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POLICY DEPARTMENT A: ECONOMIC AND SCIENTIFIC POLICY
INDUSTRY, RESEARCH AND ENERGY

The Consequences of REACH for SMEs

NOTE

Abstract

This note examines the consequences of REACH legislation for Small and Medium-Sized Enterprises (SMEs) since its entry into force in June 2007. It looks at impacts on the internal organisation of firms (including human resources), on strategy and on business activities. We also assess the experience of SMEs with available support and the perceived added value of REACH for SMEs. Our findings are based on a review of the literature and a set of interviews to a sample of firms.

CONTENTS

CONTENTS	3
LIST OF ABBREVIATIONS	4
LIST OF TABLES	6
LIST OF FIGURES	7
EXECUTIVE SUMMARY	8
1. INTRODUCTION	9
2. WHY THIS REPORT: THE IMPACT OF REACH ON SMES IS A GENUINE CONCERN	10
3. IMPACT ON THE INTERNAL ORGANISATION OF SMES	13
4. IMPACT ON BUSINESS ACTIVITY	15
4.1 Impact on internal processes and costs (not linked to own human resources).	16
4.2 Future structure of the market	20
4.3 The Substance Information Exchange Fora (SIEF) experience for SMEs	24
5. THE SME EXPERIENCE WITH AVAILABLE SUPPORT	27
6. THE ADDED VALUE OF REACH FOR SMES	30
7. CONCLUDING REMARKS	33
REFERENCES	36
ANNEX 1	38
ANNEX 2	39
ANNEX 3	42

LIST OF ABBREVIATIONS

ACEA	European Automobile Manufacturers' Association
BOM	Bill of Materials
CBI	Confidential Business Information
CEFIC	European Chemical Industry Council
CEPS	Centre for European Policy Studies
CHESAR	Chemical Safety Assessment and Reporting tool
CSES	Centre for Strategy & Evaluation Services
ECHA	European Chemicals Agency
EEA	European Economic Area
ESDS	Extended Safety Data Sheet
ETUC	European Trade Union Confederation
EU	European Union
FTE	Full-Time Equivalent
DG	Directorate General
ITRE	Committee on Industry, Research and Energy of the European Parliament
IUCLID	International Uniform Chemical Information Database
LoA	Letter of Access
NGO	Non-Governmental Organisation
PPORD	Product and Process Orientated Research and Development
R&D	Research and Development
REACH	Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals
SDS	Safety Data Sheet
SIEF	Substance Information Exchange Forum

SIN	Substitute It Now
SME	Small and Medium-Sized Enterprise
SVHC	Substance of Very High Concern
UEAPME	European Association of Craft, Small and Medium-Sized Enterprises

LIST OF TABLES

TABLE 1		
	Estimated testing costs per tonne of an average substance (in EUR)	15
TABLE 2		
	Number of helpdesk questions received annually by ECHA according to company size	28
TABLE 3		
	Comparison of cost estimations for CSES study and Commission estimates -1st registration period	33
TABLE 4		
	List of interviewees	38
TABLE 5		
	How to become and remain a REACH-compliant SME	39
TABLE 6		
	Additional processes	41

LIST OF FIGURES

FIGURE 1

Responses of firms to the increase of costs resulting from the REACH regulation (Percentage of responding firms indicating that they absorbed the costs or increase the price of their products/services frequently or always) **22**

FIGURE 2

Have you increased the price of your products in order to incorporate costs related to REACH? (Percentage of respondent indicating) **23**

FIGURE 3

Evolution of Volume of EU27 imports and exports in the chemicals sector in comparison to total level of trade (2001=100) Evolution of Volume of EU27 imports and exports in the chemicals sector in comparison to total level of trade (2001=100) **24**

EXECUTIVE SUMMARY

Background

The Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) is a very demanding system for any business either large or small. At the first registration deadline of 2010, only 13% of the registrations submitted were done by companies fulfilling the Small and Medium-Sized Enterprises (SME) definition. Hence, to date most experience with REACH was built up within larger companies. It is suspected that the 2013 and especially the 2018 registration waves may well be different: more chemicals may be involved with incomplete knowledge or even largely unknown properties; also, far more SMEs will be registering substances.

Aim

This note examines the impact that REACH legislation has had and will continue to have on SMEs since its entry into force in June 2007. Our findings are based on a review of existing reports and literature covering the experiences of SMEs, as well as on a set of semi-structured interviews to a sample of SMEs in the chemical sector. In particular, this report discusses four aspects: 1) the impact of REACH on the internal organisation of SMEs and the potential consequences for the overall functioning of a company insofar as REACH compliance is concerned; 2) the impact on business activity; 3) the support available to SMEs to better cope with REACH and the views or perceptions of (interviewed) SMEs; and 4) the value-added of REACH for SMEs nearly six years after the entry into force of the legislation. We conclude with some suggestions.

KEY FINDINGS

- REACH is widely regarded as expensive by SMEs.
- The overall (direct) cost estimates of REACH specified in the 29 October 2003 Impact Assessment turned out to be an underestimate by nearly one half. By 2012 the difference added up to around EUR 1 billion; by 2018 this might have gone up to EUR 1.5 billion or possibly much more.
- REACH might well lead to changes in market structure. Withdrawals of some chemicals may have consequences in this respect, but the complaints are also about price increases and about the risk of losing market share vis-a-vis non-EU producers.
- While the reduction of registration fees of March 2013 for SMEs is a welcome step, it is also perceived as a symbolic gesture by many companies, as fees are only a minuscule fraction of overall compliance costs.
- The perceived added value of REACH for SMEs, so far, is very limited. Many SMEs discern none up to now. Some acknowledge that knowledge is increasing and that this might be used later. It remains to be seen how the overall SME-landscape in the chemical sector will look like after the third final deadline for registration in 2018.

