

ASSESSMENT OF THE HEALTH AND ENVIRONMENTAL BENEFITS OF REACH

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Final Report
Part B – Assessment of Benefits

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1. INTRODUCTION

1.1 Study Objectives

The overall aim of this contract is to provide a better understanding and more precision in the quantification of the benefits to human health and the environment following the implementation of REACH since 2007.

More specifically, the tasks to be undertaken are:

- To build a comprehensive model capable to assess the human health and environmental benefits of REACH and all the possible changes in the specific provisions and improvements of the Regulation that the Commission might consider. The contractor will review the methodologies of the baseline study and other relevant impact assessment studies, identifying the limitations and proposing solutions;
- To assess the expected human health and environmental benefits since the entry into force of REACH, providing a qualitative and quantitative description, based on real figures and fully justified estimations;
- To propose recommendations to improve the level of protection of human health and the environment, in first instance through modifications on the implementation and enforcement of REACH, then through changes in the development of guidance and in providing interpretation, and as the last resort on the legal provisions; and
- To consult relevant stakeholders to gather more information to feed into the study.

The results of the project will feed the Commission General Report on the operation of REACH due in 2012.

1.2 Structure of this Report

This document is the final report for the study and summarises the work carried out across all of the above activities. It has been divided into two Parts: Part A sets out the suggested model for evaluating the health and environmental benefits being delivered by REACH over time, with this including a review of methodologies, their limitations and suggestions on possible solutions or alternatives to these; Part B provides a review of the human health and environmental benefits delivered to date by REACH and recommendations on improvements to its implementation and enforcement.

The remainder of this document – Part B – has been organised as follows:

- Section 2 provides a summary of the approach taken to the study;

- Section 3 briefly reviews the main provisions of the Regulation which may act as drivers of human health and environmental benefits, and the basic modelling underpinning the assessment carried out here;
- Section 4 discusses our findings with respect to registration as a driver of benefits;
- Section 5 examines information through the supply chain as a driver of benefits;
- Section 6 looks at the authorisation and restriction processes as drivers of benefits and draws conclusions on these;
- Section 7 considers evaluation, inspection and enforcement activities and synergies with other legislation as enhancers of the benefits delivered from the above drivers; and
- Section 8 pulls together our overarching conclusions from the assessment carried out and provides recommendations for improving the current implementation and enforcement of REACH.

2. APPROACH TO THE STUDY

2.1 Overview

Our approach to the study was based on three main tasks (as set out in the Specifications):

- Task 1: Develop a methodology for assessment of the health and environmental benefits of REACH;
- Task 2: Provide an assessment of the impact of the current implementation of REACH on the expected human health and environmental benefits; and
- Task 3: Suggest recommendations.

The methodology was agreed at a kick-off meeting with the Commission and refined during the progress of the study itself, following submission of the first interim report.

2.2 Task 1: Develop a Methodology

Task 1 comprised a series of sub-tasks, the outputs of which provide much of the material presented in the Part A report. Only a short period of time was available for this Task due to the need to feed the results of Task 2 into the overall REACH Reporting exercise (Article 117 Reporting).

The first step in Task 1 was to carry out a more detailed review of the EUROSTAT Baseline Study methodology and the assessments that were undertaken in the past with the aim of predicting the likely health and environmental benefits of REACH. The aim here was to identify what outputs the Baseline study would provide within the time frame for this study, so as to clarify what level of data would be available on the first set of registered substances. Members of the study team (from DHI and Oekopol) are or have been involved in the Baseline Study, with this facilitating interactions between the two studies.

With regard to previous impact assessments, the aim has been to review the approaches used, the assumptions underlying these, their relative advantages and drawbacks (from a theoretical as well as practical perspective), together with their associated data requirements. In undertaking this review, the Commission stressed the importance of giving detailed consideration to the drivers within REACH that are (and will) give rise to health and environmental benefits, and the relative importance of these.

The intention of the review was to look across the different studies to provide an overview of the key similarities and differences, and the issues arising given variations in approach, data sources and assumptions. As part of this, consideration was given to what was possible in the short term for the purposes of this study and

then in the longer term, taking into account the information that will be made available from the Baseline Study and from other source in the future.

While undertaking the critical review, a more general mapping of the data requirements of the different approaches against possible data sources was carried out. This started with consideration of the outputs of the Eurostat Baseline study and moved on to the other assessment approaches, with the aim of identifying what key data gaps are likely to exist and the types of additional information that may need to be collected or generated in the future.

Based on the above, the methodological framework to be applied in Task 2 was developed. This included identifying how the framework could be expanded or further developed for future assessments based on data that are likely to become available through the further implementation of REACH.

This includes discussion on the following:

- The health impacts that should be assessed, including both mortality and morbidity effects. This includes details of the approaches that could be taken to qualitative and quantitative analysis and options for adopting surrogate measures of impact;
- The environmental impacts that should be covered by the assessment of persistent, bioaccumulative and toxic substances, as well as endocrine disruptors, across the different environmental media. Again, this includes discussion of potential approaches, as well as the use of proxy measures such as changes in the use and exposure pattern of chemicals with certain properties, the Baseline Study Risk Scores, etc.;
- The limitations of the suggested approaches, their likely significance to understanding the benefits of REACH, and possible solutions to these both in the short and in the longer term; and
- The REACH drivers that are addressed by the above approaches and any changes in approach that may need to be adopted in order to also capture the benefits arising from possible changes in REACH provisions or its implementation.

2.3 Task 2: Assessment of the Current Implementation of REACH on Expected Human Health and Environmental Benefits

The approach to Task 2 evolved over the course of the project and was developed so as to provide an efficient means of collating quantitative evidence as to benefits, as well as gaining a more qualitative understanding of both the degree to which benefits have been realised to date and likely trends in the future. Our approach therefore involved a combination of:

- Literature collection and review, including reports produced by ECHA and a range of other organisations together with the predictions of benefits produced by previous impact assessments;
- Analysis of statistical data produced by ECHA and of other relevant data sets, including the available outputs from the EUROSTAT Baseline Study;
- Analysis of the raw data collated by CSES as part of its work for DG Enterprise on the impacts of REACH on the Competitiveness and Innovation of EU companies as well as on the Single Market¹;
- Interviews with individual companies and representatives from industry associations, as well as consultants and one laboratory analysing the presence of SVHC in articles, to discuss their experiences with the first phase of REACH, the extent to which benefits are likely to arise in the future if they have not yet been realised, and to gather any recommendations for ensuring that benefits are delivered in the future.

It should be noted that the intention of the interviews was not to duplicate the survey work carried out by CSES. Instead the aim was to discuss particular aspects of REACH (the hypothesized drivers of benefits) with the aim of gaining a more detailed understanding of the operation of REACH to date and the functioning of the mechanisms through which benefits are expected to be generated.

Interviews were carried out with 60 organisations by RPA and Oekopol, with the breakdown by type of organisation given in Table 2.1. Note that this is the total number contacted. Individual companies may have more than one role under REACH, e.g. being a formulator, downstream user and/or an article producer. Thus, the interviews will have covered all relevant REACH roles. This makes allocation of actors participating from different sectors difficult in some cases, with this based on the main role they identified for their company.

