substances generated in the simulation.

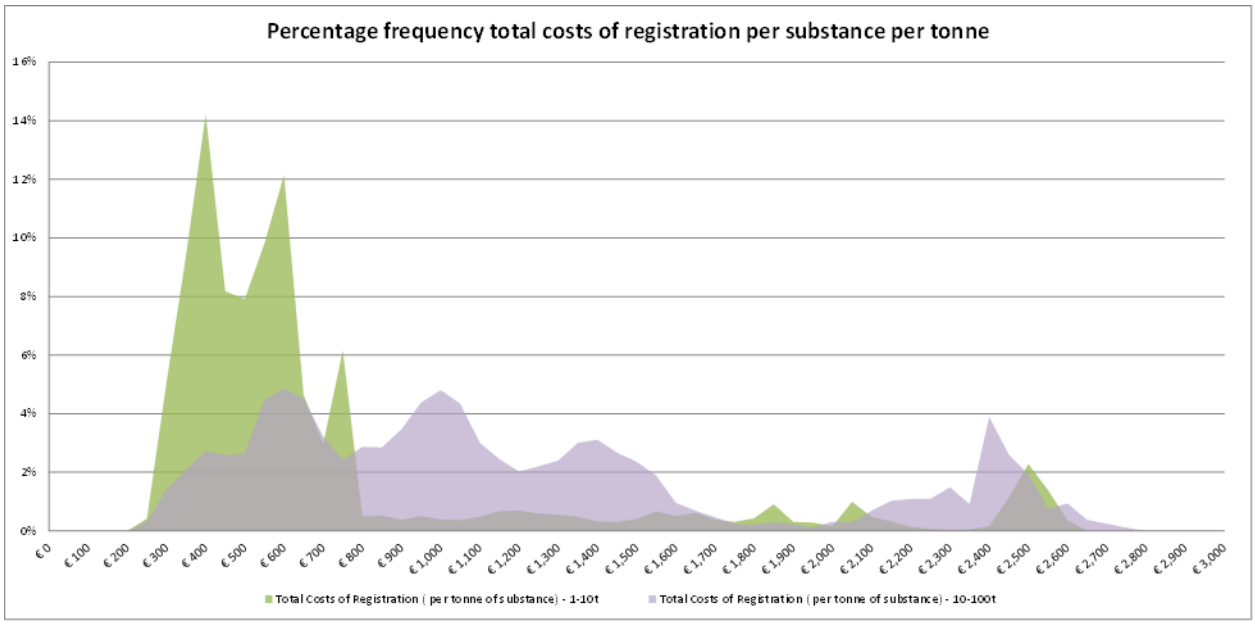
Results describing the average and distribution of costs for different substances are provided in Table 3.12.7 and Chart 3.12.3.

Table 3.12.7 Costs of Registration (€ per tonne of substance assuming no validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods)

	1-10t	10-100t
Average	€ 719	€ 1,169
Median	€ 521	€ 1,004
Min	€ 227	€ 208
Max	€ 2,600	€ 2,745

As can be seen from the Table, when expressed per tonne of total production, costs for 1-10t substances are roughly half those of the 10-100t substances.

Chart 3.12.3 Percentage frequency total costs of registration per substance per tonne (assuming no validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods)



Average costs per substance for Manufacturers/Importers of different size -1-10t substances (assuming no validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods)

In terms of the impact of costs on M/Is of different sizes, the level of total cost for each M/I depends in large part on the numbers of substance being registered by each M/I. As larger companies are expected to submit more registrations that smaller M/Is, comparison of the cost burden needs to be made on the basis of the average cost of registering substance rather than for all substances registered.

Table 3.12.8 and Chart 3.12.4 provide data on the average cost of registering a substance for M/Is of different sizes. Table 3.12.9 provides the same data as cost per tonne of substance registered.

Broadly speaking, the data suggest similar costs for M/Is of different sizes, though costs for medium enterprises appear slightly higher than for large or micro/small companies (but not significantly higher).

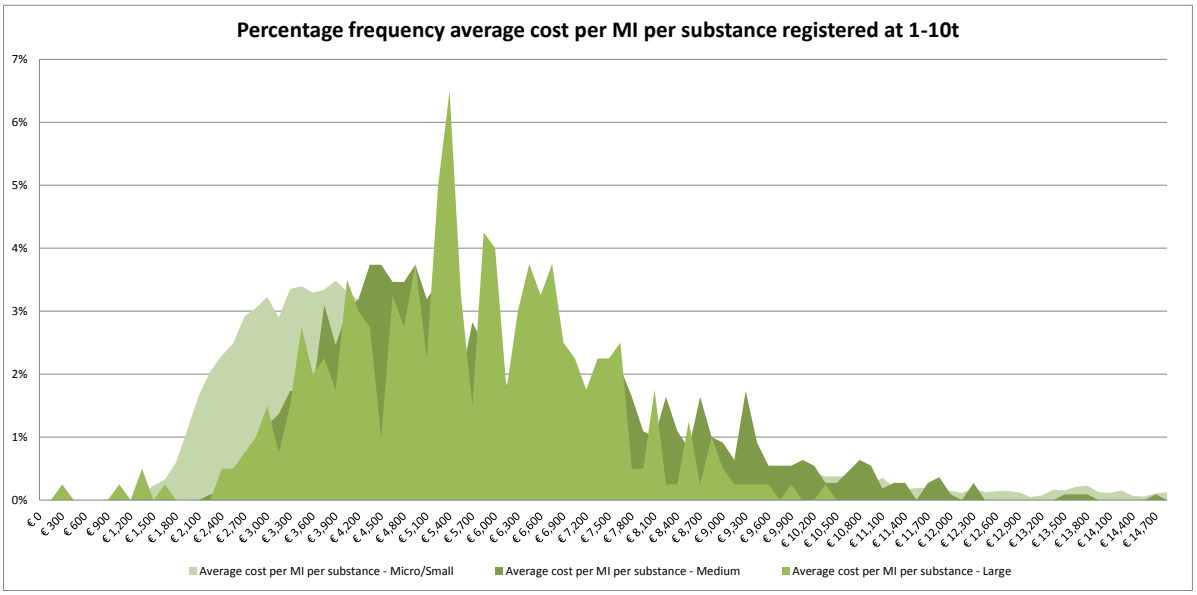
Table 3.12.8 Average cost per MI per substance registered at 1-10t (€ per substance assuming no validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods)

	Micro/Small	Medium	Large
Average	€ 5,341	€ 6,059	€ 5,489
Median	€ 4,409	€ 5,504	€ 5,385
Min	€ 892	€ 2,201	€ 181
Max	€ 25,687	€ 25,957	€ 10,310

Table 3.12.9 Average cost per MI per tonne of substance registered at 1-10t (€ per tonne production substance assuming no validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods)

	Micro/Small	Medium	Large
Average	€ 618	€ 690	€ 551
Median	€ 512	€ 630	€ 542
Min	€ 213	€ 299	€ 18
Max	€ 2,891	€ 2,596	€ 1,031

Chart 3.12.4 Percentage frequency distribution of costs per M/I per substance registered at 1-10t (assuming no validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods)



Average costs per substance for Manufacturers of different size -10-100t substances (assuming no validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods)

Similar to the estimation of cost burden across companies of different size for 1-10t, Table 3.12.10 and Chart 3.12.5 provide data on the average cost of registering a substance at 10-100t for M/Is of different sizes assuming no validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods. Table 3.12.11 provides the same data as cost per tonne of substance registered.

The data suggest that, while costs are of a similar order of magnitude for all sizes of M/I, the smaller the company size, the lower the estimated cost.

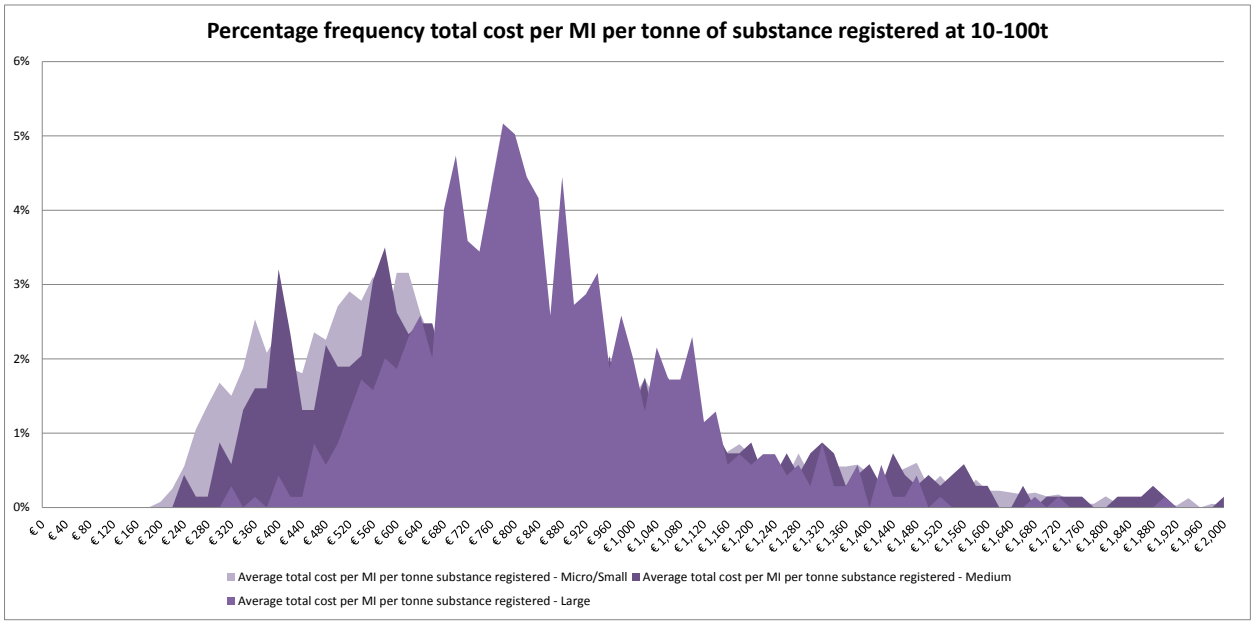
Table 3.12.10 Average cost per MI per substance registered at 10-100t (€ per substance assuming no validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods)

	Micro/Small	Medium	Large
Average	€ 65,742	€ 71,462	€ 72,294
Median	€ 55,301	€ 61,704	€ 69,813
Min	€ 8,992	€ 17,095	€ 23,311
Max	€ 272,280	€ 248,606	€ 189,281

Table 3.12.11 Average cost per MI per tonne of substance registered at 10-100t (€ per tonne production substance assuming no validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods)

	Micro/Small	Medium	Large
Average	€ 778	€ 826	€ 836
Median	€ 675	€ 738	€ 804
Min	€ 180	€ 225	€ 307
Max	€ 2,723	€ 2,486	€ 1,893

Chart 3.12.5 Percentage frequency distribution of costs per M/I per substance registered at 10-100t (assuming no validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods)



3.12.3 Cost categories with a highest room for achieving cost-efficiencies

In addition to providing new and updated estimates of the costs of the Registration 2018 exercise a further objective for the study is to establish specific cost categories with a highest room for achieving cost-efficiencies, as well as suggesting specific implementation measures to achieve them, while maintaining the capacity to deliver the expected health and environmental benefits.

SIEF and Joint Registration Administration Costs

Elsewhere in this report it has been identified that costs of SIEF formation and joint registration in 2013 may have been higher than was anticipated. As such, it might have been concluded that the same may apply to substances to be Registered in 2018.

However, analysis of registration data provided to the study by ECHA suggests that the numbers of M/Is that would be a part of each SIEF was significantly underestimated in original assessments and, hence, the complexity of the arrangements in terms of the numbers of participants. In addition, a significant number of the substances registered in higher tonnage bands have also been registered at lower tonnages and this was not accounted for in the original assessments.

The net effect of this is that, not only were there more members of SIEFs/consortia than was anticipated for the higher tonnage substances, but also that the majority of the SIEFs/consortia also had to incorporate differences in information required for different registrants at different tonnages.