1. INTRODUCTION

This note on the consequences of the Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals¹ (hereinafter, REACH) aims at assessing the impact that REACH legislation has had and will continue to have on Small and Medium-Sized Enterprises (SMEs) since its entry into force in June 2007. Our findings are based on a review of existing reports and literature covering the experiences of SMEs, as well as on a set of semi-structured interviews to a sample of SMEs in the chemical sector.²

Chapter 2 sets the scene in explaining why the impact of REACH on SMEs has proven to be a genuine concern. The report will subsequently discuss four aspects. Chapter 3 deals with the impact of REACH on the internal organisation of SMEs and the potential consequences for the overall functioning of a company insofar as REACH compliance is concerned. Chapter 4 discusses the impact on business activity. This section will demonstrate a number of practical problems or costs of REACH for SMEs, which may affect business activity.³ Chapter 5 analyses the support available to SMEs to better cope with REACH and the views or perceptions of (interviewed) SMEs.⁴ Chapter 6 comprises a search for the value-added of REACH for SMEs nearly six years after the entry into force of the legislation.⁵ Chapter 7 concludes. Annex I describes our approach to interviews and provides an anonymized list of interviewees (Tables 1); Annex II contains a step-by-step exposition of all the costs that a hypothetical SME has to incur to become and remain REACH-compliant (Tables 5 and 6). Finally, Annex III contains the questionnaire that was used as a basis for the interviews.

¹ European Parliament and Council Regulation (EC) No 1907/2006 (Corrigendum 29 May 2007).

² It should be noted that the timeframe for this report was four weeks, which provided very little time to approach SMEs and get their cooperation, structure the interviews (with a detailed questionnaire as a guidance), conduct the interviews and summarize them in a structured way. For further details, see below.

³ Unfortunately, the literature has not yet reached a sufficient degree of detail to enable a differentiation by subsectors

⁴ Only a few interviews could be held in such a short time-span and, despite our efforts to approach SMEs in different countries and activities, our sample cannot be considered "representative". The interviews serve more as a reality check. List of interviewees in Annex I.

⁵ It should be realized that it is rather early to make such an assessment because in 2010 only 13 % of the registrations came from SMEs. The bulk of SME registrations is expected in 2018. SWD(2013)25 of 5 February 2013, General report on REACH, accompanying COM (2013) 49, page 26.

2. WHY THIS REPORT: THE IMPACT OF REACH ON SMES IS A GENUINE CONCERN

REACH is a very demanding system for any business either large or small. It is expected that larger companies will have more resources available in comparison to small ones. At the first registration deadline of 2010, only 13% of the registrations submitted were done by companies fulfilling the SME definition. Hence, to date most experience with REACH was built up within larger companies. The substances registered by the 2010 deadline included many where the 'information gap' was minimal. It is suspected that the 2013 and especially the 2018 registration waves may well be different: more chemicals may be involved with incomplete knowledge or even largely unknown properties; also, far more SMEs will be registering substances.⁶ In 2010, the Danish report 'SMEs and the environment in the European Union'⁷ indicated the following: *"The level of information and specific knowledge among SMEs about environmental legislation in general is low and lacking. Few SMEs consider REACH a main issue that is related to their activities. This can be explained by information asymmetry provided by national competent authorities, but also due to lack of capacity in SMEs, which means that they seldom have an overview of sources of support (legal, technical) and how these can be used strategically. There is a lack of support for companies to implement the changes imposed by existing or new environmental legislation. Therefore, many SMEs are incurring extra costs to hire external environmental consultants and experts"*.

Although it has meanwhile become clear that awareness and knowledge of SMEs on the regulation have improved since 2010 – a finding supported by the results of our interviews as well -, at the same time, concerns about the ability of SMEs to comply with REACH increased in parallel. A recent Commission consultation on a top-ten list of most burdensome pieces of EU legislation found that SMEs consider REACH the no.1 of this list.⁸ Also the Stoiber High level Group on Administrative burdens⁹ has drawn attention to REACH as burdensome.

There are two principal reasons why there is genuine concern for SMEs when having to comply with REACH:

- 1) The first is related to an uneven share of the costs. There is a range of non-trivial aspects to REACH which may cause SMEs to be relatively disadvantaged (compared to bigger or very large firms), now and possibly even more so in future, particularly as they tend to deal with lower volumes of chemicals than bigger firms.

⁶ On this point see also the recent presentation from the European Chemicals Agency's "SME Ambassador" at: http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/docs/events/rev-tws-herdina_en.pdf.

⁷ Danish Technological Institute and PLANET S.A (2010):10.

⁸ See Commission Memo/13/168 of 7 March 2013 ; and Results of the public consultation on the TOP10 most burdensome legislative acts for SMEs, see: http://ec.europa.eu/enterprise/policies/sme/files/top10report-final_en.pdf

⁹ For further details on the mandate and composition of the Group, see: http://ec.europa.eu/dgs/secretariat_general/admin_burden/ind_stakeholders/ind_stakeholders_en.htm. For recent (i.e., January 2013) HLG debates on REACH, see: http://ec.europa.eu/dgs/secretariat_general/admin_burden/docs/130307_minutes_hlg_ab_20130131_en.pdf

This fear is not new at all. Indeed, the European Parliament has successfully insisted on mitigating measures right from the start, for example in differentiating the fees structure, making it less disadvantageous to SMEs.¹⁰

- 2) Second, SMEs and downstream users in the chemical industry represent a large number of activities ranging from manufacturing, formulating to producing and selling 'articles'. Some 27 500 companies in EU chemistry are SMEs (96% of all firms) and although impact of REACH on their activities may differ significantly, the relative disadvantages multiply over a large set of enterprises representing a huge total turnover and many workers.