The interviews generally lasted about 1 hour, although several lasted much longer than this. They were carried out either in person or by telephone and held in English, German and French, but included actors from a wider range of Member States. Most interviews were one-to-one discussions; however, several also involved multiple actors within a particular sector and coming from a range of countries. Interviewees were sent a copy of the work hypotheses that underlie the assessment prior to the interview, so that they could prepare responses. Many of the associations used this as the basis for collecting information from their members to feed into the interview. Similarly, some companies clearly consulted within their own organisations on how to respond to particular questions.

All interviewees were guaranteed the confidentiality of their responses, although

¹ CSES (2011): Impact of REACH on single market and competitiveness, draft report to DG Enterprise, December 2011. And CSES (2011): Impact of the REACH Regulation on the innovativeness of the EU chemical industry, draft report to DG Enterprise, December, 2011.

notes have been kept of the discussions and key points arising from each interview.

It is also of note that many of the interviewees, particularly those from associations, were willing to be re-contacted or to further consult with their members should additional information be required.

Table 2.1: Interview Statistics

Actor Type	Number Contacted	Sectors Represented
Manufacturers	14	Organic chemicals, metals / precious metals
Distributors/Importers	5	
Formulators	8	Construction, textiles, adhesives, pigments, photographic, paper, surface coatings (paints) and other
Downstream Users	9	Alloys, plating
Article Producers	7	Aerospace, vehicles, electrical and other consumer goods
Industry Associations	10	Precious metals, other metals, adhesives and sealants, photographic, galvanising, steel, chemicals, textile finishing agents, distributors
Article Retailers	3	DIY stores, cosmetic and beauty products
Consultants	3	Registration, SDS, Classification
Laboratories	1	
Total	60	

2.4 Task 3: Suggest Recommendations

The final activity for the study has been the development of recommendations based on the findings from the Task 2 work, as informed by feedback received from relevant stakeholders and the consultants' own analysis. As requested, the focus of these suggestions relate to two aspects, namely:

1. **Establishing a potential research agenda** - to direct further work aimed at refining methodologies for the monitoring and assessment of impacts of REACH on human and environmental burdens. These were to take into account what research programmes are currently underway and the intended outputs to ensure the efficient use of resources, but also to consider over what time scales (medium or long-term) such research could be expected to come to fruition and the likelihood of success. As part of this, we were to consider whether the research could be funded by the Commission or ECHA services or if, for particular issues, these requirements might be better served by research conducted by or funded by other industries or organisations; and
2. Actions that might be taken to meet the objective of REACH of **ensuring that a high level of protection of both human health and environment** is achieved. In line with the Specifications, we have developed recommendations using a staged approach focusing, in turn, on 1/ identification of non-legislative measures that might be taken to improve implementation and enforcement activities 2/ possible enhancements to the guidance that might be provided to Member States, ECHA and other stakeholders by the Commission; and 3/- should these be considered necessary - potential changes to the legal provisions.

3. THE BENEFIT DRIVERS IN REACH

To ensure a high level of protection of human health and the environment the REACH Regulation provides a full set of provisions organised into Titles, corresponding with the main obligations of the duty-holders.

To identify the main benefit drivers of REACH, it is important to have an overall understanding of the functioning of the legislation. Figure 3.1 shows the main obligations (registration, authorisation, restriction, information in the supply chain), the enhancement tools to check and ensure the compliance with these obligations (evaluation, inspection and enforcement, guidance and support), the main groups of actors playing a role during the life-cycle of a substance (manufacturers and/or importers, downstream users (formulators, industrial end-users, professional end-users), distributors and consumers) and the legislation with which REACH has synergies that will help in the achievement of benefits (e.g. the CLP, worker safety legislation, the WFD, IPPC, waste legislation, etc.). Since the scope of this study is specifically to assess the public health and environmental benefits, the drivers generating business benefits are not included.

The Regulation is designed to avoid gaps in responsibility among the actors of the system to identify risks, to establish and document the conditions of safe use and to take the appropriate measures throughout the life-cycle of substances. Through the main obligations placed on the various actors, REACH will generate information on substance properties to identify the pathways that link chemical effects to human health and the environment, allowing the identification, improvement, and implementation of the risk management measures. The benefits of the Regulation will be furthered through synergies with other legislation addressing specific substances with specific assessment and management measures (e.g. Persistent Organic Pollutants, Biocides, Plant Protection Products, Hazardous Waste Directive etc.) and the legislation designed to protect the workers, the consumers and the environment more generally (e.g. the Workers legislation, the Classification, Labelling and Packaging Directive, Water Framework Directive, and the Biodiversity Strategy, etc.).

For the purposes of this study, the following definitions are used to identify the significance of different provisions to the generation of potential health or environmental benefits:

- a **driver** is a set of legal provisions with a direct or indirect effect and which triggers human health and/or environmental benefits;
- a **pathway** is the qualitative description of the cause-effect link between the drivers and the benefits;
- an **indicator** is a proxy that could be used for the quantitative description of the cause-effect link; and
- **enhancers** are all those provisions that help to realise the benefits through control and enforcement and thus assist or ensure compliance with the main obligations.