For the 10-100t and 1-10t substances, the potential for such factors to have such a significant effect is much lower owing to factors including the following:

- There is only one tonnage band lower than the 10-100t band and none lower than 1-10t – thus, over all of the substances to be registered in 2018 there is much less potential for complexity compared with those registered in 2013 (or first in 2010); and
- What evidence there is suggests that a significant proportion of the substances registered at 1-10t only are likely to be speciality chemicals manufactured by one or a relatively small number of M/Is – thus there may be relatively fewer SIEFs and the number of participants much smaller.

Thus, even if there were a means to reduce the costs associated with SIEFs and joint registrations, the impact on substances to be Registered in 2018 would be relatively small.

Testing and Information Costs

From the assessment of the costs of Registration 2018 it was concluded that, for the 1-10t substances the following can be concluded:

- The total cost of registering all 1-10t substances in 2018 is estimated to be up to around €228 million, of which around a third of the cost is associated with the information elements of registration. As with other estimates for Registration 2018, costs assume that validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods and read across does not occur within the time frame first envisaged; and
- This is of a similar order of magnitude to the €295 million originally estimated in the ExIA but, clearly, lower. This difference is as a result of the criteria applied to 1-10t

substances in Annex III in combination with Article 12 (where this article did not exist at the time of the ExIA).

For the 10-100t substances the following can be concluded:

- Costs of liaising on, producing and submitting dossiers and fees are of the order of €123 million;
- This is comparable with the €116 million estimated for similar cost elements in the ExIA;
- In contrast with this, the cost of the information related elements of registration of 10-100t substances may be up to around €1,013 million if validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods does not occur within the time frame first envisaged. This is far in excess of the €465 million estimated in the ExIA (which assumed QSAR validation and acceptance);
- Owing to this, the resulting total cost of registering 10-100t substances is estimated to be potentially as high as €1,136 million if validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods does not occur within the time frame first envisaged.

The overall conclusion was that, owing to costs of the information elements, if validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods does not occur within the time period envisaged then the total cost of registering 10-100t substances may be significantly higher than was previously estimated in the ExIA underpinning the need to increase the applicability and acceptability of QSARs and other non-testing methods.

Regarding the current level of validation and acceptance of QSARs/Read Across generally:

- certain toxicological effects based on more complex processes are not yet or not fully covered by alternative methods, these include repeated-dose toxicity, skin sensitisation, carcinogenicity and reproductive toxicity;
- for developmental and reproductive toxicity endpoints there are relatively few models available and those have limited applicability domains;
- it has previously been identified (in 2011) that work to replace animal testing for this endpoint would take more than 10 years to achieve.

ECHA is intensifying its support on the alternative methods as part of Phase 4 of the REACH 2018 Roadmap. As such, it can be hoped that work in this area may produce a reduction in the maximum test costs provided here. The extent of that reduction requires more detailed examination than is possible in this short study.

With only three years until the Registration 2018 deadline it is clearly difficult to identify other specific implementation measures that will address issues should QSARs, Read Across and other non-testing methods not provide the anticipated applicability and acceptance. Whilst moving selected (more expensive) tests from Annex VIII to Annex IX would provide a 'quick route' to reducing testing and information costs this will affect the benefits side of the question, particularly in relation to the benefits of identifying substances with previously unknown reproductive/developmental effects (this being associated with the most expensive test).

We can identify only one possible specific implementation measure that may reduce costs and not affect the benefits significantly. This relates to the battery of three mutagenicity tests that are currently applied in Annex VIII, changes to which might

reduce costs relatively significantly for a small proportion of substances registered at 10-100t. At present, a positive result in any of these three tests triggers the need for further mutagenicity testing (and consideration of carcinogenicity and reproductive toxicity) and the cost of this further testing is significant (in excess of around €40 thousand). However, the potential for false positive results from the three test battery is high. In light of this, in 2011 the UK Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM) published Guidance on a Strategy for Genotoxicity Testing of Chemical Substances[143]. This reviewed the effectiveness of testing strategies, comparing batteries of two versus three tests finding that:

- A two test battery is likely to correctly identify 73% of rodent carcinogens and 78% of in vivo genotoxicants;
- A two test battery is likely to falsely identify 88% of non-carcinogens as potential rodent carcinogens that would need to undertake further in vivo studies;
- Adding a third test (as in Annex VIII) increases the sensitivity marginally, correctly identifying 75% of rodent carcinogens and 79% of genotoxicants;
- At the same time, adding the third test (as in Annex VIII) is likely to increase the percentage of non-carcinogens falsely identified as potential carcinogens to 95%.

On the basis of the lack of convincing evidence that the three test battery identifies more carcinogens/genotoxins than the two test battery combined with the increase in the numbers of substances falsely identified under the three test system, the two test system is recommended by the UK COM.

Considering the impact of this conclusion on Annex VIII and the scope for cost efficiencies, inspection of the Classification and Labelling Inventory indicates that a small percentage are mutagenic and the vast majority are non-mutagenic. As such, the same is likely to apply to the 10-100t substances. Thus, under the (current) three test battery in Annex VIII around 95% of the vast majority of the ~5,000 substances for registration will be identified as requiring further mutagenicity testing though Annexes IX and X. The UK COM evidence is that this could be reduced to 78% by eliminating the third test from the (current) three test battery.

The saving in costs that would be delivered by such a change may be substantial to the M/Is benefiting from the saving but small overall as the changes would only affect registrations of around 7% of the 10-100t substances.

It is hoped that the new implementing Regulation on Data Sharing will contribute to reducing registration costs.

[143] The UK Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM) (2011) Guidance on a Strategy for Genotoxicity Testing Of Chemical Substances. http://www.iacom.org.uk/guidstate/documents/COMGuidanceFINAL.pdf

3.12.4 Conclusion

For the 1-10t substances it is estimated that the total cost of registering all 1-10t substances in 2018 will be up to around €228 million assuming no validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods. Around a third of the cost is associated with the information elements of registration. This is lower than the €295 million originally estimated in the ExIA as a result of the criteria applied to 1-10t substances in Annex III in combination with Article 12 (where this article did not exist at the time of the ExIA).

For the 10-100t substances the total cost of registration is estimated to be potentially as high as €1,136 million if validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods does not occur within the time frame first envisaged. This is very significantly higher than the €465 million estimated in the ExIA (which assumed QSAR validation and acceptance). €1,012 million of these estimated costs are associated with the information related elements of registration of 10-100t substances assuming that negative and positive QSARs, Read Across and other non-testing methods does not occur within the time frame first envisaged.

Table 3.12.12 Estimated registration costs 1-10t and 10-100t 2018 assuming no validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods (€million)

1-10 t		10-100	
2015 Estimate*	ExIA	2015 Estimate*	ExIA
228	295	1,136	581

*estimates assume that validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods does not occur within the time frame first envisaged.

With only three years until the Registration 2018 deadline it is difficult to identify specific implementation measures. If validation and acceptance of negative and positive QSARs, Read Across and other non-testing methods does not occur within the time period envisaged then the total cost of registering 10-100t substances may be significantly higher than was previously estimated in the ExIA underpinning the need to increase the applicability and acceptability of QSARs and other non-testing methods.

Regarding the current level of validation and acceptance of QSARs/Read Across generally:

- certain toxicological effects based on more complex processes are not yet or not fully covered by alternative methods, these include repeated-dose toxicity, skin sensitisation, carcinogenicity and reproductive toxicity;
- for developmental and reproductive toxicity endpoints there are relatively few models available and those have limited applicability domains;
- it has previously been identified (in 2011) that work to replace animal testing for this endpoint would take more than 10 years to achieve.

ECHA is intensifying its support on the alternative methods as part of Phase 4 of the REACH 2018 Roadmap. As such, it can be hoped that work in this area may produce a reduction in the maximum test costs provided here. The extent of that reduction requires more detailed examination than is possible in this short study.

In terms of SIEF and Joint Registration Costs, elsewhere in this report it has been identified that costs of SIEF formation and joint registration in 2013 may have been higher than was anticipated. As such, it might have been concluded that the same may apply to substances to be registered in 2018. Analysis of registration data provided to the study by ECHA and comparison with previous estimates suggests that, even if there were a means to reduce the costs associated with SIEFs and joint registrations, the impact on substances to be registered in 2018 would be relatively small.

4. OVERALL ASSESSMENT OF THE FINDINGS

The aim of this section is to provide an overall assessment of the findings as regards the individual objectives reviewed in section 3 in terms of the criteria of coherence, efficiency, effectiveness, sustainability and impacts of REACH. Then strengths and weaknesses of REACH implementation are identified as regards conditions and structure of the market, consumer choice, compliance costs and administrative procedures; and, recommendations made that could remedy weaknesses identified and improve impacts of mechanisms that improve conditions for businesses.

4.1 Introductory remarks

In the first place it needs to be underlined that this study is not concerned with assessing the overall benefits of the REACH Regulation in terms of human health, safety and the environment. The study is about the impacts on competitiveness, innovation and SMEs. Secondly, the focus is on the REACH Regulation – it does not specifically deal with the question of a "no-REACH" counterfactual, although in the interview programme the no-REACH alternative does come up. Finally, it is recognised that it is difficult, given the plethora of regulation present in the chemical sector, to assess the impacts of one specific piece of legislation. That is why research questions have been specifically crafted to disentangle the Regulation from other pieces of legislation. This does not deny that there is not an interaction between REACH and other legislation, but that is actually the subject of a separate study on the cumulative costs of legislation in the chemical industry that is currently being undertaken by the Commission.

4.2 Effectiveness, efficiency, coherence, sustainability and impacts

The terms of reference indicate that the methodology developed should evaluate the effectiveness, efficiency, coherence, sustainability and impacts of the regulation as regards competitiveness, innovation and SMEs. Discussion of each topic is introduced by a definition of the term, as set out in the Commission Guidelines.[144] Sustainability is an additional criterion while for impacts these are as defined in the Methodology Report.

4.2.1 Effectiveness

Effectiveness analysis considers how successful EU action has been in achieving or progressing towards its objectives.

As has been mentioned in 3.2.1, competitiveness is the result of a wide range of factors, of which the regulatory environment is one. The regulatory environment itself consists of many elements in addition to the REACH Regulation. When assessing competitiveness the key dimensions of enterprise competitiveness comprise: *costs* (the cost of doing business, which includes cost of intermediate inputs incl. energy) and of factors of production (labour and capital); *capacity to innovate* (the capacity of the business to produce more and/or higher quality products and services that better meet customers' preferences); and, *international competitiveness (the* above two aspects could also be assessed in terms of an international comparative perspective, so that the likely impact

[144] http://ec.europa.eu/smart-regulation/guidelines/toc_guide_en.htm

of the policy proposal on the European industries' market shares and revealed comparative advantages is taken into account).[145]

As regards *costs*, the one-off registration costs (and possibly follow-up evaluation costs) have to be incurred by firms, and to the extent that these costs cannot be recovered from customers (tables 3.3.9 & 10), this will have impacted profitability. There may also be costs related to responding to substances appearing in the candidate list and the authorisation process. For some, particularly smaller firms, financing registration may also be a challenge, particularly in the case of the upcoming 2018 registration deadline. In addition, there are on-going compliance costs to be incurred, involving increased expenditures on staff and systems. Where companies have withdrawn from markets as a result of cost pressures, this has led to reduced competition in those markets. The survey responses and interviews suggest that it is mainly smaller firms (and supply of substances supplied in lower volumes) that are affected in this sense (both from suppliers based within and outside the EU/ EEA).

From the point of view of *international competitiveness*, some 80-85% of survey respondents indicated that no changes were experienced as regards exports or imports from within the EU/ EEA, and where there were changes, the shares of increases and decreases in exports or imports were broadly similar, with increased imports from within the EU being slightly more pronounced. The contribution to the harmonisation of the EU chemicals market is a benefit, although also difficult to quantify. In view of the complexity of the chemical industry, its suppliers and downstream users, a disadvantage for one business might well be an advantage for another and vice versa. Some two-thirds of respondents thought that their competiveness vis à vis third countries (outside the EU/ EEA) was not affected. More of large firms than SMEs considered their positions affected, and among those affected, manufacturers and formulators tended to consider themselves negatively affected, while article suppliers saw effects more often as positive.