In 2009, SMEs accounted for 28 % of EU sales and 35 % of all jobs in the chemical sector. In the EU more generally, SMEs tend to be important engines for job creation: some 85 % of all new jobs in the EU generated between 2002 and 2010 were created by SMEs, with a relatively stronger contribution by young SMEs.¹¹ Although these labour market data are not chemistry-specific, there is no obvious reason why they would not apply, approximately, to this large and so far successful EU sector as well.

The dynamism of young SMEs generates yet another concern about the impact of REACH, although it takes more the form of a forewarning than – at this moment in time – hard empirical evidence. Young SMEs are driven by entrepreneurialism, something that the EU economy not only badly needs but is often held to be in short supply (at least, compared to the US, for example).¹² The heavier the absolute efforts and costs of REACH, the greater the risk that young entrepreneurs are discouraged and forego market entry. This may lead to impairment of innovation, less green chemistry and less attention to new fields like nano-technology, areas where young chemical SMEs are expected to find niches that are not yet filled by their big competitors. Since decisions of (would-be) entrepreneurs not to enter are almost impossible to measure properly, the forewarning can unfortunately only be underpinned with anecdotal interview evidence and the like.

Concerns about the impact of REACH on SMEs will be documented in this briefing paper to the ITRE Committee in considerable detail and in accordance with the Terms of Reference. However, we would like to emphasize a major caveat when focusing solely on the concerns or costs when discussing REACH. There is the general axioma of 'better regulation' that the attention ought to go first and foremost to the benefits of REACH or any other EU regulation. If there are few or no or very uncertain benefits, why regulate in the first place?

¹⁰ See for instance Council of the European Union, 14228/05 JCD/Isd of November 25, 2005 and the debate surrounding amendment 379, available at: <http://register.consilium.europa.eu/pdf/en/05/st14/st14228.en05.pdf>

¹¹ All data mentioned in this paragraph are from the Single Market, Competitiveness and Innovation section of the Commission background report on REACH. SWD(2013)25 of 5 February 2013, General report on REACH, accompanying COM (2013) 49 of the same date.

¹² See also the important contribution by Veugelers & Cincera (2010) on young and innovative SMEs (called 'yollies') and their role in stimulating economic growth in the EU.

And by implication, if a regulation is very imposing – and that is certainly the case for REACH - the societal benefits for the EU, which may justify the burden on business, should clearly be outweighing both one-off fixed costs (e.g. consultancy costs to prepare registration dossiers) of the regulation as well as variable costs over time (e.g. cost of additional testing of substances, costs for responding to request for additional information from public authorities¹³). Moreover, and as will be explained below, several costs tend to become recurrent over the long term, for instance when submitted dossiers need to be updated e.g. due to changes in the tonnage band or availability of new information on use. In the case of REACH, precisely the identification and the (very rough) magnitude of benefits have been a major problem from the start.¹⁴ Recently, more efforts have been undertaken to appreciate the long-run benefits of this piece of legislation.¹⁵ However, the 2013 REACH Review still speaks about benefits in only ten to twenty years and acknowledges that the short-run benefits do not seem to match the short-run costs for business. This constellation exacerbates the skepticism in business circles, not least among SMEs.

¹³ On this point, see UEAPME's contribution to the "Technical Workshop on the follow-up to the Review of REACH" organised by the European Commission on 27 June 2013, at:

http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/docs/events/rev-tws-susnik_en.pdf

¹⁴ The Commission Impact Assessment of 29 October 2003 has less than half a page on benefits (in a 30 pages document) and only at the end(!) as an afterthought, based on a very simple back-of-the-envelope calculation and with assumptions lacking any substantiation from prior EU research (the reports commissioned at the time were all on technical issues or costs). Moreover, in a single line the text acknowledges that no benefits are known in the environmental area (only in public health), although the Environment Commissioner was co-proposing the draft Regulation.

¹⁵ Following the 2007 baseline report of EUROSTAT, an update was published in 2012 as an Eurostat Methodologies and Working paper (see Oekopol, Ineris et al, 2012) on the quality of data and the risk reduction; and a report on health and environmental benefits by RPA, Oekopol and DHI, 2012.

3. IMPACT ON THE INTERNAL ORGANISATION OF SMES

As far as the authors know, there have been only two systematic attempts to document the intra-firm responses of SMEs to the challenges of REACH.¹⁶ The first report addresses REACH obligations in general and will be used for the present section, whereas the second one deals with innovation (see next section). The official 'REACH Review from the European Commission of 5 February 2013'¹⁷ leans heavily on these two reports and contains no information (on this question) additional to these reports.¹⁸

CSES (2012a) finds that 35% of small and micro firms created a dedicated REACH-unit, in contrast to 63% of surveyed large firms. The report also specifies that companies have allocated 1 to 5 full time equivalents (FTE)¹⁹ to REACH compliance, but smaller companies allocate less than 1 FTE, with the relevant person having also other responsibilities for health and safety within the company. Costs or resources for REACH compliance are mostly linked to registration activities, as pre-registration was reportedly rather quick and not so demanding in terms of extra staff and additional costs. Overall, in monetary terms, CSES estimates that additional human resources costs range from EUR 25 000 to EUR 50 000 for a small firm. Most SMEs use consultants, and CSES suggests a strong replacement (of using internal staff) effect due to outsourcing. We come back to this point below. The CSES study²⁰ does not provide specific figures on consultants' fees but finds that the costs of consultants correspond to some 10% of registration costs, at times more like 10% - 25%.