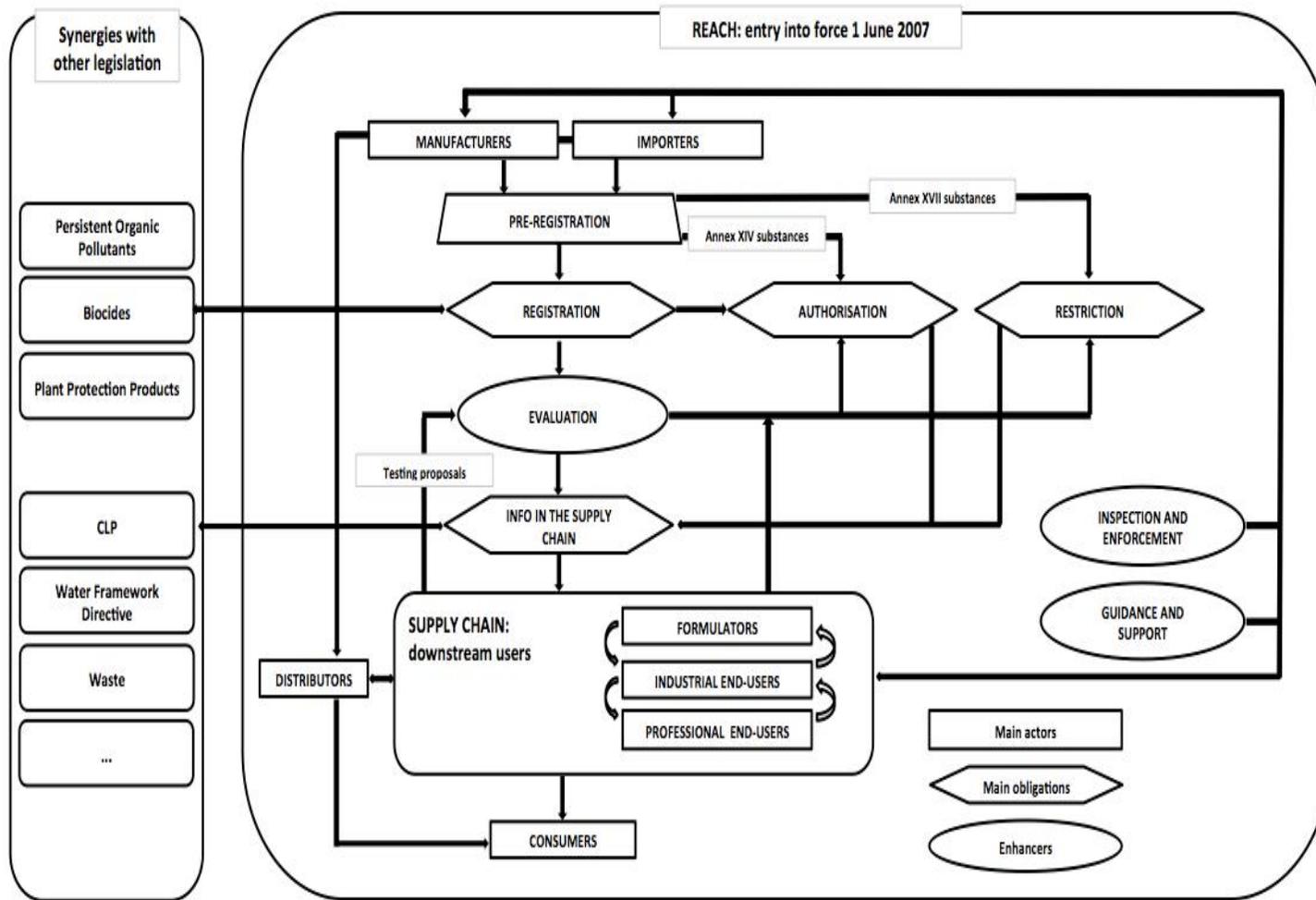


Figure 3.1: Main Actors, Main Obligations, Enhancement Tools and Synergies with Other Legislation

The key drivers relate to the main obligations of REACH, with those of particular relevance to the generation of human health and environmental benefits being:

- Registration;
- Information through the supply chain;
- Authorisation;
- Restriction; and
- Evaluation, Inspections and Enforcement activities.

The first four of these are considered to act as direct generators of benefits, while evaluation, inspections and enforcement activities have been defined for the purposes of this study as “enhancers” of the benefits delivered by the four main sets of provisions. In addition, the provision of guidance by ECHA and dissemination of reports on the operation of REACH as well as other forms of feedback to industry and Member States on how best to fulfil their duties and obligations can be considered to act as an enhancer. Benefits may be further enhanced by the linkages and complementarities that exist between REACH and other legislation.

These drivers are discussed in Sections 4 to 7 of this report, with tables setting out the relevant REACH provisions to each and the associated pathways through which they deliver benefits. Flow charts are also provided to aid an understanding of these pathways and how benefits are expected to be realised, as well as the indicators of benefits associated with these different pathways.

4. REGISTRATION REQUIREMENTS

4.1 Introduction

4.1.1 Pathways to the Realisation of Benefits

In order to remain on the market, manufacturers and importers of substances in quantities of one tonne per year or higher have to submit a registration including information on hazardous properties. For substances registered at ten tonnes per year or higher, and found to be hazardous or to meet the criteria for being Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) substances, as set out in Annex XIII to REACH, manufacturers and importers shall undertake exposure and risk assessments for all uses for which the substance is to be supplied (Title II).

Table 4.1 lists all the key provisions, grouping them by drivers and expected benefits to human health and/or the environment. The flow chart given in Figure 3.1 presents the different legislative drivers and the action of the enhancers, and suggests indicators that could be used in the development of the methodology to assess the effects of the Regulation.

The mandatory generation, collation and assessment of hazard and exposure data, risk assessment and the identification of risk management measures to ensure safe use are expected to be key drivers for the control and reduction of harmful impacts on human health and the environment from the use of chemical substances. It is expected that a proportion of existing classified substances will be found to have previously unidentified hazardous properties, and as a consequence be reclassified, as a result of activities under REACH. This will result in benefits through the identification and recommendation of appropriate risk management measures under REACH, as well as through the implementation of exposure reducing measures triggered by other legislation (e.g. Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work). In addition, communication within the supply chain on uses of substances will have identified new uses to registrants, enabling them to identify appropriate risk management measures.

A registration dossier must include a **Chemical Safety Report (CSR)** for any substance manufactured or imported in quantities of ten tonnes per year (t/y) or more. The CSR documents should be based on the **Chemical Safety Assessment (CSA)** which, for substances classified as hazardous, also includes the development of exposure assessments and risk characterisations for the substance and all its identified uses. As indicated above, the CSA must also include an exposure assessment also for substances that meet the criteria for being PBT or vPvB substances.

The generation of this information has a cost that the manufacturers and importers might not be willing to bear for some substances, leading to their withdrawal from the market and, subsequently, to a lowering/cessation of exposure of workers, consumers and the environment. However, such potential substance withdrawal for economic reasons (rather than risk considerations) is not necessarily regarded as a trigger of

human health and the environmental benefits under REACH. The additional requirements for an exposure scenario for each of the relevant uses and a risk characterisation for each of the substances meeting the criteria for EU classification or assessed to be a PBT or vPvB are expected to strengthen the effect of information generation as driver. Similarly, withdrawal of a substance due to difficulties in ensuring safe use strengthens the effect of information generation as a driver.

The need to fulfil the Annex VII to XI information requirements through the provision of new information (potentially including test data) will also lead to a review of the classification and labelling of many substances. Thus, in addition to the above benefits, this driver will act synergistically with the CLP Regulation and the other legislation that draws on such classifications. The exposure assessment carried out as part of a Chemical Safety Assessment should identify waste management measures that will minimise exposure during the waste disposal or recycling of the substance. This provision (under Annex I of the Regulation) has been highlighted because it is a new requirement expected to realise additional benefits in comparison with the previous legislation.

All of this information is to be used in identifying the risk management measures (RMMs) that will be circulated through extended Safety Data Sheets (SDS). The circulation of such data throughout chemical supply chains is intended to enable the safe use of chemicals, thereby delivering improvements to the protection of human health and the environment by either by providing clearer information on safer conditions for use or by requiring a higher level of risk management than has previously taken place. The provisions regarding the transmission of information in the supply chain, including the requirements placed on downstream users to communicate information up the supply chain on any new information on hazardous properties or on the appropriateness of the RMMs in the supplied SDS and which could lead to an improvement in the quality of extended Safety Data Sheets, are also analysed in Section 4.

4.1.2 The Work Hypotheses

Following on from the above, we have developed a series of ‘work hypotheses’ which set out the pathways and associated mechanisms through which registration related activities are expected to deliver benefits. The four main work hypotheses developed for registration are as follows.

- 1) **Chemical Safety Assessment as part of the Chemical Safety Report:** The requirements for a chemical safety assessment for substances registered at greater than 10 t/y where they have hazardous properties should create benefits through a reduction in unsafe uses because: uses where adequate control of risks cannot be demonstrated are not supported by the registration and this is indicated in the SDS; risk management measures are (newly) identified and communicated so as to ensure safe use; by collecting information on uses, manufacturers learn more about uses and can better target their information provision towards controlling and reducing risks; and advice on waste management will become more specific and ensure safe disposal.