Section 3.8 dealing with *innovation* makes the point that the regulation has led to a substantial level of research and development activity, which while qualifying as innovation in terms of the OECD/ European Commission (2005) definition[146], many firms are of the view that the activity is purely driven by the need to comply with legislation and has not led to more and/ or higher quality products or services that better meet customers' preferences. However, several industry representatives and enterprises expressed the view that in the longer term the benefits of focusing research and new product development on using safer chemicals would become apparent

Looking at the overall position, it can be said that as regards competitiveness between firms within the single market, the effect appears to have been neutral on the whole, with some differences between market participants. Among the EU firms whose competitive position as regards third countries is affected by REACH, larger manufacturers and importers have tended to see the effect as negative, whereas those further downstream (e.g. article suppliers) have seen it as more positive. In sum, the evidence points to a differential impact of REACH on different market participants. In terms of effectiveness as regards enhancing competitiveness and innovation, some have been affected negatively, others in a more positive manner. Given the diversity of the

[145] European Commission (2012): final Commission Staff Working Document Operational Guidance for Assessing Impacts on Sectoral Competitiveness within the Commission Impact Assessment System, Brussels, 27.1.2012, SEC(2012) 91, A "Competitiveness Proofing" Toolkit for use in Impact Assessments", p.8

[146] See 3.8.1

sector it is not realistic or meaningful to draw an overall conclusion for the sector and downstream users as a whole.

4.2.2 Efficiency

Efficiency considers the relationship between the resources used by an intervention and the changes generated by the intervention.

The study did not assess total costs (resources used) involved in the implementation of the Regulation as such an exercise was beyond its scope. However, case study 1 shows that direct and indirect compliance costs (familiarisation, adaptation and administration) emerge throughout the value chain of the enterprise and that many of these are on-going and not just one-off costs (e.g. also costs of evaluation of dossiers after registration) that are not captured under the assessment of one-off registration costs. In addition, a substantial level of resource used by the REACH relates to enforcement (including relevant costs of the agency involved – ECHA), which need to be included as part of overall cost assessment. No full cost study has been carried out on this major piece of legislation since it came into operation in 2007 – neither *ex-ante* nor *interim*. Without such data it is not possible to make comparisons with any identified or potential benefits that may result from implementation so as to gauge the overall efficiency of the Regulation.

However, the study assessed Registration costs incurred by enterprises in 2013, and these were found to be in the order of €459 million. While the scope of error within the estimate is potentially large, they are of a similar magnitude to those estimated for the ex-ante impact assessment.

The estimates for the 2018 registration suggest that while registration costs for 1-10tpy substances will be similar to what was foreseen in the initial studies (€228 million compared to the ExIA estimate of €295 million), registration costs for 10-100tpy substances will be significantly higher than foreseen (€1,136 million as compared to €581 million), and there is no readily available or apparent way of reducing this cost.

As regards human resources involved in implementing the regulation, the survey findings indicate that at enterprise level there was a gradual increase in FTEs employed for compliance in the period leading up to the 2013 registration.

The preceding paragraphs relating to effectives indicate that it is not possible to readily characterise a level of benefit as regards enhanced competitiveness and innovation for the sector as a whole, given the diversity of responses between different market participants in terms of their roles and sizes. Together with the absence of data on the overall costs of the intervention, this means that statistically robust statements about its efficiency in terms of enhancing competitiveness and innovation are precluded.[147] However, there is a view that the costs incurred for implementation have, for the present, delivered little in terms of enhanced competitiveness and innovation, although the position might change in the future, and that benefits of implementation in as much as they exist need to be sought in the wider health, safety and environmental benefits of the legislation.

[147] It has been noted that DG Environment has launched a separate study to assess the benefits of REACH in terms of health and the environment.

4.2.3 Coherence

There are two aspects to coherence: external coherence – the extent to which an intervention is coherent with other interventions which have similar objectives; and, the extent to which legislation is coherent internally.

The surveys and interviews did not gather detailed data on the question of coherence. However, on the basis of responses in the company and stakeholder interview programmes, as well as other projects the research team has carried out, some remarks in this respect can be made. REACH links with a wide range of EU legislation aimed at improving health, safety and the environment, both at enterprise level and in society as a whole. As such it is coherent with high-level community goals. However, as pointed out in section 3.1 dealing with harmonisation and the single market, there is scope for improvement.

As regards internal coherence in terms of supporting innovation, competitiveness and SMEs, no feedback was received suggesting issues in this respect, other than the general one that it was not considered clear how the increased costs required to comply with the Regulation would support innovation and competitiveness.

4.2.4 Sustainability

Sustainability deals with the question of how likely the effects are to last after the intervention ends.

The REACH Regulation is implemented with a view to being an element of the EU/ EEA industry operating environment for the foreseeable future, while similar approaches are being put in place also in non-EU/EEA countries.[148] Industry and other stakeholders are largely supportive of the high-level aims of REACH and take the view that once the registrations are completed after 2018 and the regulation has "settled" a few years later, the benefits envisaged in terms of competitiveness and innovation should emerge.

However, there are voices that warn against possible reductions in the supply of new innovative small volume chemicals from the USA and other countries outside the EU, and possible consequences for EU industry due to small importers of existing substances having to shoulder high costs of letters of access which could lead to reductions in supply and/ or the number of suppliers. REACH also contributes to increasing operating (compliance) costs, while EU industry is facing increasing international competition. On the other hand, the introduction of REACH-related systems and principles in some countries (e.g., Korea and China) may place companies from those countries on an equal footing with EU industry, if the different regulatory authorities apply similar tests and recognise each other's data.

[148] Dg GROW has commissioned a study on the international aspects and impacts of REACH, which will provide a more detailed analysis of these aspects.

4.2.5 Impacts

In terms of the impact model developed in the Methodology Report, three levels of outcome are presented. These are: outputs (immediate outcomes); results (intermediate outcomes); and, impacts (longer term outcomes).

A very wide range of impacts has resulted from the implementation of the regulation. This study has a major focus on the period up to and including the 2013 registration, particularly as regards identification of costs, operation of SEIF, etc. but in instances where more recent relevant information has come to light, such as to do with authorisation for example, as well as is information that could be relevant for the 2018 registration, that is also included.

The impacts listed below are those considered most relevant in terms of competiveness, innovation and SMEs.

- **Outputs (immediate outcomes)**

As regards outputs, with the 2013 deadline, the second round of registration (100-1,000tpy) has been completed. In addition, a wide number of additional outputs have been realised:

  - Additional substances have been classified and registered.
  - Information on uses (and exposure scenarios) of SVHCs for which authorisation has been granted is now publicly available.[149]
  - Additional substances have been identified as SVHCs and added to the candidate list - that companies have had to respond to.
  - 31 substances are currently in Annex XIV, for about half of which no applications for authorisation have been received.

- **Results (intermediate outcomes)**

Results refer to medium term outcomes that are usually discernible in quantitative or qualitative data. The main results identified in the study are presented in the order of the study's 12 objectives as follows:

- *Harmonisation and the Single Market*

The majority of respondents reported no changes (80-85%) as regards imports or exports as result of the implementation of REACH, but some have reported increases and others decreases in imports from/ exports to other EU/ EEA countries. There is no significant trend discernible either way.

- *External competitiveness*

The majority of survey respondents (two thirds) have identified no impacts as regards international competitiveness. Larger firms have tended to experience impacts more often than SMEs, and among those that have experienced an impact, the impact on manufacturers and importers has tended to be negative (due to increased prices related

[149] http://echa.europa.eu/view-article/-/journal_content/title/notify-echa-of-your-uses-covered-by-a-reach-authorisation . The document is "List of Authorisation decisions by the European Commission"

to costs of REACH compliance and increased transaction costs with non-EU suppliers that can't be recovered through higher prices). Article suppliers have experienced impacts as more positive.

The increased investment in supply chains by EU/ EEA companies, especially in countries outside the EU/EEA, in order to ensure REACH compliance in those supply chains, reduces flexibility in supply chain choice for those EU/ EEA-based companies and may reduce their competitiveness.

- *Registration 2013*

Registration costs for 2013 have been estimated as in the region of €459 million, which is within the range predicted by the ExIA. Some 30% of survey respondents (OBS) have experience of substance withdrawals. Where withdrawals have occurred, the most typical response has been to switch suppliers or reformulate.

As part of the registration exercise and the authorisation process (both candidate list and Annex XIV- listing) the knowledge about chemicals and their safe handling has been augmented.

- *Business opportunities*

A wide range of businesses has grown to provide REACH-related services to firms (e.g. inspection, testing, consulting, legal). (These are additional costs to be borne by the industry). Some survey respondents report an increase of awareness among firms of products being REACH compliant which could lead to business advantages. Few potential business opportunities resulting from the implementation of REACH have been realised among survey respondents. More proactive risk management activities have been introduced.

There is a greater awareness of chemicals management issues by the chemical industry and in particular DUs and changes and improvements in risk management and environmental management practices have been implemented.

- *SIEF and consortia*

While SIEF and Consortia have operated successfully through the two registration deadlines that have occurred so far, and rules are widely accepted, a significant share of firms still thinks that cost sharing is a problem. There are issues surrounding cost for smaller and micro firms related to letters of access. Looking ahead to 2018 more capacity building will be required. A case study on cost-sharing in SIEF found that some conditions in the 2010 cost sharing rules are unfair and discriminatory.

- *SMEs*

SMEs have been more acutely affected than large enterprises by the compliance costs and issues related to the legislation, while few benefits have been experienced.

- *DUs*

An important share of DUs still remains unaware of their current/ impending REACH obligations. Communication throughout the supply chain has increased, but there are still important gaps in the information passed down, especially from formulators. Articles 7 and 33 appear not to be well-implemented.

- *Innovation*

There has been an increase in R&D activity for some 26% of companies surveyed (CATI), although in the OBS only 10% indicated that their R&D budgets had increased. For nearly half of the companies sampled, R&D resources were transferred to compliance activities, and there was increased expenditure on compliance.

Improved and increased communication in the supply chain provides for the potential of more innovation, business development opportunities and more efficient and effective supply chain management practices in the longer term.

Companies have revised their product portfolios – for example, withdrawing low volume low value substances and those at the end of their product cycle (economic criteria) and also those with an undesirable hazard profile. There has been a gradual increase in the use of PPORDs, although still mainly by German companies (39%) and increasingly by large firms (>80%).

Time to market has been affected negatively for about a third of companies.

- *HR and consultants*

The number of staff in companies involved in compliance activities has increased slightly compared to the 2010 registration period, some employees having been reallocated from R&D activities. Most enterprises prefer to train existing staff on REACH compliance duties to recruiting from outside. Smaller firms tend to be more reliant on external training and external consultants. Availability of staff or consultants is not the issue, it is rather their costs and quality.

- *SVHCs*

The first authorisations have been processed and granted and others are in the pipeline. Costs of Authorisation have been estimated by ECHA to be in the region of €230k, and declining as experience with the process is gained. The ability of SMEs to carry out authorisations remains to be tested.

Inclusion of substances on the PACT, CORAP, the candidate list and ultimately Annex XIV leads to significant levels of activity as regards substitution, withdrawal and replacement.

Areas within Authorisation that the Commission is currently looking into are: low volume uses, legacy spare parts, substances subject to type-approval, and biological essential ingredients.

- *Support and assistance*

While a strong support system has developed to help companies deal with REACH related-obligations, some tools support the 2018 registration, in particular the standardised electronic (e)SDS, are still missing.

A significant share of the industry, especially DUs is not yet aware of their REACH obligations and of those that are, a significant share has yet to start preparing for REACH 2018.

- *Registration 2018*

Estimates of registration costs for 2018 for 1-10t substances appear to be slightly below those of the ExIA (€228m compared to the estimate of €295 million owing to the

introduction of Article 12 and Annex III), but the total cost of registering 10-100t substances may be significantly higher than formerly estimated (€1,136 million as compared to €581million) if validation and acceptance of both negative and positive QSARs and read across does not occur within the time frame first envisaged (as it seems likely at present).