In terms of job creation, CSES reports some informal evidence indicating that new positions have been created in 'technical and legal consulting services'.²¹ Another source of new jobs comes from the establishment of 'Only Representatives', although many of them "*were already active in... the chemicals industry*".²²

¹⁶ Centre for Strategy & Evaluation Services (CSES), "Interim Evaluation: Functioning of the European chemical market after the introduction of REACH", 30 March 2012 (hereinafter, CSES 2012a); and "Study on the impact of REACH Regulation on the innovativeness of the EU chemical industry", 14 June 2012 (hereinafter, CSES 2012b).

¹⁷ Commission Staff Working Document accompanying the General Report on REACH. Report from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions in accordance with article 117(4) REACH and article 46(2) CLP, and a Review of Certain Elements of REACH in line with articles 75(2), 138(3) and 138(6) of reach. SWD(2013)25, of 5 February 2013.

¹⁸ Some additional data on the experience of SMEs were presented during the "Technical Workshop on the follow-up to the Review of REACH" organised by the European Commission on 27 June 2013, Brussels. Further details available at:

http://ec.europa.eu/enterprise/sectors/chemicals/reach/events/index_en.htm.

See for instance UEAPME's presentation at:

http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/docs/events/rev-tws-susnik_en.pdf,

and CEFIC's presentation at:

http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/docs/events/rev-tws-annys_en.pdf

¹⁹ A Full-Time Equivalent of 1.0 indicates that the person is equivalent to a full-time worker, 0.5 FTE indicates half-time work.

²⁰ CSES (2012a), p. 40.

²¹ CSES (2012a), p. 71.

²² CSES (2012a), p. 72.

Finally, REACH-related 'regulatory jobs' are presented as a potential long-term opportunity for graduates. The European Trade Union Confederation (ETUC)²³ is reportedly not concerned about job losses and sees REACH as a good means to maintain quality jobs for skilled and highly skilled labour in the EU, which is also reflected by the many universities that offer REACH related education²⁴.

It is, however, a misunderstanding that the total amount of resources (both human and financial) necessary to achieve REACH compliance is inversely related to the size of a company. The number of substances (dossiers) and the number of products produced, imported or formulated determine the size of tasks foreseen to a large extent. This leads to an imbalance between the efforts of large companies versus SMEs, as is also reflected by the number of registrations expected to be made by SMEs (82% of the pre-registering companies were SMEs.²⁵ Therefore it may be expected that the impact on the internal organisation for SMEs is substantial.²⁶

Yet, from the interviews it was found that, so far, the internal organisation of many SMEs seems not to have changed significantly with the implementation of REACH. The feedback we gathered seems to confirm that between 0.5 and 1 full-time equivalent is *de facto* dedicated to REACH, as far as the registration deadlines of 2010 and 2013 are concerned. When probed about possible changes in view of the 2018 deadline, when several interviewees plan to undertake most of the registration efforts, no significant changes in human resources were foreseen. Overall, interviewees reported that REACH compliance has essentially resulted in an internal re-allocation of tasks to certain members of staff. However, some firms have hired a dedicated person, most often in the position of 'regulatory manager'. In general, REACH was not seen as a driver for job creation among SMEs. As regards job losses, most of our interviewees indicated that conclusions can only be drawn after 2018, with some fearing a non-trivial fall-out for SMEs.

As mentioned, a trend that has clearly emerged from the interviews is the widespread (and often unavoidable) use of external consultants.²⁷ Consultants can either be employed in lieu of internal staff to take care of the entire registration process for their client, or as a complement to own human resources, to ensure e.g., the legal or scientific soundness of the reports prepared by the SME. These two roles may have different consequences for the company, particularly as regards learning and the development of in-house REACH know-how. After all, REACH compliance does not end with registration, but requires sustained attention over time.²⁸ A representative from Belgian sectoral association VLARIP-Essenscia²⁹ explained that *"the smaller the company, the higher the tendency to look for external help"*.

²³ www.etuc.org

²⁴ See http://echa.europa.eu/documents/10162/13602/universities_with_reach_courses_en.pdf

²⁵ COM(2013) 25.

²⁶ See also the presentation of SME-Case 2 at the "Technical Workshop on the follow-up to the Review of REACH" organised by the European Commission on 27 June 2013, at:

http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/docs/events/rev-tws-vanloon_en.pdf

²⁷ One of the interviewees rather colourfully described REACH as "a bonanza for consultants".

²⁸ For further details on this point, see Annex I, Tables 1 and 2.

²⁹ <http://www.essenscia.be>

4. IMPACT ON BUSINESS ACTIVITY

The essence of REACH is to pursue two pairs of central objectives (cf. Art. 1 of the REACH Regulation): *“a high level of protection of human health and the environment, as well as enhancing competitiveness and innovation”*.

It is an extremely difficult balancing act to avoid or to overcome ‘trade-offs’ between these two pairs of central objectives. To date, from the perspective of SMEs, competitiveness seems to be the main loser in this equation, particularly as the benefits in terms of human health and environmental protection are expected to materialize only in the longer term. As a result, REACH may prove to lead to a competitive disadvantage for SMEs, due to costs, training, resources required, etc.

Costs and time (to-market) are important restrictions for market access for SMEs.³⁰ For instance, testing, risk assessment and letters of access within SIEFs (Substance Information Exchange Forum) tend to be very expensive in absolute terms. Given that, for SMEs, such costs have to be spread over many substances, each with a relatively small volume of production, the unit costs for SMEs are pushed up, much to their disadvantage. The effect of volume on costs per unit is shown in table 1. This explains the effect of many low volume substances on overall costs. In addition, the time necessary to become and remain compliant e.g. fulfill processes like volume tracking, submission/maintenance of registrations, preparation of Safety Data Sheets (SDS) with exposure scenarios and communication up and down the supply chain is expensive and may draw attention and resources away from other business processes.