- 2) **Generation of new data leads to revised classifications of chemicals (and mixtures):** The generation of new (test) data will lead to improved information on the properties of chemicals. This will lead to benefits by: updating of the classifications of individual chemicals providing registrants and downstream users with improved information on the hazards associated with their use; the updated classifications will act as the basis for preparing exposure scenarios, improving the quality of recommendations on safe use and handling and appropriate risk management measures; and new classifications will feed across into other legislation, with this creating indirect benefits.
- 3) **The assessment of PBT properties as part of the Chemical Safety Assessment:** The explicit requirement to carry out a PBT assessment as part of the CSA should help ensure that substances that currently are not recognised as PBT or vPvB substances are identified. This information could support a possible further identification of SVHC and prioritisation with respect to the potential need for authorisation.
- 4) **Registration and substance withdrawal:** The requirement to register substances will create benefits for human health and the environment where a substance is no longer supported due to its hazardous properties, and thus withdrawn from the market, and are substituted by less hazardous alternatives through the following mechanisms: an overall lower tonnage of hazardous substances will enter the market, uses which may have posed risks to people or the environment in the past are no longer supported.

In addition to these four main hypotheses, the **evaluation** components of REACH should act as an enhancer of the above benefit drivers because they should help registrants learn to improve their registration dossiers. Guidance should also act as an enhancer by providing tools or assessing safe use. It is also suggested that **inspection and enforcement** of REACH registration requirements should act as an enhancer of the above benefit drivers because: it ensures that there is an incentive for manufacturers and importers to comply with the registration provisions within the Regulation; and compliance should help ensure that the above mechanisms are able to deliver benefits as expected.

4.1.3 Indicators of Benefits

In the discussion that follows, we provide a summary of pre-REACH implementation predictions as to the benefits that might result from associated mechanisms, where these exist, for each of the four main work hypotheses. We also provide an indication of any post-implementation data that is available on potential benefits.

The key indicators of benefits in this regard are listed in the Figure 4.1, with these acting as proxies of the effects of the legal provisions set out in Table 4.1. These are data on:

- New data on substance properties lead to new classifications or changes in existing substance classifications, higher data quality and (re-)assessment of risks;

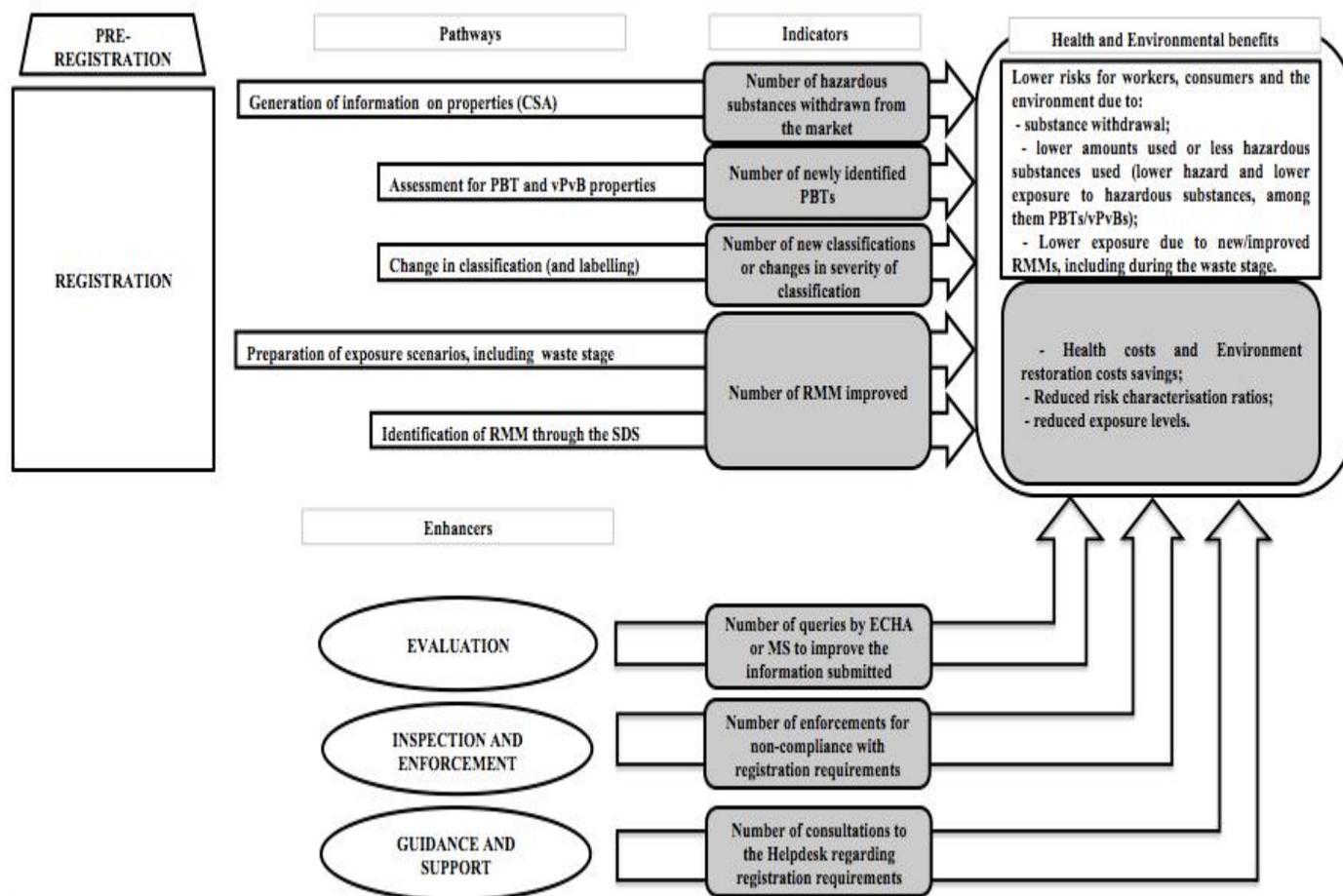


Figure 4.1: Flow Chart of the Drivers, Pathways and Indicators of Benefits under Registration

Table 4.1: List of the Key Provisions by Duty-holders, Pathways and Benefits for Registration				
Article	Provisions	Duty-holders	Pathways	Human health and environmental Benefits
5	Prohibition on manufacture or import of substances on their own, in mixtures or in articles unless they have been registered	M, I	Withdrawal from the market of hazardous substances (partial or complete) and substitution with less hazardous ones. Number of newly introduced non-hazardous substances compared to pre-REACH notifications	Lower number of exposed people/ environments due to the withdrawal and substitution of specific hazardous substances from certain uses in the market, where exposure acts as a proxy for the likelihood of an adverse health or environmental effect
6(1)	Requirement on a manufacturer or importer of a substance, either on its own or in one or more mixture(s), in quantities of one tonne or more per year to submit a registration to the Agency	M, I		
6(2)	Obligation to register for monomers that are used as on-site intermediates or transported isolated intermediates	M		
6(3)	Requirement on a manufacturer or importer of a polymer to submit a registration to the Agency for the monomer substance(s) or any other substance(s) that have not already been registered by an actor up the supply chain (under conditions)	M, I		
7(1)	Requirement on a producer or importer of articles to submit a registration to the Agency for any substance contained in those articles and which are present in quantities over one tonne and where the substance is intended for release under normal or reasonably foreseeable conditions of use	Article producer or Importer		
7(2) and (4)	Requirement on a producer or importer of an article to notify the Agency of information provided in Article 7(4)	Article producer or Importer	Generation of information	Cost savings through more controlled use of the substance and the adoption of more appropriate risk management measures (thereby preventing potential future damages)
7(3)	Requirement on a producer or importer to supply appropriate instructions to the recipient of the article	Article producer or Importer		