Registration costs (€ millions)			
1-10 t		10-100t	
2015 Estimate*	ExIA	2015 Estimate*	ExIA
228	295	1,136	581

*estimates assume that validation and acceptance of negative and positive QSARs and read across does not occur within the time frame first envisaged.

- *Impacts (longer term outcomes)*

Assessment of longer term outcomes is based on less concrete factors than outputs and results, so qualitative factors are more important and will contain a certain hypothetical or speculative element, but this does not mean that they should be underestimated.

- While more remains to be done, there has been on-going harmonisation of the European chemicals legislation and integration of the Single Market.
- It is expected by some stakeholders that REACH will support gradual longer term penetration of non-EU markets not only for firms with a proactive and green/ eco-friendly position but also, in some instances, simply for being REACH-compliant. However, to date the survey results show that this has not been widespread. As some of the non-EU countries implement their own REACH-like laws, this advantage, in as much as it exists, may diminish over time. Equally, the disadvantage of increased operating (compliance) costs for the EU companies may also diminish.
- Despite REACH-like laws being introduced in some non-EU/EEA countries, there is no evidence so far that being REACH compliant facilitates compliance with regulatory regimes of third countries. EU REACH-data are not necessarily accepted by other jurisdictions, and the nature of the actual legislation implemented in many instances waits to be seen.
- There are concerns expressed about increases in the cost base of companies as a result of compliance with REACH which will force smaller firms out of the market, or inhibit entry of new ones, and reduce the overall supplier base of the industry. Given the innovativeness of small and micro-firms, this could have longer term consequences for the EU chemicals industry.
- Some sub-sectors have expressed a concern that due to their industrial structure (e.g. firm sizes and dependence on imports of low cost low volume substances), or due to the globalised nature of their industry which offers many alternative location possibilities, they are particularly vulnerable to REACH compliance costs. Such an example is the case of dyes and leather treatment where the costs of letters of access can be well beyond what is affordable for small and micro firms and lead to migration out of the EU of additional elements of the value chain that have not already left the EU. Authorisation presents another such a challenge. In other cases, as set out in the withdrawals case study, firms talk about a slow but gradual process.
- Concerns have also been expressed about the potential lack of entry of new innovative mixtures, substances and low volume research substances into the EU from non-EU/ EEA sources due to REACH costs and the impact that this could have

on EU industry in the long term. Only Representatives have provided details of such instances.

- The regulation has helped identify areas in which companies can focus longer term research and innovation efforts – the candidate list, PACT, CORAP list help provide guidance on development directions in this respect. Many interviewees from industry have expressed the view that in time, as a result of the directions for research indicated by REACH, they hope that a new approach to chemicals will develop that is safer and more environmentally friendly.

4.3 Strengths and weaknesses of implementation

Strengths and weaknesses of implementation are assessed in terms of conditions and structure of the market, user choice, compliance costs and administrative procedures.

4.3.1 Conditions and structure of the market

As regards the conditions and structure of the market, REACH has made an important contribution to strengthening the market by increasing harmonisation, by putting in place a forum for discussion of legislation, its implementation and enforcement. Feedback from stakeholders indicated that there is still scope for improved harmonisation with areas such as health and safety, or other chemicals related legislation such as ROHS, Cosmetics and Waste. Assessment of this issue was, however, not subject to this study but may be worth undertaking.

The chemicals market is segmented and a highly diverse group of enterprises and downstream users participate in market activities. It is therefore not surprising that implementation has affected different parts of the market in different ways, as has been set out in the discussion of the separate objectives in section 3 and the preceding paragraphs. The effects of implementation have not been neutral – for many companies, REACH has become part of business strategy.

No evidence has been identified that the withdrawal of substances has led to insurmountable problems for firms, except in some special cases of some Annex XIV substances where some firms and branches of industry were impacted, in a few cases potentially severely. As more Authorisations take place, it will be necessary to look at the market impacts of the Authorisation decisions.

The establishment of, and improvement in the quality of, institutions and processes to support implementation has had a positive effect on conditions in the market.

Concerns have however been expressed as regards the potential loss of smaller businesses and reduction of suppliers (both from within and outside the EU/ EEA) and what this could imply for competitiveness, flexibility in supply chains and innovation.

Companies have tended to reduce the use of SVHC and adjustments to improve risk management practices have been made.

4.3.2 User choice

As regards choice available for users of chemicals, the survey shows cases of withdrawals of substances from the market (both due to economic factors and hazard profiles). This has often been due to their replacement by other or less hazardous substances or mixtures (and in such cases may have led to increased consumer protection and safety of consumer products). There are also fewer sources to obtain

chemicals from as companies have withdrawn from supply of some substances. Quantitative data indicating the extent to which this has occurred is not available.

Generally, this has led to use of more expensive substitutes and, in some instances that have been documented, this has also led to the provision of less effective products. However, users have the possibility of accessing and requesting more information about products, should they desire to do so, to make more informed choices.

While the evidence as regards the awareness of REACH compliance as a market factor among consumers is mixed, businesses have indicated that REACH does present a marketing opportunity for some.

4.3.3 Compliance costs

As was pointed out in Case Study 1 and the discussion of efficiency (4.2.2), no full assessment of the compliance costs of the REACH Regulation has been carried out.

However, based on the work carried out for this study, the following comments can be made as regards compliance costs:

- Registration costs at €459 million for 2013 remain a substantial industry expense, and in particular for SMEs.
- However, with more experience gained by those companies that are in contact with and familiarising themselves with the legislation, as well as the REACH-related support organisations, the efficiency with which companies comply with and adjust to REACH obligations is increasing.
- Having said that, the 2018 registration is expected to involve many companies that are new to REACH and that will have to go through the REACH-learning experience from scratch. However, they should be able to benefit from lessons learnt by support institutions during previous registrations.
- Compliance cost has led to increased costs of labour in the chemicals sector and with DUs due to the requirement to employ staff to carry out compliance and because, in many instances, to obtain staff with the required skills requires higher remuneration levels and/ or additional training or retraining costs. Where these activities are outsourced this is even more the case.
- At Member State level, due to the differences between Member States' industry structures (e.g. in terms of firm sizes and types of activity carried out) there is a differential impact of the cost of compliance to legislation.
- No assessment of REACH enforcement costs has been carried out.

4.3.4 Administrative procedures /Implementation

The carrying out of REACH administrative procedures has become more efficient in the course of the two registration periods as those involved have learnt from experience. For example, the feedback has been that the 2013 registration went more smoothly than that of 2010 and the authorisation process is also expected to become more streamlined. However, there are still areas where challenges remain. These include:

- Implementing standardised eSDS.
- Issues surrounding participating in SIEF and Consortia – e.g. Letters of Access and cost-sharing.
- Implementation of Article 33.
- Treatment under the REACH Regulation of imported of articles that contain SVHCs.

- Many companies, primarily smaller firms, targeted by the legislation are still unaware of its existence and their obligations in terms of REACH (especially DUs).
- Preparation for the 2018 registration.
- Differences in enforcement and surveillance regimes.

4.4 Recommendations

The following recommendations are proposed:

Studies

1. To carry out a study to determine what the key **legislation is that is holding up further harmonisation** in the EU chemicals markets and to develop an action plan to increase harmonisation.

2. To carry out a study to determine the full **costs of the REACH Regulation** (along the lines set out in *Assessing the costs and benefits of Regulation*, (CEPS and Economisti Associati). It is only once such a study has been carried out that it will be possible to assess the efficiency of the REACH Regulation, in terms of its environmental, health and safety benefits, as well as those pertaining to competitiveness and innovation. Such a study should pay particular attention to small and micro firms, and distinguish between different Member States.

3. A study should be carried out to determine whether there are **sub-sectors that are particularly vulnerable to REACH compliance** issues and to consider what can be done to support firms in those sectors and firms, particularly in the run-up to the 2018 registration.

4. While the current study has considered the position of SMEs as a group, it became increasingly clear throughout the study that within the category of SMEs, small and micro firms were particularly difficult to make contact with to determine their views and responses to the Regulation and its implementation. Where responses were obtained they were often quite at variance to those of other size categories. As these firms are the backbone of the EU economy, it is recommended that a study is addressed to determining the impacts of the regulation specifically on small and micro firms, and looking ahead at the 2018 registration, with due regard to differences between Member States in this respect.

Support

5. There are **several legal acts with requirements on (hazardous) substances**. Especially DUs often do not only have to comply with REACH but have to fulfil other product related laws. Therefore, a database should be developed that sets out the different provisions on a substance level (this demand was also formulated during the REACH review 2012 and has lately been renewed by some industry associations).

6. **Many companies are still unaware** of their REACH roles and the obligations they have to meet. This is particularly true with a view to the 2018 registration. Member States' relevant government departments and the appropriate industry associations and other relevant networks and organisations need to develop innovative campaigns (e.g. working through the Enterprise Europe Network as in the case of Italy) to deal with this lack of awareness. This will be particularly an issue in countries without obligatory membership of industry associations. This

recommendation also includes capacity building to deal with the needs of companies identified as new to REACH.

7. Some firms stated that the complexity of industry processes cannot be reflected with an adequate detail in many **guidance documents** as these tend to generalise. In such cases more tailored support instruments with input from and voluntary actions by industry organisations from the particular sectors need to be developed. Such instruments could cover: collection of best practice for specific situations; generation of more sector specific solutions; and, translation of documents into national languages as this is a major stumbling block for SMEs.

8 A pan-EU body should assess the development of certification (or equivalent qualification) for **a "REACH practitioner",** or inclusion of such a skill base in existing certifications for those dealing with chemical products (possibly along the lines of such a scheme as in Slovenia). Although it may not be possible to implement in time for the 2018 registration it could still serve a useful purpose subsequently as compliance with REACH obligations will be an on-going activity for the foreseeable future, and in particular small and micro firms need external support at affordable costs.

9. With regard to **registration in 2018, those firms who already want to start working through their SIEF** often have difficulties finding serious partners among those pre-registered to work with. A system needs to be developed whereby it is possible to identify firms in the SIEF that are serious about registration and are prepared to or want to take a more active role.

10 The Commission should assess what the **scope and impact is of SMEs having to pay substantial sums for Letters of Access** – well beyond what they consider affordable – and identify and investigate what the options are for dealing with the problem. This issue is important for the run-up to the 2018 registration.

11. **Dealing with (e)SDS remains a key issue**. Best practice and guidance targeting the development and supply of (e)SDS should be further developed.[150] As the "exposure scenario" is still very new to the market, specific guidance is needed to transform rather scientific risk assessment information into more practical information that can be used on-site. Special focus should also be given to SME dominated non-industrial sectors like e.g. the building sector. Representatives of such sectors should be involved in developments of tools and standards. The support currently being provided for supply chain communication through various industry organisations such as the DUCC in coordination with ECHA (ENES) is commendable and should be continued with and expanded.

12. Support activities at EU and Member State level should also be directed to the implementation of **substitution / alternatives assessment** to ensure that substance withdrawal and candidate listing / authorisation of SVHC can be compensated for in the supply chains.

13 A further action to support innovation would be to **evaluate the usefulness of PPORD** as an instrument and if needed, to see what can be done to widen its use beyond the current group.

[150] E.g. in the already existing ENES network http://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios

14 **REACH-IT use, especially in SMEs**, is another area where support is required through industry associations and other innovative ways to reach companies currently out of the ambit of usual industry communication initiatives.

15 With a view to avoiding significantly higher costs than were anticipated as regards registration of 10-100tpa substances, steps need to be taken to ensure that **negative and positive QSARs and read across** are validated and accepted within a sufficient time frame.