Table 1: Estimated testing costs per tonne of an average substance (in EUR)³¹

Scenario	1-10 tonnes/year	10-100 tonnes/year	100-1000 tonnes/year	> 1000 tonnes/year
Minimum test needs	285	135	43	6
Average test needs	404	244	54	7
Maximum test needs	548	506	81	9

Based on averages of 3, 30, 300 and 3000 tonnes/year respectively.

Source: Van der Jagt et al. (2004) in Geldsetzer (2008), p. 28.

Existing reports³² and our interviews raise several issues as regards the current and future impact of REACH on SMEs. The available space does not allow us to cover each point in detail; we will therefore focus on some key areas.³³

³⁰ COM (2013)25, p. 127.

³¹ Calculations on the testing costs per tonne of an average substance estimated assuming the production of 3, 30, 300 and 3000 tonnes per year respectively, and that the relevant costs would be distributed equally over 10 years. SMEs generally produce a less substances than larger companies and also produce lower tonnages, hence the costs per tonnage band are proportionally higher for SMEs than for larger companies.

³² E.g. CSES (2012a) and CSES (2012b), Danish Technological Institute and PLANET S.A (2010).

³³ For a more detailed review of each point, see CSES (2012a and 2012b).

4.1 Impact on internal processes and costs (not linked to own human resources).

The cost of REACH compliance is seen as considerable, at times throttling, to smaller firms. CSES (2012a) compares the estimated aggregated direct costs of REACH foreseen in the impact assessment of 29 October 2003 with current cost estimates. CSES shows that, with only some (mid-range, as they call it) registrations done so far, the overall costs are clearly higher than expected: some EUR 1.1 billion (in Euros of 2011) in 2003 as against some EUR 2.1 billion today. The underestimation is nearly one-half and can be traced back to two reasons: (a) Quantitative structure-activity relationship models (QSAR) were expected to save some EUR 1.3 billion in testing costs, but current experience shows that almost no savings were made in this respect;³⁴ (b) the Letter of Access (LoA) costs were not foreseen. Assuming that these figures remain valid for 2013 and 2018, the direct 'cost overrun' compared to the initial impact assessment of 2003 might easily be as high as EUR 1.5 billion or more. Such an overrun is particularly 'painful' in a system like REACH, where the costs come first (and even higher than foreseen), while the benefits are not known and, if they materialize, this will happen much later. When expressed as a percentage of the yearly turnover of a firm, these costs amount to 0.1% at times up to 0.5-1%.³⁵

As noted by the European Association of Craft, Small and Medium-Sized Enterprises (UEAPME)³⁶, the major sources of costs relate to testing, consultants and other forms of support to navigate through REACH's complexity and complete a registration dossier.³⁷ According to CSES,³⁸ 93% of surveyed SMEs reported that they always or sometimes rely on external laboratories for testing. For some firms, a major cost item is also the need to restructure existing plants in order to comply with stricter requirements for containment systems as REACH allows safe use only.³⁹ This cost item might well become more important after 2013 and 2018. WKO⁴⁰ (National industry association from Austria) as well as UEAPME explained that in some cases, misunderstandings of REACH obligations by SMEs led to the establishment of costly compliance mechanisms that were wrong and needed to be corrected or scrapped, thus resulting in lost investments. Finally a more trivial point, some reported that travel costs (to meet with consortium partners, attend courses, etc.) proved to be much higher than expected for an SME-budget.

³⁴ Opinion of the authors: this may also be caused by the numerous and very strict scientific prerequisites that ECHA (the European Chemical Agency) has set to allow the use of "validated" QSARs (see guidance on information requirements R6 QSARs and grouping of chemicals). To be fair, even the European Commission in 2003 had expressed doubts of the magnitude of cost savings from QSAR.

³⁵ CSES (2012a), p. 45.

³⁶ www.ueapme.com

³⁷ UEAPME (2013), *Position paper on the REACH review*, forthcoming. The authors are grateful to UEAPME for sharing an early draft of the paper, ahead of publication.

³⁸ CSES (2012a), p.50.

³⁹ Safe use will lead in most cases to more stringent production processes limiting human and environmental exposure. These processes will be laid down in exposure scenarios that are included in the extension of the SDS and need to be followed in order to become REACH compliant.

⁴⁰ <http://portal.wko.at/>

Another issue, widely reported elsewhere,⁴¹ and confirmed both by industry associations and interviewed firms, is the diversion of R&D resources to REACH-compliance, which hampers innovation. Besides for direct work on compliance, resources from R&D are also increasingly used for investigations on substitution of raw materials, for instance to replace a non-REACH compliant supplier with a REACH compliant one. As a result, time is spent in market search and identification of a suitable supplier, not in research itself, let alone innovation. A similar pattern is reported when R&D is devoted to replacing a hazardous material with a supposedly non-hazardous material. This process may, but need not, imply innovation.

Box 1: Selected quotes on the impact of REACH on business activities

"We spent much more on human resources than pre-REACH. The cost of registration is more the time and resources than money."

"There is a misconception that REACH and innovation go hand in hand. Innovation cannot be stimulated by law...with the exception of dangerous substances."

"One aspect [to improve the situation, the authors] would be just to give us a bit more time. For instance with a new substance, we could have 1 year so that an SME can put the substance on the market, without the data, be given some leniency for 10-20 tons per year and then start registration".

"I have to be stricter in monitoring production just to remain in the right tonnage band, if I get more orders it can be a problem."