Table 4.1: List of the Key Provisions by Duty-holders, Pathways and Benefits for Registration				
Article	Provisions	Duty-holders	Pathways	Human health and environmental Benefits
7(5)	A registration shall be submitted if the Agency takes this decision based on the criteria set in Article 7(5)	Article producer or Importer	Withdrawal from the market of hazardous substances	Lower exposure due to the withdrawal from the market of hazardous substances and the replacement by less hazardous alternatives, where exposure acts as a proxy for reduced adverse effects
10	The information to be submitted for registration shall contain the technical dossier and the CSR	M, I	Generation of information	Improved information on substance properties, CSA and resulting RMMs should provide the information needed to ensure the improved management of risks to human health and the environment
12(1)	Requirement to include in the technical dossier all physicochemical, toxicological and ecotoxicological information that is relevant and available to the registrant	M, I		
12(2)	Requirement on a manufacturer and importer to notify ECHA with additional information where it reaches the next tonnage threshold	M, I		
14(1)	A CSA shall be performed and a CSR completed for all substances subject to registration in accordance with this Chapter in quantities of 10 tonnes or more per year per registrant.	M, I		
14(3) and (4)	The CSA shall follow the steps described in Article 14(3) and the additional steps of Article 14(4) if the substance is classified under the CLP Regulation or is a PBT or vPvB	M, I	Generation of information on risks, including for PBT and vPvB properties	Reduction of environmental effects if this results in lower exposures to PBT and vPvB

Table 4.1: List of the Key Provisions by Duty-holders, Pathways and Benefits for Registration				
Article	Provisions	Duty-holders	Pathways	Human health and environmental Benefits
ANNEX I	Under the Exposure Assessment the CSR should identify the waste management measures to reduce or avoid exposure of humans and the environment to the substance during waste disposal and/or recycling	M, I	Creation of Waste Management Measures	Reduction of risk expressed as lower exposures to substances during waste disposal and/or recycling
14(6)	Requirement on a registrant to identify and apply the appropriate measures to adequately control the risks identified in the CSA and where suitable recommend them in SDS.	M, I	Generation of Risk Reduction Measures through the SDS	Exposure reduced as Risk Reduction Measures will be improved
14(7)	The CSR shall be kept available and up to date.	M, I	Generation of information	Improved information on substance properties, CSA and resulting RMMs should provide the information needed to ensure the improved management of risks to human health and the environment
17(1) and (2)	Requirement on a manufacturer to register on-site isolated intermediate manufactured in quantities of one tonne or more per year. Registration shall include information as listed in Article 17(2)	M	Generation of information	Improved information on substance properties, CSA and resulting

Table 4.1: List of the Key Provisions by Duty-holders, Pathways and Benefits for Registration				
Article	Provisions	Duty-holders	Pathways	Human health and environmental Benefits
18(1), (2) and (3)	Requirement on a manufacturer to register transported isolated intermediate manufactured or imported in quantities of one tonne or more per year. Registration shall include information as listed in Article 18(2). Requirements on manufacturers registering transported isolated intermediate manufactured or imported in quantities of more than 1000 tonnes per year to include information specified in Annex VII	M		RMMs should provide the information needed to ensure the improved management of risks to human health and the environment
20(2)	Requirement to complete the registration and to submit it to ECHA within the deadline set in case of incomplete registration	M, I		
21(1)	Requirement for registration of substance prior to starting or continuing the manufacture or import of a substance or production or import of an article if there is no indication to the contrary from ECHA	M, I		
22(1)	Requirement on a registrant to update its registration whenever needed	M, I	Generation of information	Improved information on substance properties, CSA and resulting RMMs should provide the information needed to ensure the improved management of risks to human health and the environment
22(2)	Requirement on a registrant to submit ECHA an updated registration providing information as required by a decision.	M, I		
24(2)	Requirement on a registrant to notify, in accordance with articles 10 and 12, where the quantity of a notified substance reaches the next tonnage threshold.	M, I		

- The degree to which information on previously unknown uses became known to registrants; linked to this is the number of uses subsequently ‘advised against’ as they are not/no longer considered ‘safe’;
- The extent to which REACH may have triggered the implementation of more stringent operating conditions or RMMs;
- The number of substances withdrawn from the market due to hazardous properties (where the use of alternatives does not lead to an increase in exposure to other hazardous substances);
- Linked to the above is information on the number of new, non-hazardous (or potentially low hazard) substances added to the market and the degree to which this varies from the numbers and hazard profile of such substances being newly notified before REACH; and
- The number of newly identified PBTs or vPvBs.

4.2 Changes in Substance Classification and Data Quality

4.2.1 Pathway to Benefits and Associated Indicators

Where the generation of new test or other data, or the more detailed assessment of existing data, leads to new or better information on the hazardous properties of a chemical, this may lead to the revised classification of that chemical under the CLP Regulation. This in turn should result in benefits through a better understanding of the conditions of use that will ensure that potential health or environmental risks are controlled or minimised for both the chemical itself and mixtures based on the chemical. Information on these safe conditions of use would be provided to downstream users through the extended SDS, which detail the associated exposure scenarios and recommended risk management measures.

In order to assess the extent to which REACH may trigger benefits through improved classification of substances, information would ideally be collected on:

- The number of newly classified substances; and
- The number of substances which have changed classification as a result of new information.

In addition, the degree to which there is an increase in the level of harmonisation of classifications across manufacturers and importers may also be an indicator of potential benefits, through increased clarity for downstream users of the substance (or mixture) on its properties and hence safe use.

Generation and/or publication of new substance data is an expected benefit of REACH leading to an increase in the quality of the substance data. Introduction of RMM to control exposure as well as the introduction of “uses advised against” is expected to decrease the risk, as characterised by the Risk Characterisation Ratio (RCR).

4.2.2 Expectations Prior to REACH

In the Impact Assessment (RPA, 2006²) on implementing the Globally Harmonised System for the classification and labelling of substances and mixtures in the EU (i.e. the CLP Regulation), a range of calculations were undertaken to estimate the number of substances that would be newly identified as “dangerous” (i.e. the term used instead of hazardous under the Dangerous Substance Directive) or that would change classification due to new information becoming available as a result of REACH. Based on data for new substances, the starting assumption was that 70% of the total number of substances has one or more dangerous properties. Of these substances (RPA, 2006):

- Some are already known as “dangerous” on the basis of good existing test data (substance type 1);
- Some are known as having one or more “dangerous” properties on the basis of existing, poor data (type 2);
- The remaining proportion is composed of substances that are not currently known to be “dangerous” but will be identified as such through new information (type 3).

Table 4.2 below presents the estimated percentage of substances belonging to each of these categories by production tonnages (please see RPA, 2006 for further details of how these figures were derived).

Substance type	1-1,000 t/y	>1,000 t/y
1 (good test data)	11.9%	15.4%
2 (poor data)	35%	35%
3 (not identified yet)	23.1%	19.6%
4 (not dangerous)	30%	30%

The substances belonging to the first and second type (good and poor test data), i.e. already known as having dangerous properties, would be subject to classification and labeling under CLP before and/or after their registration under REACH. Substances of the third type would be subject to classification and labeling after their REACH registration. Table 4.3 shows the predicted number of substances by type after combining the Table 4.2 percentages with estimates of the total number of substances assumed to be placed on the market in the EU as part of the REACH Impact Assessment (based on JRC, 2003). As can be seen from Table 4.3, it was therefore predicted that around 6,700 substances in total would be identified as having new classifications for dangerous properties as a result of new information becoming available through REACH.