16 **SMEs, especially small and micro firms, should be more strongly represented in panels that are intended to develop REACH implementation instruments** (like CSR/ES) so that SME requirements are considered from the beginning (is the outcome applicable for a wide range of firms? Is the outcome only "high level" or are they tested by e.g. SME?). As it can be expected that resources are limited in this area it should be considered to provide financial support for use of external experts

17. The treatment of **imported articles that contain SVHCs** under the Regulation should be reviewed. Views of different participants in the chemicals market need to be obtained to understand what the impacts on them are and to assess the implications in terms of fairness and competition. If appropriate, amendments should be made to the legislation.

18. **Member States should continue with efforts to improve co-ordination and harmonisation** between market surveillance and enforcement practices.

ANNEX A: INTERVIEW LIST

A.1 List of stakeholder interviews

	Type of organisation	Country	Name of association	Form of input
1.	EU Commission	EU	DG Environment	Interview
2.	EU Commission	EU	DG Growth	Interviews (3)
3.	EU Agency	EU	ECHA	Interviews (4)
4.	Environmental and Consumer Groups	EU	BEUC – European Consumers Organisation	Interview
5.	Environmental and Consumer Groups	EU	European Environmental Bureau	Interview
6.	Environmental and Consumer Groups	EU	Health and Environmental Alliance	Interview
7.	Environmental and Consumer Groups	SE	Chemsec	Interview
8.	Environmental and Consumer Groups	UK	CLIENT EARTH	interview
9.	Trade union	EU	ETUI - European Trade union institute	Interview
10.	EU Industry associations	EU	AISE	Interview
11.	EU Industry associations	EU	CONCAWE - The oil companies' European organisation for environment, health and safety in refining and distribution	Interview
12.	EU Industry associations	EU	ECVM - European Council of Vinyl Manufacturers	Interview
13.	EU Industry associations	EU	Beryllium Science and Technology Association	written
14.	EU Industry associations	EU	ETRMA – European Tyre and Rubber Manufacturers' Association	Interview
15.	EU Industry associations	EU	ASD – Aerospace and Defence Industries Association of Europe	Interview
16.	EU Industry associations	EU	EURATEX - European Apparel and Textile Organisation	written
17.	EU Industry associations	EU	Eurometaux - European association of metals	Interview
18.	EU Industry associations	EU	European General Galvanisers Association	Interview
19.	EU Industry associations	EU	COTANCE - European Confederation of the Leather industry	written
20.	EU Industry associations	EU	FECC - European Association of Chemical Distributors	Interview
21.	EU Industry associations	EU	ECFIA - represents the European High Temperature Insulation Wool	written
22.	EU Industry associations	EU	European Precious Metals Federation	written

	Type of organisation	Country	Name of association	Form of input
23.	EU Industry associations	EU	CEMBUREAU - European Cement Association	written
24.	EU Industry associations	EU	EIGA -European Industrial Gases Association	written
25.	EU Industry associations	EU	EDANA - International association for the nonwovens and related industries	written
26.	EU Industry associations	EU	EFCC - European Federation for Construction Chemicals	Interview
27.	EU Industry associations	EU	Orgalime - European Engineering Industries Association	Interview
28.	EU Industry associations	EU	UEAPME - The European Association of Craft, Small and Medium-sized Enterprises	Interview
29.	EU Industry associations	EU	ORO - Only Representatives Association	Interview
30.	EU Industry associations	EU	Eucomed	Conf Call
31.	EU Industry associations	EU	EDMA	Conf Call
32.	EU Industry associations	EU	ISOPA	Interview
33.	EU Industry associations	EU	ALIPA	Interview
34.	EU Industry associations	EU	CEPE	Interview
35.	EU Industry associations	EU	EUROPUR	
36.	International industry association	CN	China Petroleum and Chemical industry federation	written
37.	Member States Authorities	AT	Ministry for the Environment	interview
38.	Member States Authorities	BE	Department of Economy,Science and Innovation	Interview
39.	Member States Authorities	BE	Federal Public Service Health and Environment	written
40.	Member States Authorities	CY	Department of Labour Inspection	written
41.	Member States Authorities	CZ	Ministry of Industry and Trade	written
42.	Member States Authorities	DE	Federal Ministry for Economic Affairs and Energy	interview
43.	Member States Authorities	DE	Ministry for the environment	interview
44.	Member States Authorities	DK	Environment Protection Agency	Interview
45.	Member States Authorities	EE	Health Board	written
46.	Member States Authorities	ES	Ministry of Agriculture, Food and Environment	written
47.	Member States Authorities	HU	National Institute of Chemical Safety	written
48.	Member States	IE	Environmental Protection Agency	written

	Type of organisation	Country	Name of association	Form of input
	Authorities			
49.	Member States Authorities	IE	Irish Health and Safety Authority	interview
50.	Member States Authorities	IT	Ministry of Health - Directorate-General for health prevention	written
51.	Member States Authorities	LT	Environmental protection agency	written
52.	Member States Authorities	LV	Latvian Environment, Geology and Meteorology Centre"	written
53.	Member States Authorities	MT	Malta Competition and Consumer Affairs Authority, Technical Regulations Division	Interview
54.	Member States Authorities	NL	Inspectorate of Housing, Spatial Planning and the Environment	Interview
55.	Member States Authorities	NO	Norwegian Climate and Pollution Agency	Interview
56.	Member States Authorities	PL	Ministry of Economy - Department of Innovation and Industry	
57.	Member States Authorities	PL	Bureau for Chemical Substances	written
58.	Member States Authorities	RO	Romanian Labour inspection	written
59.	Member States Authorities	SE	KemI - Swedish Chemicals Agency	Interview
60.	Member States Authorities	SI	Ministry of Health - National Chemicals office	Interview
61.	Member States Authorities	SK	Ministry of Economy of the Slovak Republic, Dept. Centre for Chemical Substances and Preparations	written
62.	Member States Authorities	UK	Health and Safety Executive	Interview
63.	National industry association	AT	WKÖ – Austrian Economic Chamber	interview
64.	National industry association	BE	Belgian Association of Chemical Distributors	interview
65.	National industry association	CZ	Czech Association of Chemical Industry	written
66.	National industry association	DE	Chamber of commerce - DHIK	interview
67.	National industry association	DE	ZVEI - German Electrical and Electronic Manufacturers' Association	interview
68.	National industry association	DE	BDI - Federation of German Industries	interview
69.	National industry association	DE	Wirtschaftsvereinigung Metalle	interview
70.	National industry association	DK	Brancheforeningen SPT	written
71.	National industry association	EE	Federation of Estonian Chemical Industries (EKTL)	written
72.	National industry	ES	Fedequim - Catalan Chemical	written

	Type of organisation	Country	Name of association	Form of input
	association		Industry Federation	
73.	National industry association	ES	FEIQUE - Spanish Chemical Industry Federation	interview
74.	National industry association	FI	Kemianteollisuus - Chemical Industry Federation of Finland	Interview
75.	National industry association	FR	UIC - Union of Chemical Industries	interview
76.	National industry association	FR	Union Française du Commerce Chimique	interview
77.	National industry association	GR	HACI - Hellenic Association of Chemical Industries	interview
78.	National industry association	IE	Irish Association of Chemicals & Ingredients	interview
79.	National industry association	IT	Associazione Italiana Commercio Chimico	written
80.	National industry association	IT	Centro REACH	interview
81.	National industry association	IT	FEDERCHIMICA - Italian Federation of the chemical industry	interview
82.	National industry association	NL	VVVF - Dutch paint industry organization	written
83.	National industry association	NL	VNCI- Association of the Dutch Chemical Industry	interview
84.	National industry association	PT	APEQuimica - Portuguese association of chemical industry	interview
85.	National industry association	UK	British coatings federation	written
86.	National industry association	UK	Chemical Business Association	interview
87.	National industry association	UK	The United Kingdom Lubricants Association	written
88.	National industry association	UK	Chemical industries association	Interview
89.	National industry association	UK	Scottish leather group	written
90.	National industry association	UK	OIL AND CHEMICAL RECYCLING ASSOCIATIONS	written
91.	National industry association	UK	EEF - the Manufacturers' Organisation	interview
92.	REACH consortium	EU	Lead REACH Consortium	written
93.	REACH Helpdesk	BE	Department of Economy, Science and Innovation	Interview
94.	REACH Helpdesk	BG	REACH Helpdesk	interview
95.	REACH Helpdesk	CZ	CENIA - Czech Environmental Information Agency	written
96.	REACH Helpdesk	ES	PORTAL DE INFORMACIÓN REACH-CLP	written
97.	REACH Helpdesk	FI	Finnish Safety and Chemicals Agency (Tukes)	Interview
98.	REACH Helpdesk	LU	REACH&CLP Helpdesk Luxembourg	written
99.	REACH Helpdesk	PT	General Directorate for Economic	written

	Type of organisation	Country	Name of association	Form of input
			Activities	
100.	REACH Helpdesk	RO	National Environmental Protection Agency (NEPA)	written

A.2 List of in-depth interviews with firms

No	Name of firm	Country	Firm size	Role
1.		AT	Large	Article supplier
2.		BE	Large	Manufacturer
3.		BG	Large	Manufacturer
4.		CZ	SME	End user
5.		CZ	Large	Formulator
6.		CZ	Large	End user
7.		CZ	Large	Manufacturer
8.		DE	Large	Manufacturer
9.		DE	Large	Manufacturer
10.		DE	Large	Manufacturer
11.		DE	SME	Manufacturer
12.		DE	Large	Formulator
13.		DE	SME	Manufacturer
14.		DE	SME	Manufacturer
15.		DE	Large	Manufacturer
16.		DE	Large	Formulator
17.		DE	Large	Manufacturer
18.		EE	Large	Manufacturer
19.		ES	Large	Formulator
20.		ES	SME	Formulator
21.		ES	Large	Article supplier
22.		FI	Large	Manufacturer
23.		FI	Large	Manufacturer
24.		FR	Large	End user
25.		FR	Large	Distributor
26.		FR	SME	Manufacturer
27.		IT	SME	Distributor
28.		IT	SME	Importer
29.		IT	SME	Distributor
30.		IT	SME	Article supplier
31.		IT	SME	Distributor
32.		IT	SME	Formulator
33.		IT	SME	Formulator
34.		IT	SME	Formulator
35.		IT	Large	Formulator
36.		NL	SME	Distributor
37.		NL	SME	Importer

No	Name of firm	Country	Firm size	Role
38.		NL	Large	Article supplier
39.		NL	SME	Importer
40.		NL	Large	Article supplier
41.		NO	SME	Article supplier
42.		PL	Large	Article supplier
43.		PL	Large	Manufacturer
44.		UK	SME	Importer
45.		UK	SME	Article supplier
46.		UK	SME	Formulator
47.		UK	SME	Manufacturer
48.		UK	Large	Article supplier
49.		UK	Large	End user
50.		MULTINATIONAL	Large	Manufacturer
51.		MULTINATIONAL	SME	Formulator
52.		MULTINATIONAL	Large	Manufacturer
53.		MULTINATIONAL	SME	Importer
54.		NON EU	Large	Article supplier
55.		NON EU	Large	Manufacturer
56.		UK	Large	Article supplier

ANNEX B: SIEF COST SHARING MODEL DATA

Cost sharing Approach 1:

- Each registrant has to pay for the data he needs for his registration tonnage
  - Study costs are shared by tonnage band
  - CSR costs are shared from 10 tpa on

Administration costs are shared equally

Registrant tonnage band (tonnage)	Administrative Costs	Studies	CSR	total	€ per kg (factor highest tonnage lowest tonnage)	Administrative costs per kg	Technical costs per kg
LR > 1000 tpa (2000 tpa)	1/5 x 110,000.00 **= 22,000.00**	½ x Annex X (0.5 x 9,100.00) + 1/3 x Annex IX (0,33 x 9,100.00) + ¼ x Annex VIII (0.25 x 5,200.00) + 1/5 x Annex VII (0.2 x 2,600.00) 4,550.00 + 3,033.33 + 1,300.00 + 520.00 **= 9,403.33**	¼ x CSR (0.25 x 26,000.00) **= 6,500.00**	**37,903.33**	**0.02** (1)	**0.01** (1)	**0.01** (1)
MR A > 1000 tpa (1000 tpa)	1/5 x 110,000.00 **= 22,000.00**	½ x Annex X (0.5 x 9,100.00) + 1/3 x Annex IX (0,33 x 9,100.00) + ¼ x Annex VIII (0.25 x 5,200.00) + 1/5 x Annex VII (0.2 x	¼ x CSR (0.25 x 26,000.00) **= 6,500.00**	**37,903.33**	**0.04** (2)	**0.02** (2)	**0.02** (2)