Due to the obligations to communicate within the supply chain, relationships between suppliers and downstream users have changed, and in the process, many companies struggle with their confidential business information (CBI). This is mentioned by some of our respondents (formulators) as an issue, because their business depends on secret recipes (a specific feature of a mixture, e.g. viscosity is determined mainly by the precise constituents present in the mixture and perhaps the presence of one very specific chemical). Knowledge gained by either customers or suppliers on the specific chemicals present in a mixture due to communication in the SDS may provide competitors with sufficient information to copy products. Although our respondents did not voice any particular concerns as regards the treatment of intellectual property and confidential business information in the context of the SIEF, it may thus be an issue in the communication along the supply chain.

The management of significant information flows relates to the preparation of Safety Data Sheets and Extended Safety Data Sheets (eSDS). The SDS in itself is not new: it existed before REACH. Industry associations (e.g. UEAMPE, and the European Chemical Industry Council–CEFIC)⁴² explain that there are several problems in this area today, not so much in connection to the SDSs *per se* but rather linked to the underlying communication flows.

⁴¹ CSES (2012a), p. 49. CSES (2012b) finds that 63% of surveyed firms reported a diversion of R&D resources from "truly" innovative research after REACH entered into force (although the figures do not distinguish between small and large firms).

⁴² For further details, see www.ueapme.com; and www.cefic.org

To name but a few: the level of response from downstream users ranges from little or mere limited reactions to an overload of requests for reassurance (e.g., request for confirmation that the supplier will register a substance; request to substitute a substance that is on the candidate list of Substances of Very High Concern (SVHC)) beyond what is necessary; when asked to communicate usages, suppliers were provided with non-usable information by their downstream clients, or instead asked to register 'all possible uses under the sun' just to be on the safe side. This complex web of interactions and information exchange triggers the need for IT tools to manage these streams adequately and provide insight in the bill of materials.⁴³ These tools are available in the market, but are expensive and need to be tailor-made for the company. SMEs often have less overview of their tasks and may look for cheap solutions that in the end meet only part of their specific needs.

Box 2: Selected quotes on communication in the value chain and SDSs

"One of the main changes are SDSs. The level is still not right, [the enforcement authorities, the authors] should improve communication, especially downstream. We could lose market if our customers are not compliant with the regulation. There is no problem with the suppliers, they are better informed."

"Companies have to adapt the information for all their SDS for each formula. A lot of work without a software behind...if there is a change in the format, as in December 2012, there was not so much content change, but companies had to re-fill the same information according to the new format."

"It is difficult to work out what information should be in a SDS, it's difficult to put it into a usable document. The quality also varies: some are too thin, others way too long..."

"I have noticed a lack of chemical know-how to fill the 'use descriptor'. Wrong codes are being used, we try to educate our customers, but sometimes even language is a problem."

"We had a lot of communications with people downstream...it was important to standardize our communications. Most of our customers were large companies with sufficient knowledge of REACH. In the case of SME customers, we chose the top-down approach. In order to explain the reason for that decision, we downloaded the CEFIC model letter and modified to our own situation."

In terms of firm strategy and business models, the CSES reports do not find clear evidence of change in the business model among surveyed SMEs, but rather smaller effects on business operations. However, the absence of flexibility in REACH seems to be a central concern for SMEs. REACH is perceived as a constraint to innovation, affecting time-to-market and limiting the possibility to test new uses or substances.⁴⁴ Reportedly, companies 'take into account the REACH cost of any new idea', and discard more projects than before, as scaling up to test real market potential would automatically trigger the need to register.

⁴³ A bill of materials (sometimes bill of material or BOM) is a list of the raw materials, sub-assemblies, intermediate assemblies, sub-components, parts and the quantities of each needed to manufacture an end product.

⁴⁴ [CSES\(2012b\)](#), p.60.

ANNEX 1

Our approach to interviews

The CEPS team approached a number of SMEs in chemistry, of which 12 were eventually interviewed via telephone. In order to structure the interviews according to the terms of reference provided by the European Parliament, and for the sake of comparability of results, we developed a questionnaire focusing on the four parts the European Parliament wants to be verified. Altogether, the questionnaire comprises 49 questions. The questionnaire was emailed to the companies beforehand so that they could prepare. During the interviews, the questionnaire was merely used as a guide to both interviewees and CEPS. Interviews typically took one hour, with two up to one and a half hour. The same questionnaire was made available to CEFIC, UEAPME, ACEA, and a non-chemical “downstream user” (a textile SME) as a help for these interviews as well. Due to availability and the short time-span, interviewed SMEs are not spread over the full EU and cover the following countries: the UK, the Netherlands, Belgium, France, Italy, and the US. Interviewed SMEs belong to the following categories: manufacturers of chemicals, importers of chemicals, formulators, and end users (on firm classification, see e.g., CSES 2012a: 30).

Table 4: List of interviewees

Interviewee	Description	Country
SME 1	Manufacturer	BE
SME 2	Formulator	BE
SME 3	Manufacturer	FR
SME 4	Manufacturer	FR
SME 5	Textile manufacturer	IT
SME 6	Importer	NL
SME 7	Importer	NL
SME 8	Manufacturer	NL
SME 9	Formulator	UK
SME 10	Manufacturer	UK
SME 11	Confidential	UK
SME 12	Confidential	US
CEFIC	European Association	EU
VLARIP -Essencia	National Association	BE
UEAMPE	European Association	EU
WKO	National Association	AT
ACEA	European Association	EU