² RPA (2006): *Impact Assessment of Implementing GHS: Work Package 1*, prepared for DG Enterprise and Industry, April 2006.

	<10	10-100	100-1,000	>1,000	Total
Number of substances	19,200	4,977	2,461	2,704	29,342
1 (good test data)	2,285	592	293	416	3,586
2 (poor data)	6,720	1,742	861	946	10,270
3 (not identified yet)	4,435	1,150	568	530	6,683
4 (non dangerous)	5,760	1,493	738	811	8,803

Source: RPA (2006): Impact Assessment of Implementing the GHS

The study further assumed that around 20% of the well known dangerous substances and 40% of the substances for which poor test data are available will change their classification after registration. Table 4.4 applies these proportions across the different tonnage bands.

Substance types	<10	10-100	100-1,000	>1,000	Total
1 (good test data)	457	118	59	83	717
2 (poor data)	2,688	697	344	378	4,108

4.2.3 REACH Baseline Study Outputs

From the REACH Baseline Study³ and the 2011 updated version, it has been possible to carry out an analysis of changes in RCR, data quality and classification (DPD). The baseline study encompassed 237 reference substances. The update study in 2011 included 71 of the 237 reference substances. The remaining substances are not yet registered.

Changes in Risk and Data Quality

The REACH baseline study has been updated after 5 years: the Risk Scores and the Quality Scores (and the related figures) were calculated to establish the situation in 2011 and can be compared with the figures of 2007. For further details of the approach adopted for these purposes, please refer to the full study results.

Key findings of the update can be summarised as follows.

- The Risk Score is derived from the Risk Characterisation Ratios (RCR) multiplied with a Population Risk Modifier (PRM), indicating how common the use of a chemical is – where a high value indicates a widely used chemical. Note that different approaches have been used for calculating the PRM for the impact areas related to the environment and the workers. The Quality Scores have a value between 1 and 100. A low value indicates a good data quality. The observed changes in RCR, Risk Scores and quality scores are shown in Table 4.5.

³ Oko-Institut, FoBiG, DHI and INERIS (2011): REACH Baseline Study: 5 Years Update, Progress Report IV, Eurostat study Reference No 2010/S 167-255573, Freiburg, December.

- A marked decrease in the Risk Scores was found for the aggregated evaluation of 62 substances (46 HPV chemicals and 16 SVHC). The decline in Risk Scores is almost entirely due to decreases in RCR. Further analysis showed a pronounced reduction of the fraction of substances with RCRs above 1 and/or RCRs above 10 for all four impact areas. For almost all substances, changes in at least one of the key input parameters for the RCR (toxicity and exposure estimates) reflected additional information on hazard and use of the substance. This included both more information on exposure, e.g. a refined assessment showing lower exposure and better information on hazard properties where a refinement may give a lower DNEL. Consequently the results of the update of the REACH Baseline study showed a marked decrease in the nominal risk associated with the registered reference substances, a result which is believed to be due to the assessments made in the REACH registration process.
- The quality of the underlying data was considerably improved, expressed in a reduction of the Quality Score from 2007 to 2011. The improvement in quality was evident in all four impact areas. For the majority of HPV chemicals and SVHC, the quality of the data underlying the estimate of the exposure and of toxicity was improved because more data on hazard properties and more detailed information on uses have become available for a large number of substances.
- In 2011, a remarkable number of reference substances still showed RCRs above 1. This is mainly due to four reasons:
 - the REACH Regulation does not require a chemical safety assessment (intermediates);
 - the REACH Regulation does not require an exposure assessment and risk characterisation of non-classified substances;
 - the limited scope of exposure assessment by some registrants.
 - the absence of or poor quality DMELs for SVHC.

In most of the CSRs analysed, no quantitative risk assessments have been made for the impact areas related to consumers and humans via the environment.

Table 4.5: Observed Changes in RCR, Risk Scores and Quality Scores								
	RCR		PRM		RISKSCORE		QS_{total}	
	2007	2011	2007	2011	2007	2011	2007	2011
HPVs								
Workers								
Median (n=46)	0.86	0.78	5.0	7.0	4.5	5.4	30	14
GM (n=46)	2.5	0.99	5.5	6.0	14	6.0	21	11
Environment								
Median (n=46)	0.058	0.022	2.3	1.0	0.12	0.086	9.4	3.8
GM (n=46)	0.084	0.059	2.5	1.9	0.21	0.12	12.2	3.8
Man-via-the-environment (n=16)								
Median	-	-	-	-	302	11.4	37	13

Table 4.5: Observed Changes in RCR, Risk Scores and Quality Scores								
	RCR		PRM		RISKSCORE		QS _{total}	
	2007	2011	2007	2011	2007	2011	2007	2011
GM	-	-	-	-	368	10.6	34	15

<i>SVHC</i>								
Worker								
Median (n=16)	670	8.3	6.0	6.0	3300	33	24	12
GM (n=16)	220	7.4	5.9	5.2	1300	38	21	10
Environment								
Median (n=16)	1.6	0.056	3.7	1.0	4.8	0.092	11.7	3.0
GM (n=16)	10	0.090	3.0	1.3	3.2	0.13	9.9	3.5
Man-via-the-environment								
Median (n=16)	-	-	-	-	3137	513	27	14
GM (n=16)	-	-	-	-	9193	856	31	16
<i>HPV+SVHC</i>								
Consumer								
Median (n=20)	-	-	-	-	19	2.2	64	14
GM (n=20)	-	-	-	-	9.8	1.9	48	15
<i>Source:</i> REACH Baseline Study 2007 and the 2011 up-date (pre-publication)								

4.2.4 Changes in Substance Classification

Using data from REACH Baseline Study for 2007 and the updated study carried out in 2011, we have carried out our own further analysis to assess the degree to which there have been changes in classifications of substances to date⁴. This assessment compares the classifications of the 71 reference substances considered in the REACH Baseline Study as indicated in their registration dossiers compared to classifications under the Dangerous Substances Directive. The findings of this analysis are given in Table 4.6.

It should be noted that, of the substances reviewed in the REACH Baseline Study, 21% were not classified before REACH registration. After REACH registration this number decreased to 11% of the substances. Probably this is because more data on hazard has become available during the registration process triggering classification for endpoints that were not previously classified (mainly due to a reliance on self-classification). From the table, it can be seen that the percentage being classified within the various groups has increased with registration. It can also be seen that although some of the self-classifications have become less restrictive, a higher number have become more restrictive.

⁴ This has been possible because of DHI's involvement in both studies and with the permission of EUROSTAT.