Registrant tonnage band (tonnage)	Administrative Costs	Studies	CSR	total	€ per kg (factor highest tonnage lowest tonnage)	Administrative costs per kg	Technical costs per kg
		2,600.00) 4,550.00 + 3,033.33 + 1,300.00 + 520.00 **= 9,403.33**					
MR B > 100 tpa (200 tpa)	1/5 x 110,000.00 = **= 22,000.00**	+ ¼ x Annex VIII (0.25 x 5,200.00) + 1/5 x Annex VII (0.2 x 2,600.00) 3,033.33 + 1,300.00 + 520.00 **= 4,853.33**	¼ x CSR (0.25 x 26,000.00) **= 6,500.00**	**33,353.33**	**0.17** (8.5)	**0.11** (11)	**0.06** (6)
MR C > 10 tpa (20 tpa)	1/5 x 110,000.00 **= 22,000.00**	+ ¼ x Annex VIII (0.25 x 5,200.00) + 1/5 x Annex VII (0.2 x 2,600.00) 1,300.00 + 520.00 **= 1,800.20**	¼ x CSR (0.25 x 26,000.00) **= 6,500.00**	**30,320.00**	**1.52** (67)	**1.10** (110)	**0.42** (42)
MR D > 1 tpa (2 tpa)	1/5 x 110,000.00 **= 22,000.00**	+ 1/5 x Annex VII (0.2 x 2,600.00) **= 520.00**	-	**29,020.00**	**11.26** (563)	**11.00** (1100)	**0.26** (26)

Cost sharing Approach 2:

- Differentiation of all costs by tonnage bands (factor 10 – according to lowest tonnage in each band)
- Basic fee for admin (equal for all, 5 % of overall costs)
- Note: costs for the CSR are also assigned to the lowest tonnage band

Registrant tonnage band (tonnage)	Administrative Costs (basic fee)	Administrative costs (variable)	Studies/CSR	total	€ per kg (factor highest tonnage lowest tonnage)	Administrative costs per kg	Technical costs per kg
LR > 1000 tpa (2000 tpa)	200,000.00 x 5% x 1/5 **= 2,000.00**	47.37 % x 100,000.00[151] **= 47,370.00**	47.37 % x 90,000.00 **= 42,633.00**	**92,003.00**	**0.05** (1)	**0,02** (1)	**0.02** (1)
MR A > 1000 tpa (1000 tpa)	200,000.00 x 5% x 1/5 **= 2,000.00**	47.37 % x 100,000.00 **= 47,370.00**	47.37 % x 90,000.00 **= 42,633.00**	**92,003.00**	**0.09** (1.8)	**0,05** (2.5)	**0.04** (2)
MR B > 100 tpa (200 tpa)	200,000.00 x 5% x 1/5 **= 2,000.00**	4.74 % x 100,000.00 **= 4,740.00**	4.74 % x 90,000.00 **= 4,266.00**	**11,006.00**	**0.06** (1.2)	**0,03** (1.5)	**0.02** (1)
MR C > 10 tpa (20 tpa)	200,000.00 x 5% x 1/5 **= 2,000.00**	0.47 % x 100,000.00 **= 470.00**	0.47 % x 90,000.00 **= 423.00**	**2,893.00**	**0.14** (2.8)	**0,12** (6)	**0.02** (1)
MR D > 1 tpa	200,000.00 x 5% x 1/5	0.05 % x 100,000.00	0.05 % x 90,000.00	**2,095.00**	**1.05**	**1,03**	**0.02**

[151] Share of overall administrative cost without the share divided as a basic fee.

Registrant tonnage band (tonnage)	Administrative Costs (basic fee)	Administrative costs (variable)	Studies/CSR	total	€ per kg (factor highest tonnage lowest tonnage)	Administrative costs per kg	Technical costs per kg
(2 tpa)	**= 2,000.00**	**= 50.00.**	**= 45.00**		(21)	(51.5)	(1)

Cost sharing Approach 3:

- Differentiation of data costs by tonnage bands (factor 10 – according to lowest tonnage in each tonnage band)
- Differentiation of CSR cost by tonnage bands only for tonnage bands that need the CSR (factor 10 – according to lowest tonnage in each tonnage band)
- Admin costs equally shared (equal for all, 10 % of overall costs)

Registrant tonnage band (tonnage)	Administrative Costs (basic fee)	Studies/CSR	CSR costs	total	€ per kg (factor highest tonnage lowest tonnage)	Administrative costs per kg	Technical costs per kg
LR > 1000 tpa (2000 tpa)	1/5 x 110,000.00 **= 22,000.00**	47.37 % x 64,000.00 **= 30,316.80**	~47.40 % x 26,000.00 **= 12,322.70**	**64,640.00**	**0.03** (1)	**0,01** (1)	**0.02** (1)
MR A > 1000 tpa (1000 tpa)	1/5 x 110,000.00 **= 22,000.00**	47.37 % x 64,000.00 **= 30,316.80**	~47.40 % x 26,000.00 **= 12,322.70**	**64,640.00**	**0.06** (2)	**0,02** (2)	**0.04** (2)
MR B > 100 tpa (200 tpa)	1/5 x 110,000.00 = **= 22,000.00**	4.74 % x 65,000.00 **= 3,033.60**	4.74 % x 26,000.00 **= 1,232.40**	**26,266.00**	**0.13** (4.25)	**0,11** (11)	**0.02** (1)
MR C > 10	1/5 x 110,000.00	0.47 % x 64,000.00	0.47 % x	**22,423.00**	**1.12**	**1,10**	**0.02**

Registrant tonnage band (tonnage)	Administrative Costs (basic fee)	Studies/CSR	CSR costs	total	€ per kg (factor highest tonnage lowest tonnage)	Administrative costs per kg	Technical costs per kg
tpa (20 tpa)	**= 22,000.00**	**= 300.80**	26,000.00 **= 122.20**		(37.33)	(110)	(1)
MR D > 1 tpa (2 tpa)	1/5 x 110,000.00 **= 22,000.00**	0.05 % x 64,000.00 **= 32.00**	**-**	**22,032.00**	**11.02** (367.33)	**11,00** (1100)	**0.02** (1)

The basic setting defined above referred to a SIEF with 5 registrants. For the exemplification of the effect of the affiliate rule the following shall apply:

Case 1

LR[152]	2,000 tpa	Single firm
MR[153] A:	1,000 tpa	Holding
MR B:	200 tpa	Affiliate of B
MR C:	20 tpa	Affiliate of B
MR D:	2 tpa	Single firm

[152] Lead Registrant
[153] Member Registrant

Case 2

LR[154]	2,000 tpa	Holding
MR[155] A:	1,000 tpa	Affiliate of LR
MR B:	200 tpa	Single firm
MR C:	20 tpa	Single firm
MR D:	2 tpa	Single firm

[154] Lead Registrant
[155] Member Registrant

In consequence the cost will be shared among three entities instead of 5 with the following effect. The cost sharing model 2 will be used for demonstration as here the cost effects per kg substance between the different tonnage bands show the least differences. Similar effects are likely to be observed in the other models.

Case 1/ Cost sharing Approach 2: with affiliate rule - Differentiation of all costs by tonnage bands (factor 10 – according to lowest tonnage in each band)

- Basic fee for admin (equal for all, 5 % of overall costs)

Registrant tonnage band (tonnage)	Administrative Costs (basic fee)	Administrative costs (variable)	Studies/CSR[156]	total	€ per kg (factor highest tonnage lowest tonnage)	Relative change of price	Relative change in cost per kg
LR > 1000 tpa (2000 tpa)	200,000.00 x 5% x 1/3 **= 3,333.33 (2,000.00)**	49.98[157] % x 100,000.00 **= 49,975.00 (47,370.00)**	49.98 % x 90,000.00 **= 44,977.50 (42,633.00)**	**98,285.83 (92,003.00)**	**0.05 (0.05 LR)** (1)	**± 0%**	**± 0%**
MR A > 1000 tpa (1000 tpa)	200,000.00 x 5% x 1/3 **= 3,333.33 (2,000.00)**	49.98 % x 100,000.00 **= 49,975.00 (47,370.00)**	49.98 % x 90,000.00 **= 44,977.50 (42,633.00)**	**98,285.83 (92,003.00)**	**0.08 (0.09 LR; 0.6 MR B; 0.14 MR C** (1.6)	**- 7 % (compared to the accumulated price of the 3 affiliates)**	**-7%**
MR B > 100 tpa (200 tpa)	no cost share, covered by MR A	no cost share, covered by MR A	no cost share, covered by MR A	no cost share, covered by MR A	no cost share, covered by MR A	**-100 %**	**-100%**

[156] note cost for CSR are also assigned to lowest tonnage band
[157] Due to application of rounding rules only the factor for the higher tonnage bands does change (rounding in lowest tonnage band already performed in basic assessment.

Registrant tonnage band (tonnage)	Administrative Costs (basic fee)	Administrative costs (variable)	Studies/CSR[156]	total	€ per kg (factor highest tonnage lowest tonnage)	Relative change of price	Relative change in cost per kg
MR C > 10 tpa (20 tpa)	no cost share, covered by MR A	no cost share, covered by MR A	no cost share, covered by MR A	no cost share, covered by MR A	no cost share, covered by MR A	**-100 %**	**-100%**
MR D > 1 tpa (2 tpa)	200,000.00 x 5% x 1/3 **= 3,333.33 (2,000.00)**	0.05 % x 100,000.00 **= 50.00.**	0.05 % x 90,000.00 **= 45.00**	**3,428.33 (2,095.00)**	**1.71 (1.05)** (34)	**+ 64%**	**+64%**

Case 2 Cost sharing Approach 2: with affiliate rule (cost without affiliate rule in brackets)

- Differentiation of all costs by tonnage bands (factor 10 – according to lowest tonnage in each band)
- Basic fee for admin (equal for all, 10 % of overall costs)

Registrant tonnage band (tonnage)	Administrative Costs (basic fee)	Administrative costs (variable)	Studies/CSR[158]	total	€ per kg (factor highest tonnage lowest tonnage)	Relative change of price	Relative change of price per kg
LR > 1000 tpa (2000 tpa)	200,000.00 x 10% x 1/4 **= 2,500.00 (2,000.00)**	90.01 % x 100,000.00 **= 90010.00 (47,370.00)**	90.01 % x 90,000.00 **= 81,009.00 (42,633.00)**	**173,519.00 (92,003.00)**	**0.06 (0.05 LR; 0.09 MR A)** (1)	**- ~6%**	**- 5%**
MR A > 1000 tpa (1000 tpa)	no cost share, covered by LR	no cost share, covered by LR	no cost share, covered by LR	no cost share, covered by LR	no cost share, covered by LR	**-100 %**	**-100%**
MR B > 100 tpa (200 tpa)	200,000.00 x 10% x 1/4 **= 2,500.00 2,000.00**	9.00 % x 100,000.00 **= 9,000.00 (4,740.00)**	9.00 % x 90,000.00 **= 8,100.00 (4,266.00)**	**19,600.00 (11,006.00)**	**0.10 (0.6)** (1.7)	**+ 78 %**	**+67%**
MR C > 10 tpa (20 tpa)	200,000.00 x 10% x 1/4 **= 2,500.00 2,000.00**	0,90 % x 100,000.00 **= 900.00 (470.00)**	0.90 % x 90,000.00 **= 810.00 (423.00)**	**4,210.00 (2,893.00)**	**0.21 (0.14)** (3.5)	**+ 46%**	**+50%**
MR D > 1 tpa (2 tpa)	200,000.00 x 10% x 1/4 **= 2,500.00 (2,000.00)**	0.09 % x 100,000.00 **= 90.00 (50.00).**	0.09 % x 90,000.00 **= 81.00 (45.00)**	**2,671.00 (2,095.00)**	**1.34 (1.05)** (22.3)	**+27%**	**+ 28%**