ANNEX 2

Table 5 : How to become and remain a REACH-compliant SME

Consecutive steps for acquiring and maintaining REACH compliance	Costs generated	Notes
<p>1. A (Late) pre-registration</p> <p>B Inquiry dossier</p>	<p>All administrative costs related to preparation of pre-registration dossier (no substance identification based on spectral and analytical data)</p> <p>Limited costs, but needs to include spectral and analytical data (for identification)</p>	<p>Purely administrative</p> <p>Some knowledge on IUCLID software necessary (additional costs for training/outsourcing of the analytics)</p>
<p>2. Identification of the substance</p>	<p>Phase where the company has to clarify and prove with data which substance it is registering. Related costs for analytical support (see under 1) and sameness check.</p>	<p>Costs will vary on a case-by-case basis depending on complexity of the substance (mono constituent versus UVCB substance) and the time necessary to assess sameness within the context of the SIEF (knowledge on chemistry is essential)</p>
<p>3. SIEF or Consortium management</p>	<p>Costs incurred by companies either as a lead registrant or as a member of a SIEF. These costs include coordination and management, costs of legal and technical consultants, where applicable.</p>	<p>These costs can differ substantially related to the effectiveness of the SIEF/consortium. In principle the LoA contains a part for costs related to SIEF/consortium tasks.</p>
<p>4. Data and testing</p> <p>A Available data</p> <p>B Data-gap analyses</p> <p>C Alternative methods</p> <p>D Testing</p>	<p>Costs can be reduced by effectively using A-C. Thereafter there will be the testing of substances and/or the process of acquiring access to existing data and tests, most often through Letter of Access (LoA).</p>	<p>Focuses on the toxicological properties of the substance. Generally very costly, depending also on how costs are shared within a SIEF (where applicable) and how effectively existing data and alternatives are used (requires toxicological knowledge). Steps A to C may be difficult to check for SMEs.</p>
<p>5. Exposure assessment</p>	<p>Preparation of scenarios by specialists and internal costs related to identification of own and customer's uses.</p>	<p>Knowledge of own processes and processes used by customer(s) need to be assessed (implies</p>

		knowledge of supply-chain).
6. Chemical Safety Report	Preparation of the Report for the registration and all the underlying costs, including consultant fees etc.	Refinements may be necessary to prove safe use leading to more costs.
7. Fees	Fee to be paid to ECHA for the registration process	Fees depend on the size of the company and are a small percentage of overall costs.
8. (e-)SDS	Costs of an IT system, human resources and expert help for preparation and/or interpretation of the extended part with the exposure scenarios	The IT system that generates SDSs in different languages may be already available. The extended part is new and complex to understand
9. Internal company costs	Refers to all costs in terms of time and human resources for the company. Includes also the opportunity cost of reallocating resources internally, for instance by using R&D personnel to deal with REACH compliance. These costs includes IT tools, updating the dossier when IT tools and other forms are changed.	In case knowledge on REACH is not available, this will lead to substantial costs related to training/education and the use of external consultants. In addition maintenance of administrative (IT) systems to capture data on volumes, registrations and REACH related business processes will need additional human and financial resources.
10. Updates to submitted dossier	Costs of updating dossiers submitted for registration to reflect internal changes (volume, new use) or to answer ECHA's requests for clarification. Also includes updates related to testing proposals and revised classification	Costs of updating dossiers will continue during the years. In case additional testing needs to be performed extensive additional costs are faced

Table 6: Additional processes

Consecutive steps for acquiring and maintaining REACH compliance	Costs generated	Notes
<p>11. Evaluation:</p> <p>A Dossier Evaluation by ECHA</p> <p>B Substance evaluation by Member States.</p>	<p>A: costs of submitting additional information.</p> <p>B: in addition to what is mentioned under A this will lead to further work in the SIEF/consortium (substances under substance evaluation are published under the CoRAP).</p>	<p>These vary depending on whether authorities ask for minor data adjustment or have identified considerable gaps in the dossier (thus the quality of the initial dossier).</p>
<p>12. Authorisation</p>	<p>Costs related to application for authorisation of specific uses of the substance (can be repeated in time if the company decides to reapply each time the authorisation expires), includes the costs of updating the Chemical Safety Report, preparation of a socio-economic assessment (optional, but with substitution plan) and the payment of significant fees</p>	<p>Possible withdrawal of substances or conditions imposed/required by downstream clients to avoid SVHCs that are expected to end on the authorisation list. Loss of raw materials for the same reason.</p> <p>Companies reported "pressure" both from upstream and downstream users in terms of ensuring that each link in the value chain is REACH-compliant or that a substitute will be available. SVHC substances are banned and even non-official lists are used to delete substances.</p>
<p>13. Restriction</p>	<p>Administrative costs related to check of the Annexes of REACH to assure a company is not producing or importing restricted substances.</p>	<p>These substances are not allowed on the market and demand no further direct action under normal circumstances.</p> <p>This may affect especially importers of chemical mixtures.</p>
<p>14. Enforcement by national authorities</p>	<p>All costs related to e.g., inspection, request for additional information, meeting of regular information obligations etc.</p>	<p>See also under internal company costs.</p>

ANNEX 3

Questionnaire

1. Could you please position your company in terms of sector, size, specific activity and place in the value and/or supply chain (e.g., formulator, importer)?

The impact of REACH on the functioning of your company

2. Have you re-organised human resources in your business to cope with the requirements of REACH?
3. If you have answered yes to the previous question:
 - Did you hire new staff? If so, how many?
 - Did you reallocate the work among existing staff?
 - Did you or other members of your team attend any specific training?
 - Did you use the help of external experts/consultants?
4. Could you indicate how these re-organisation costs relate to your yearly turnover to date?
5. If you have not yet incurred any of the reorganisation costs of Question 3, are you planning some re-organisation for the upcoming two deadlines of 2013 and 2018? In particular:
 - Will you hire new staff? How many?
 - Will you reallocate the work among existing staff?
 - Will you or other members of your team attend any specific training?
 - Will you use the help of external experts/consultants?
6. Overall, would you say that REACH has generated new jobs in your industry sector? Did it lead to job losses? Why?
7. Did REACH have other effects in the structure and quality of employment in your company?
8. Did REACH have other effects in the structure and quality of employment in the chemical businesses you usually interact with?
9. Did you experience contacts with up-stream and down-stream users related to REACH? Were you able to respond adequately to their questions?