Table 4.6: Changes in Substance Classification – Further Analysis of Baseline Study Information										
	Physical hazard	Acute toxicity	Acute toxicity – irreversible damage after single exposure	Repeated dose toxicity	Irritation / Corrosion	Sensitisation	Carcinogenicity	Mutagenicity – Genetic Toxicity	Reproduction toxicity	Environment
% classified substance (before registration)	21	41	0	6	49	15	21	7	4	32
% classified substance (after registration)	27	51	0	15	52	24	23	13	13	51
% with no changes	58	39	-	36	41	41	50	56	22	28
% Less restrictive	16	22	-	0	43	6	38	0	11	28
% More restrictive	26	44	-	64	19	59	25	44	78	58
<i>Source:</i> The above analysis has been carried out for the purposes of this study, but draws on the 2007 and 2011 up-date of the REACH Baseline Study										

4.2.5 Information from Discussions with Industry

The hypothesis put forward to consultees was that the generation of new (test) data will lead to improved information on the properties of chemicals, which may in turn lead to revised classifications. This would have the following benefits:

- The classification of individual chemicals will become more reliable, providing downstream users with improved information on hazards;
- More reliable classifications will act as the basis for the exposure scenarios, improving the quality of recommendations on safe use and handling and appropriate risk management measures; and
- New classifications will feed across into other legislation, with this creating indirect benefits.

Several examples of revised classifications stemming from the work carried out to fulfill REACH requirements were identified from the consultation exercise. For example, companies noted that new data has been generated for some substances resulting in new classifications, while others indicated that classifications may change in the future depending on the outcome of any further testing that is undertaken.

In most cases, changes in classification were due to the **harmonisation of self-classifications** across different companies in response to the 2011 CLP Classification and Labelling Notification process. In particular, a representative of the precious metals sector indicated that the sector took advantage of the 2011 deadline to up-date

all of its classification data and to ensure that all substances not previously classified were classified and that there was a harmonized classification across companies. This was considered possible due to the creation of SIEFs under REACH, which enabled the adoption of a coordinated group approach to classification.

Another company indicated that it agreed to the harmonisation of the classification for two of its substances as a Reprotoxin Cat 1b based on the data generated through the SIEF for the corresponding Chemical Safety Reports; previously, it had not classified this substance as a Reprotoxin. A metals industry association also indicated that it has changed the classification for one of its substances as a result of information brought together for REACH registration purposes. In this case, the self-classification of the substance is one which is more hazardous than as applied under its CLP Annex VI listing (and previous DSD Annex I listing).

A number of companies stated that the registration and discussion in SIEFs was helpful because the existing data on substances has been re-evaluated and also tests that existed, but were not available before REACH, were used for the hazard assessment and classification. Hence, data has been consolidated, resulting in an overall increase in the reliability of the basis for self-classification and labeling, as well as for the derivation of DNELs and PNECs. It was also stated as helpful that the information is now “in one place”. The process of agreeing on a harmonized classification in the SIEF was also seen as successful in general.

One manufacturer reported that in the SIEF an existing harmonised classification was questioned and contradicted by the data collated – a less strict classification was derived from the assessment of information. However, due to the requirement to use a legal classification (i.e. a CLP Annex VI classification) if that is available, the SIEF participants now have to classify differently than is suggested by the result of their assessment. These consultees suggested that there should be a mechanism in place for the downward revision of classifications as a result of the new information generated through REACH (and not only the more stringent classification), even if this implies that other legislative controls such as those for worker health and safety should also be relaxed.

Another company noted that REACH has forced people to do more work on some of the lower volume metal substances that would not necessarily have been done otherwise. Prior to REACH, there was no legal pressure to have the same level of knowledge for some of these lower volume substances. As a result, in their view, REACH has been valuable in acting as a trigger for ensuring that the science surrounding the properties for some of these materials is improved and for ensuring that they are properly classified; the respondent also noted that this work is resulting in some changes in classification and will result in changes in recommended risk management measures when the substances are registered. These changes will help ensure both protection of worker safety but also the environment.

Such changes in classification are triggering companies to take action in relation to either the recommended risk management measures included as part of their extended SDS, or as a downstream user in response to the SDS and exposure scenarios that they receive. However, some downstream users reported that they receive different

classification information on a single substance from different suppliers. Moreover, due to the change of classification systems and discrepancies in classifications listed in different publicly available sources, formulators in particular are currently having difficulties in deciding which classification should be communicated with the mixtures, whether this should be the most stringent classification or one which is less stringent given that there may be good reasons for differences in classifications.

Classification issues were not directly addressed through the competitiveness or innovation surveys and from the data provided by CSES, none of the responses that included reference to classification are relevant to the issues discussed here.

4.2.6 Linkages to Other Pathways and Benefits

Clearly, the requirement for notifications of classifications in 2011 under the CLP Regulation has in itself resulted in efforts being put into providing better information on the hazard properties of chemicals placed on the market in the EU. It has resulted in the classification of substances that were not previously classified. The timing of CLP notification requirements with REACH SIEF activities has also, in at least a few cases, led to an increasing level of harmonisation in self-classifications prior to formal REACH registration.

One industry association noted though that information in relation to classifications needs to be analysed carefully and any conclusions drawn with respect to changes in classification should be caveated. It is reviewing information in the REACH IT and is sometimes finding that there are 10 to 15 classifications for the same substance. In its view, this reflects confusion with respect to substances that are actually being differently classified across their varying forms (e.g. hydrate versus anhydrous forms). The association would like to be able to explain why there are different classifications (to avoid a worst case approach being adopted) and to provide a basis for better communication on this issue; for example, there was no field in the REACH IT to allow different classifications to be entered for different substance forms.

4.2.7 Conclusions

Based on our own analysis of the findings of the REACH Baseline Study, it is clear that the information being generated from REACH is resulting in changes in classification, with the majority of these being more restrictive classifications. This is particularly noticeable for endpoints such as acute toxicity, sensitisation, reproductive toxicity and the environment. Overall, the percentages classified after registration increased across all endpoints being considered. However, it is also of note that some of the classifications have become less restrictive, as indicated in Table 4.7 above.

None of the interviewees for this study could specify the number of new classifications that had arisen across their substances, but the majority was of the opinion that only a few new classifications have occurred. This is mainly because the substances registered to date already had high levels of data available before REACH. Where classifications do change, interviewees anticipated that these would be mainly in relation to the environment.

More generally, the above findings support the main work hypotheses.

- Classifications would appear to be becoming more reliable as more and improved information on substances properties is generated and as registrants harmonise classifications. There are some outstanding issues, such as the continued existing of multiple classifications which is giving rise to problems for formulators, but these should be reduced over time as more substances go through registration.
- As noted above, changes in classification are triggering companies to take action in relation to either the recommended risk management measures included as part of their extended SDS, or as a downstream user in response to the SDS and exposure scenarios that they receive.
- Although not identified from the above discussions, these changes in classification will feed through into other legislation. However, as also highlighted by consultees and by our analysis of the information collated by the REACH Baseline Study, not all changes are resulting in classifications becoming more restrictive. Thus, there should be the potential for authorities to recognise downward changes in classification (e.g. in respect of OELs) as well as more restrictive classifications. In other words, the information generated through REACH should provide a mechanism for relaxing risk management requirements as well as for identifying where they need to be tightened.

The analysis presented in Section 4.2.4 above illustrates the above points and supports the conclusion that benefits will arise from changes in classification. For example, the classifications for acute toxicity and repeated dose toxicity have increased markedly for both endpoints following REACH registration probably because of new data and/or the re-assessment of available data. This will be reflected in the derivation of DNELs as well as recommendations for more stringent RMM than before.