[158] note cost for CSR are also assigned to lowest tonnage band

ANNEX C: SME DATA

Member State	Micro	Small	Medium	Large	Total	% EU Chem Sales
Belgium %	69%	20%	8%	3%	100	6.9
Number	1566	443	188	64	2262	
Bulgaria %	74%	19%	6%	1%	100	-
Number	1381	354	114	21	1870	
Czech Rep %	91%	6%	3%	1%	100	1.3
Number	7630	488	232	63	8413	
Denmark	65%	23%	10%	3%	100	-
	494	171	76	23	764	
Germany	65%	22%	10%	3%	100	28.4
Number	8564	2922	1276	375	13137	
Estonia	70%	19%	10%	1%	100	-
Number	196	54	27	4	281	
Ireland	54%	15%	13%	n.a	100	0.9
Number	220	61	53	n.a	n.a	
Greece	91%	7%	1%	0%		-
Number	4313	351	71	8	4743	
Spain	75%	19%	4%	1%	100	7.4
Number	9654	2492	565	90	12801	
France	82%	12%	5%	2%	100	14.9
Number	9700	1398	550	185	1183	
Croatia	84%	13%	3%	1%	100	-
Number	1354	202	52	10	1618	
Italy	80%	17%	3%	1%	100	9.6
	20576	4387	758	135	25856	
Cyprus	n.a	27%	n.a	0%	n.a	-
Number	Na	103	n.a.	0	Na	
Latvia	78%	17%	4%	0%	100	-
Number	469	103	26	3	601	
Lithuania	87%	9%	3%	1%	100	-
Number	1163	126	43	9	1341	
Luxembourg	57%	12%	27%	4%	100	-
Number	29	6	14	2	51	
Hungary	84%	11%	4%	1%		1.1
Number	2253	291	98	25	2667	
Malta	78%	19%	3%	0%	100	-
Number	154	38	5	0	197	
Netherlands	78%	13%	7%	2%	100	9.6

Member State	Micro	Small	Medium	Large	Total	% EU Chem Sales
Number	2117	356	193	65	2731	
Austria	69%	20%	8%	2%	100	2.6
Number	1149	331	141	38	1659	
Poland	83%	11%	5%	1%	100	2.8
Number	8745	1158	486	158	10547	
Portugal	81%	15%	3%	0%	100	0.9
Number	4100	761	161	23	5045	
Romania	74%	19%	5%	2%	100	-
Number	2390	631	159	55	3235	
Slovenia	80%	13%	6%	1%	100	-
Number	604	94	49	8	755	
Slovakia	92%	6%	2%	1%	100	-
Number	2789	172	62	20	3043	
Finland	73%	17%	7%	3%	100	1.5
Number	774	183	74	30	1061	
Sweden	88%	7%	3%	1%	100	1.8
Number	2,583	215	101	39	2,938	
United Kingdom	66%	23%	8%	2%	100	6.8
	4,055	1395	510	139	6,099	

GDP Growth rates

geo\time	2007	2008	2009	2010	2011	2012	2013	2014	2009-2014	2010-2014
EU (28 countries)	3.1	0.5	-4.4	2.1	1.7	-0.5	0.1	1.3	0.1	0.9
Belgium	**3**	**1**	**-2.6**	**2.5**	**1.6**	**0.1**	**0.3**	**1.1**	0.5	1.1
Bulgaria	6.9	5.8	-5	0.7	2	0.5	1.1	1.7	0.2	1.2
Czech Republic	5.5	2.7	-4.8	2.3	2	-0.9	-0.5	2	0.0	1.0
Denmark	0.8	-0.7	-5.1	1.6	1.2	-0.7	-0.5	1.1	-0.4	0.5
Germany	**3.3**	**1.1**	**-5.6**	**4.1**	**3.6**	**0.4**	**0.1**	**1.6**	0.7	2.0
Estonia	7.9	-5.3	-14.7	2.5	8.3	4.7	1.6	2.1	0.8	3.8
Ireland	4.9	-2.6	-6.4	-0.3	2.8	-0.3	0.2	4.8	0.1	1.4
Greece	3.5	-0.4	-4.4	-5.4	-8.9	-6.6	-3.9	0.8	-4.7	-4.8
Spain	**3.8**	**1.1**	**-3.6**	**0**	**-0.6**	**-2.1**	**-1.2**	**1.4**	-1.0	-0.5
France	**2.4**	**0.2**	**-2.9**	**2**	**2.1**	**0.2**	**0.7**	**0.2**	0.4	1.0
Croatia	5.2	2.1	-7.4	-1.7	-0.3	-2.2	-0.9	-0.4	-2.2	-1.1
Italy	**1.5**	**-1**	**-5.5**	**1.7**	**0.6**	**-2.8**	**-1.7**	**-0.4**	-1.4	-0.5
Cyprus	4.9	3.6	-2	1.4	0.3	**-2.4**	**-5.4**	**-2.3**	-1.7	-1.7
Latvia	9.8	-3.2	-14.2	-2.9	5	4.8	4.2	2.4	-0.1	2.7
Lithuania	11.1	2.6	-14.8	1.6	6.1	3.8	3.3	2.9	0.5	3.5
Luxembourg	6.5	0.5	-5.3	5.1	2.6	-0.2	2	:		
Hungary	0.5	0.9	-6.6	0.8	1.8	-1.5	1.5	3.6	-0.1	1.2
Malta	4	3.3	-2.5	3.5	2.1	2.5	2.3	3.5	1.9	2.8
Netherlands	3.7	1.7	-3.8	1.4	1.7	-1.1	-0.5	1	-0.2	0.5
Austria	3.6	1.5	-3.8	1.9	2.8	0.8	0.3	0.4	0.4	1.2
Poland	7.2	3.9	2.6	3.7	4.8	1.8	1.7	3.4	3.0	3.1
Portugal	2.5	0.2	-3	1.9	-1.8	-4	-1.6	0.9	-1.3	-0.9
Romania	6.9	8.5	-7.1	-0.8	1.1	0.6	3.4	2.8	0.0	1.4
Slovenia	6.9	3.3	-7.8	1.2	0.6	-2.6	-1	2.6	-1.2	0.2
Slovakia	10.7	5.4	-5.3	4.8	2.7	1.6	1.4	2.4	1.3	2.6
Finland	5.2	0.7	-8.3	3	2.6	-1.4	-1.1	-0.4	-0.9	0.5
Sweden	3.4	-0.6	-5.2	6	2.7	-0.3	1.3	2.3	1.1	2.4
United Kingdom	**2.6**	**-0.3**	**-4.3**	**1.9**	**1.6**	**0.7**	**1.7**	**3**	0.8	1.8

:=not available p=provisional
e=estimated
Source of Data: Eurostat.
Date of extraction: 13/07/2015

ANNEX D: MONTE CARLO SIMULATION DATA

Key data, estimates and rules applied in the model			
	Substances registered 1-10t only	Substances registered at 10-100t only	Notes (where relevant)
Number of substances registered in each tonnage band	20,000	5,000	Applied in the Extended Impact Assessment
Availability of (test) information	17% of substances have information on all Annex VII endpoints; 13% have test information on skin/eye corrosion and irritation and acute toxicity (oral); and 70% have no test information	17% of substances have information on all Annex VII endpoints and also of these: • 30% also have Annex VIII 8.5.3. Acute toxicity - Toxicity via Dermal routes • 5% also have Annex VIII 8.5.2. Acute toxicity - Toxicity via Inhalation • 5% also have Annex VIII 8.6.1. Repeat dose toxicity - Short term (1 route only) • 30% also have Annex VIII 9.1.3. Aquatic Toxicity - Fish – short-term 13% have test information on all Annex VII endpoints 70% have no test information	Drawn from the 2001 ECB assumptions on the percentage of substances with a complete data set and altered to reflect availability of additional information
Number of substances requiring data from Annexes	40% require full Annex VII Information by the application of Article 12 and Annex III; 60% require information on physico-chemical information in Annex VII only by the application of Article 12 and Annex III.	100% require Annex VII and VIII information	Modelled from classification of substances on CLI combined with availability of data and applicability of screening QSARs and Read Across (RA) and assuming 40% of substances have a dispersive/diffuse use as per the Commission's assessments in 2003 and 2006 (see 1-10t report)

Key data, estimates and rules applied in the model			
	Substances registered 1-10t only	Substances registered at 10-100t only	Notes (where relevant)
Cost of screening QSARs for Article 12 and Annex III	€1,500 per substance for which there is not existing test information on all Annex VII endpoints (83%) and for which there is not already QSAR information (assumed to be 60% of these – 50% overall)	N/A	Based on discussions with laboratories providing QSAR information but equally could apply to in-house assessments using QSAR software (which might be expected to take around 1.5 days at €1,500 per day).
Percentage of substances requiring further mutagenicity testing after screening tests in Annex VII (and VIII for10-100t substances)	52% of mutagens and 28% of non-mutagens test true or false positive in the single battery mutagenicity test.	97% of mutagens and 90% of non-mutagens test true or false positive in the battery of three mutagenicity tests (a positive result in any triggers further mutagenicity testing)	Based on application of sensitivity and specificity data for the GMBact test (alone in the case of 1-10t substances) and GMvitro and MNT/Cabvitro (the three screening tests required for 10-100t substances) – see UK Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM) *Guidance on a Strategy for Genotoxicity Testing of Chemical Substances*[159].

[159] the UK Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM) (2011) Guidance on a Strategy for Genotoxicity Testing Of Chemical Substances. http://www.iacom.org.uk/guidstate/documents/COMGuidanceFINAL.pdf

<table>
<tr><th colspan="4">Key data, estimates and rules applied in the model</th></tr>
<tr><td></td><td>Substances registered 1-10t only</td><td>Substances registered at 10-100t only</td><td>Notes (where relevant)</td></tr>
<tr><td>Cost of testing and producing study summaries or robust study summaries</td><td colspan="2">See separate Table</td><td>Testing costs based on 2012 CEFIC testing catalogue. Study summary costs are estimated.</td></tr>
<tr><td>Number of M/Is per substance</td><td>2.3 M/Is per substance distributed as follows:
<table><tr><th></th><th>Expected percentage of substance registrations</th></tr><tr><td>Only one M/I</td><td>60%</td></tr><tr><td>2-3 M/Is</td><td>25%</td></tr><tr><td>4-6 M/Is</td><td>8%</td></tr><tr><td>6-10 M/Is</td><td>5%</td></tr><tr><td>>10 M/Is</td><td>2%</td></tr></table></td><td>3.4 M/Is per substance registering at 10-100t only and distributed as follows:
<table><tr><th></th><th>Expected percentage of substance registrations</th></tr><tr><td>Only one M/I</td><td>20%</td></tr><tr><td>2-3 M/Is</td><td>50%</td></tr><tr><td>4-6 M/Is</td><td>20%</td></tr><tr><td>6-10 M/Is</td><td>7%</td></tr><tr><td>>10 M/Is</td><td>3%</td></tr></table></td><td rowspan="2">Based on a comparison of ECHA data on average number of registrants for 2010 and 2013 registration with data in the ExIA and Eurostat data on companies.</td></tr>
<tr><td>Numbers of M/Is registering and average size of portfolios</td><td>Average portfolio size is derived by adjusting estimates so that the average M/IS per substance also equals 2.3 as follows:
<table><tr><th></th><th>Number of M/Is Registering</th><th>Average size of Portfolios</th></tr><tr><td>Micro</td><td>8,600</td><td>2.9</td></tr><tr><td>Small</td><td>2,500</td><td>3.5</td></tr><tr><td>Medium</td><td>1,100</td><td>5.6</td></tr><tr><td>Large</td><td>400</td><td>16</td></tr></table></td><td>Average portfolio size is derived by adjusting estimates so that the average M/IS per substance registering at 10-100t only also equals 3.4 as follows:
<table><tr><th></th><th>Number of M/Is Registering</th><th>Average size of Portfolios</th></tr><tr><td>Micro</td><td>4,300</td><td>1.2</td></tr><tr><td>Small</td><td>1,500</td><td>1.5</td></tr><tr><td>Medium</td><td>800</td><td>2</td></tr><tr><td>Large</td><td>1,100</td><td>7.3</td></tr></table></td></tr>
<tr><td>10-100t substances also registered at 1-10t</td><td colspan="2">15% of 10-100t substances will also be registered at 1-10t and the number of registrants at 1-10t is equal to 40-60% of number of M/Is registering the substance at 10-100t.</td><td>Based analysis of ECHA data on registrations in 2010 and 2013.</td></tr>
<tr><td>Cost of producing a full registration dossier for an individual</td><td><table><tr><th></th><th>Lower bound</th><th>Upper Bound</th></tr><tr><td>Micro</td><td>€ 2,200</td><td>€ 3,200</td></tr><tr><td>Small</td><td>€ 2,000</td><td>€ 3,000</td></tr></table></td><td><table><tr><th></th><th>Lower bound</th><th>Upper Bound</th></tr><tr><td>Micro</td><td>€ 8,000</td><td>€ 10,000</td></tr></table></td><td>Estimation informed by the results of the cost components calculated for Registration 2013 and</td></tr>
</table>