Impact on business activity

10. Will REACH have consequences for your business operations (other than human resources re-organisation, see above) and strategy?
11. Did REACH lead you to revise your business model? If so, could you please elaborate?

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12. What would you say have been the major categories of costs incurred by your business to comply with REACH until now?
 - Cost of registration
 - Cost of testing
 - ECHA fees for first registration period
 - Costs related to innovation
 - Other costs (please specify)
 13. Could you indicate how these costs relate to your yearly turn-over to date?
 14. What do you expect will be the impact on these costs (see above, question 12) for your business until the next two deadlines of 2013 and 2018?
 15. How do these costs influence other activities of your company like innovation, R&D, exploration of new markets, and greening of your products?
 16. We would like to zoom in on some aspects. In particular, do you have an overview of the resources necessary (human and financial) in the near future, e.g. what would be the costs of registration of a substance with a volume above 100 tons/annum (2013 deadline)? What do you expect in relation to registration: number of substances, preparation of registration as lead registrant, buying access to data/dossiers?
 17. And for the 2018 deadline?
 18. How will these costs be distributed along the value chain? And over time? Is there a difference between the distribution of costs for the 2013 deadline and the distribution for the 2018 deadline?
 19. What are and have been the main uncertainties for your business when it comes to complying with REACH (e.g. time constraints, knowledge, finances, resources, IT tools)?
 20. Has REACH affected the price and the variety of products offered by your business or by its suppliers? Please select all that apply:
 - Price of my products
 - Variety of products offered by my company
 - Price applied by suppliers
 - Variety of products offered by suppliers
 21. Do you take REACH compliance into account when choosing suppliers?
 22. Do you foresee strategic changes in your company's policy related to products and markets due to the burden of REACH (e.g., will you or have you withdraw(n) products from the market, have you introduced substitutes)?
 23. As regards REACH and R&D:
 - Is your R&D department aware of regulatory matters like REACH?

- Is your R&D department and/or are funds allocated for R&D diverted to REACH-related testing etc. and research on substances that you already had in your portfolio, thus pre-empting innovation for a while?
 - Did REACH foster innovation in your company, and if so how?
24. Has REACH influenced the relationship between different stakeholders within your company like production, sales, R&D and regulatory compliance?
25. What impact in terms of knowledge transfer did REACH have for your business?
26. Did the process of pre-registration generate new knowledge or other positive spillovers for your business, or was this a purely administrative process?
27. Do you have experience with registration? If so, as a lead registrant or by buying a letter of access?
28. If you are part of a SIEF, what has been your experience?
- Have you observed abuses of dominant position in SIEFs with respect to access letters?
 - Have you observed withdrawals in specialized chemicals that might lead to submarkets with only a few or a single supplier?
 - Have you observed other possible infringements of EU competition law?
29. What is your opinion on protection of confidential business information (CBI) when working with your competitors in a SIEF? What would you consider as your main IP (e.g., unique substances, recipes, production methods)?
30. Have there been any positive changes in the way you interact with other businesses (both upstream and downstream) following REACH?
31. Have there been any negative changes in the way you interact with other businesses (both upstream and downstream) following REACH?
32. Has REACH affected import and export patterns for your business (this question does not only relate to your products, but also to raw materials or mixture purchased by your company)? Please explain.
33. Overall, would you say that REACH has been an opportunity or a barrier for the competitiveness of your business?

Support for SMEs

34. What type of information did your organisation receive as regards compliance requirements with REACH (e.g., how to take part in pre-registration and steps after pre-registration)?
35. When was this information provided? Was this timely enough to ensure compliance? Was it of direct help or too general? What about IT tools?

36. Who was and is your main source of information as regards compliance with REACH (e.g., local chamber of commerce, industry association, consultants, the European Commission's website, the ECHA website) and support?
37. Have you ever used national Helpdesks? If so, what was your experience?
38. Have you relied on the online, written support provided by the ECHA in Helsinki (e.g., fact sheets, guidance and other publications, IT tools, as well as webinars)?
39. If so, could you please give us your feedback on the support provided by ECHA?
40. What improvements in terms of support would you like to see in the future?

Added Value for SMEs

41. What would you say are the main benefits of REACH for your organisation until today? And what do you expect the benefits to be in the future, once the 2013 and 2018 registrations are done?
42. What has been the return on investment for your organisation as regards REACH?
43. Did the recent economic and financial crisis affect your ability to comply with REACH?
44. Do you think that REACH has contributed to improving the overall image/reputation of the chemicals sector? If so, has there been a more generic benefit for your business as well? In which terms?
45. What were your initial expectations of REACH? Have they changed after these first five years of implementation?
46. Is REACH compliance for your company different than for non-SMEs competitors? Is it (relatively) more costly for you? If yes, please specify up to three cost categories which are (relatively) more costly for your company.
47. Would you have any concrete suggestions for the lowering of costs of REACH for SMEs and/or the reaping of REACH-dependent benefits for SMEs?
48. If and as long as REACH does not change, except for marginal questions, what do you suggest would be helpful for your company?
49. Do you see possibilities for a fair and transparent way of reducing the overall costs?

NOTES

DIRECTORATE-GENERAL FOR INTERNAL POLICIES

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