<table>
<tr><th colspan="5">Key data, estimates and rules applied in the model</th></tr>
<tr><th></th><th colspan="2">Substances registered 1-10t only</th><th colspan="2">Substances registered at 10-100t only</th><th>Notes (where relevant)</th></tr>
<tr><td>registration</td><td colspan="2"><table><tr><td>Medium</td><td>€ 2,000</td><td>€ 2,800</td></tr><tr><td>Large</td><td>€ 1,500</td><td>€ 2,000</td></tr></table></td><td colspan="2"><table><tr><td>Small</td><td>€ 7,200</td><td>€ 9,300</td></tr><tr><td>Medium</td><td>€ 7,200</td><td>€ 8,800</td></tr><tr><td>Large</td><td>€ 7,000</td><td>€ 8,000</td></tr></table></td><td>values used in previous assessments including the revised BIA/ExIA.</td></tr>
<tr><td>Cost of producing a full registration dossier for a joint</td><td colspan="2"><table><tr><td></td><td>Lower bound</td><td>Upper Bound</td></tr><tr><td>All members are micro enterprises</td><td>€ 2,800</td><td>€ 3,800</td></tr><tr><td>Small is the largest member (no medium or large M/Is)</td><td>€ 2,500</td><td>€ 3,500</td></tr><tr><td>Medium is the largest member (no large M/Is)</td><td>€ 2,500</td><td>€ 3,300</td></tr><tr><td>Large</td><td>€ 2,000</td><td>€ 2,500</td></tr></table></td><td colspan="2"><table><tr><td></td><td>Lower bound</td><td>Upper Bound</td></tr><tr><td>All members are micro enterprises</td><td>€ 11,000</td><td>€ 15,000</td></tr><tr><td>Small is the largest member (no medium or large M/Is)</td><td>€ 9,821</td><td>€ 13,816</td></tr><tr><td>Medium is the largest member (no large M/Is)</td><td>€ 9,821</td><td>€ 13,026</td></tr><tr><td>Large</td><td>€ 9,000</td><td>€ 12,500</td></tr></table></td><td>Estimation informed by the results of the cost components calculated for Registration 2013 and values used in previous assessments including the revised BIA/ExIA.</td></tr>
<tr><td>Cost of producing a registration dossier containing physico-chemical information only (for 1-10t substances only)</td><td colspan="2">90-95% of the equivalent cost for a full registration</td><td colspan="2">N/A</td><td>Estimation informed by values used in previous assessments including the revised BIA/ExIA.</td></tr>
<tr><td>Joint registration and SIEF administration costs</td><td colspan="2">Cost of engaging on information (applies to each registrant) = € 1,000 per M/I registering.
Cost of engaging on dossier preparation (applies to each registrant in a consortium) = € 750 per M/I jointly registering.
For registrations that only include only physico-chemical information, costs are 80-90% of the above.</td><td colspan="2">Cost of engaging on information (applies to each registrant) = € 2,000 per M/I registering.
Cost of engaging on dossier preparation (applies to each registrant in a consortium) = € 3,000 per M/I jointly registering.</td><td>Estimation informed by the results of the cost components calculated for Registration 2013.</td></tr>
<tr><td>Costs of revising Substance Safety Data Sheets</td><td colspan="2">€500 per substance</td><td colspan="2">Incorporated into cost of producing CSA/CSR (see costs below)</td><td>Estimation informed by the results of the cost components calculated for</td></tr>
</table>

<table>
<tr><th colspan="4">Key data, estimates and rules applied in the model</th></tr>
<tr><th></th><th>Substances registered 1-10t only</th><th>Substances registered at 10-100t only</th><th>Notes (where relevant)</th></tr>
<tr><td>(SDSs)/producing eSDS</td><td></td><td></td><td>Registration 2013.</td></tr>
<tr><td>Cost of Producing CSA/CSR</td><td>N/A</td><td>
<table>
<tr><th>CSA element</th><th>Lower bound</th><th>Upper Bound</th></tr>
<tr><td>Physico-chemical, environmental and human health hazard assessment</td><td>€3000</td><td>€6000</td></tr>
<tr><td>Cost of PBT/vPvB screening</td><td colspan="2">€750</td></tr>
<tr><td>Cost of exposure assessment and risk characterisation (when required)*</td><td>€4000</td><td>€7000</td></tr>
<tr><td>Cost of further testing for PBT/vPvB Assessment and write up**</td><td colspan="2">€21,000</td></tr>
<tr><td colspan="3">* only required for dangerous substances – assumed to be 40% as per EIA – see below
** only required where PBT/vPvB screening suggests may meet criteria – see below</td></tr>
</table>
</td><td></td></tr>
<tr><td>Dangerous 10-100t substances</td><td>N/A</td><td>As per the EIA, 40% of substances are estimated to have dangerous properties that will require exposure assessment and risk characterization in</td><td>As per the ExIA.</td></tr>
</table>

Key data, estimates and rules applied in the model			
	Substances registered 1-10t only	Substances registered at 10-100t only	Notes (where relevant)
		addition to hazard assessment and PBT/vPvB screening.	
Potential PBT/vPvB substances identified by screening that would require full PBT/vPvB assessment	N/A	Screening identifies 2% of substances as potentially meeting PBT and, by inference (using probabilities) 5% potentially meet vPvB. These substances would be subjected to PBT/vPvB assessment requiring the generation of additional information.	The work of Strempel *et al* (2012)[160] and others suggests that 2% of substances would be identified as potential PBTs/vPvBs by screening.
Cost of proposals for animal tests	€500 per proposal per substance	€500 per proposal per substance	Estimation informed by values used in previous assessments including the revised BIA/ExIA.
Information and cost sharing	For substances for which information on all current Annex VII endpoints already exists the lead registrant (or only registrant in the case of substances where there is only one M/I) owns that information and this M/I is a large enterprise. For substances for which information on some Annex VII endpoints already exists the first registrant (or only registrant in the case of substances where there is only one M/I) owns that information and there is a 75% chance that this M/I is a large enterprise and a 25% chance that it of medium size. Testing and information costs, SIEF administration, study summaries and SDS and, for 10-100t registrations, CSA costs, are shared equally between registrants according to quantities manufactured/imported by each. Where there is existing test information, the cost of access to this information is shared between all but the first registrant (who, as noted above, is assumed to own the information and receives payment from the others equal to the cost of that information according to the 2012 CEFIC test cost catalogue). Where the registration is for a 1-10t substance also registered at 10-100t, registrants in the lower		

[160] Strempel et al (2012): *Screening for PBT Chemicals among the "Existing" and "New" Chemicals of the EU*, Environ. Sci. Technol. 2012, 46, 5680−5687.

Key data, estimates and rules applied in the model			
	Substances registered 1-10t only	Substances registered at 10-100t only	Notes (where relevant)
	tonnage band share only the costs for Annex VII information but the administrative costs of consortium and information sharing are applied at the rate appropriate to 10-100t substances. The additional cost of the Annex VIII information and also CSA costs is shared only between registrants at 10-100t.		
Joint submissions	Registration dossier submission costs are shared between the members of the consortium only and where there are also individual registrations, the appropriate individual registration cost applies to each individual registrant for the relevant tonnage band for which the registration is being submitted.		
Fees	As established under Commission Regulation[161]. Under Article 74(2) of REACH these fees do not apply when full toxicological and ecotoxicological data from Annex VII are provided.	As established under Commission Regulation.	

[161] Regulation No 340/2008 of 16 April 2008, as amended by the Commission Implementing Regulation (EU) No 254/2013 of 20 March 2013.

Costs of test information and presentation in (robust) study summaries			
	Cost of information	**Study summaries/presentation of information in Dossier (1-10t)**	**Robust Study summaries/presentation of information in Dossier (10-100t)**
Cost of QSARs for Annex III	€ 1,500	€ 500	N/A
Annex VII 8.1. Skin irritation/ corrosion - In vitro skin corrosion/irritation	€ 2,580	€ 100	€ 150
Annex VII 8.2. Eye irritation - In vitro eye irritation	€ 1,552	€ 100	€ 150
Annex VII 8.3. Skin sensitisation - In vivo LLNA	€ 7,117	€ 100	€ 150
Annex VII 8.4.1 GMbact: gene mutation test in bacteria (Ames test)	€ 3,465	€ 250	€ 300
Annex VIII 8.4.2 CAbvitro, in vitro chromosome aberration test	€ 20,080	€ 250	€ 300
Annex VIII 8.4.2 MNTvitro, in vitro micronucleus test	€ 16,518	€ 250	€ 300
Annex VIII 8.4.3 GMvitro:gene mutation assay in mammalian cells	€ 17,615	€ 250	€ 300
Annex IX 8.4.4 Cytvivo:cytogenetic assay in experimental animals	€ 27,730	€ 500	€ 600
Annex VIII 8.4.3 GMvivo:gene mutation assay in experimental animals - Mouse micronucleus assay	€ 12,620	€ 500	€ 600
Annex VII 8.5. Acute toxicity - Oral toxicity	€ 1,486	€ 100	€ 150
Annex VIII 8.5.2. Acute toxicity - Toxicity via Inhalation	€ 12,267	N/A	€ 300
Annex VIII 8.5.3. Acute toxicity - Toxicity via Dermal routes	€ 2,486	N/A	€ 300
Annex VIII 8.6.1. Repeat dose toxicity - Short term (1 route only)	€ 52,925	€ 250	€ 300
Annex VII 9.1.1. Aquatic Toxicity - Invertebrate - short-term	€ 5,232	€ 100	€ 150
Annex VII 9.1.2. Aquatic Toxicity - Algal - short-term	€ 5,806	€ 100	€ 150
Annex VIII 9.1.3. Aquatic Toxicity - Fish – short-term	€ 4,845	€ 100	€ 150
Annex VII 9.2.1.1. Degradation - Biotic - Ready biodeg	€ 3,705	€ 100	€ 150
Annex VIII 8.1.1 *In vivo* skin irritation	€ 1,535	N/A	€ 150
Annex VIII 8.2.1 *In vivo* eye irritation	€ 1,460	N/A	€ 150

Costs of test information and presentation in (robust) study summaries			
	Cost of information	**Study summaries/presentation of information in Dossier (1-10t)**	**Robust Study summaries/presentation of information in Dossier (10-100t)**
Annex VIII 8.7.1.Screening for reproductive/ developmental toxicity, one species (OECD 421 or 422)	€ 97,120	N/A	€ 600
Annex VIII 9.1.4 Activated sludge respiration inhibition	€ 3,651	€ 100	€ 150
Annex VIII 9.2.2 Abiotic degradation 9.2.2.1. Hydrolysis as a function of pH	€ 13,055	€ 100	€ 100
Annex VIII 8.8.1 Assessment of toxicokinetic behaviour	€ 1,278	€ 0	€ 0
Annex VIII 9.3.1. Adsorption/desorption screening	€ 3,189	€ 100	€ 100

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