4.3 Registration and Safety Assessment in the CSR

4.3.1 Pathway to Benefits and Associated Indicators

As indicated above, changes in information on the properties of a substance and hence its classification may trigger changes in recommendations on what constitutes the safe use of a chemical and hence the risk management measures recommended to downstream users. Similarly, changes in information on the uses of a substance may result in registrants either advising against such uses or developing new recommendations on appropriate risk management measures. As such changes would be aimed at reducing exposures to a ‘safe level’, and may also result in a reduction in risks to health or the environment.

Indicators of such benefits are linked to identifying the extent to which new (test) data on chemical properties/hazards has led to:

- Changes in DNELs, PNECs, etc.;
- Changes in recommended risk management measures; and, hence
- Changes in the information communicated through the extended SDS via the exposure scenarios.

4.3.2 Expectations Prior to REACH

Data on the number of chemicals predicted as being likely to have new classifications as a result of REACH are given in Section 4.2.2, based on work done in relation to introduction of the CLP Regulation. As will be seen from Section 4.2.2, based on data for new substances, it was assumed that around 70% of all substances would be identified as having one or more hazardous properties, with 35% of substances having only poor quality information on their properties and a further 23% of substances not yet identified as having dangerous properties. The latter corresponded to around 6,700 substances as predicted to be identified as having hazardous properties through REACH.

Estimates were also developed of the numbers of substances which would be newly identified to have SVHC properties as a result of new information from REACH; and, thus, which could fall under authorisation or, where safe use could be demonstrated, would be subject to new risk management measures. In order to estimate the costs to the chemicals industry of the authorisation provisions included in REACH, the BIA⁵ provided estimates of the expected number of substances likely to be put forward for the authorisation process. The following categories were considered:

- Category 1a and 2a carcinogens, mutagens and reproductive toxins (CMRs) (Category 1 and 2 as then classified under the Dangerous Substances Directive);
- Substances meeting the criteria for being persistent, bioaccumulative and toxic (PBT) and substances meeting the criteria for being very persistent and very bioaccumulative (vPvB); and
- Sensitisers and substances with chronic toxicity or persistence.

Following consultation with industry, sensitisers and highly chronic toxic substances were not identified as requiring authorisation; instead, substances which have endocrine disrupting properties were considered to give an equivalent level of concern to the CMRs and PBTs.⁶ Table 4.7 below shows the estimates for these categories and the sources of information. Note that these figures suggest a maximum of 4,510 substances which might meet the criteria for authorisation. However, there is likely to be overlap between the categories (e.g. between CMRs and sensitisers). Thus, these figures are consistent with those quoted above of some 6,700 substances being newly

⁵ **RPA and Statistics Sweden (2002):** *Assessment of the impact of new regulations in the chemicals sector*, prepared for DG Enterprise, May 2002, p89.

⁶ **RPA (2003):** *Revised Business Impact Assessment for the Consultation Document*, prepared for DG Enterprise, October 2003.

identified as dangerous and some 10,270 substances having improved data which indicates that they have hazardous properties.

Table 4.7: Estimated Number of Substances of Very High Concern		
Categories	Estimate	Source
CMRs	1,400 substances: 850 currently known plus another 500 to be identified	White Paper of the European Commission ⁷
PBTs and vPvBs	2,000 substances	Working group and OSPAR provided a figure at around 70; the Danish EPA, using a QSAR, predicted a rough figure of 2,000
Sensitisers and substances with chronic toxicity or persistence	550 - unknown	90 respiratory sensitisers plus 16 skin sensitisers plus 49 hazardous chronic toxic substances, plus 400 already classified as skin sensitisers. An unknown number to be identified through registration
Endocrine disruptors	560 substances	List of priority substances for further evaluation of their role in endocrine disruption (COM (2001)262): 550 man-made substances plus 9 synthetic/natural hormones.

4.3.3 REACH Baseline Study

Aim of the REACH Baseline study was to develop an indicator system being able to monitor the impact of REACH. A set of indicators were developed and data were collected to establish the baseline (i.e. before the first registration deadline):

- Administrative indicators: these are used to monitor the REACH process. They refer to the registration, evaluation, authorisation and restriction steps defined by REACH;
- The risk & quality indicator system (R&Q): this system directly tracks two major goals of REACH: reduction in the nominal risks of chemicals for humans and the environment as well as improvement in the quality of available data;
- Supplementary indicators: these indicators address specific objectives of REACH not yet covered by the other two indicator types (e.g. increase in quality of safety data sheets, changes in classification and labeling, changes in use patterns in Scandinavia (via the database SPIN), use of alternative methods for assessment of chemicals instead of animal testing). They can support specific findings from the risk & quality indicator system.

The R&Q indicator system was designed to cover the main impact areas: workers, consumers, environment, general public via the environment.

⁷ CEC (2001): *White Paper – Strategy for a Future Chemicals Policy*, European Commission, Brussels.

Substances were divided into 4 groups:

- HPV - High Production Volume Chemicals (more than 1000 tonnes/year);
- MPV – Medium Production Volume Chemicals (100 - 1000 tonnes/year);
- LPV – Low Production Volume Chemical (10 - 100 tonnes/year); and
- SVHC – Substances of Very High Concern.

The REACH Baseline Study randomly selected a subset of substances within each of the four groups, resulting in a set of 237 reference substances.

The R&Q indicator system assesses the nominal risk of exposure to chemicals and identifies the quality of the data on which this risk assessment is based. Such parameters were calculated for the baseline (2007) and they will be followed over the next implementation phases of the Regulation.

The R&Q indicator system permits relative comparisons of changes in the risk and in the quality of information between substances from the different production bands (HPV, MPV and LPV) as well as SVHC. It does not provide results on the absolute and “real” risk at the baseline or in the future, but the calculated risk figures are in correlation with a plausible risk profile.

The measure of the parameters at the baseline showed that the highest quality of data was observed for HPV and the SVHC chemicals.

The Baseline study was updated in 2011 using registration data for the reference substances actually registered in 2010. Changes in data quality and risk characterisation ratios were evaluated.

4.3.4 Discussions with Industry

The consultation exercise focused on the hypothesis that the requirement for a chemical safety assessment creates benefits, as fewer unsafe uses occur because:

- Uses where adequate control of risks cannot be demonstrated are not supported;
- Risk management measures are (newly) identified and communicated so as to ensure safe use;
- Manufactures learn more about uses and can better target their information provision to critical aspects / give more realistic advice; and
- The new requirements for waste management advice ensures that it is more specific and thus that there is safe disposal.

Uses Advised Against

Few registrants or downstream users indicated that they had indicated or had observed an explicit “use advised against” for particular uses of a substance in its registration or its safety data sheet. One interviewee noted that a use may be advised against in one

dossier but not in another for the same substance, where more than one CSR has been submitted for the same substance by different registrants.

Another consultee observed that substances classified as sensitisers are frequently not supported for consumer uses (anymore); however no reasoning to support this was provided and hence it is not clear if this is founded on an assessment or is simply a precaution or simply the decision of this company. It was also observed by some interviewees that for substances classified as CMR there may be cases where use in consumer products is advised against (e.g. for Category 2 CMRs).

Other consultees replied that uses that were supported before the registration are not listed in the identified uses in the SDS anymore because the registrant does not regard them as “critical” to his main markets. It is therefore left up to the downstream users in such cases to either check that they are within the exposure scenarios set out in the eSDS or to notify ECHA themselves.

Identification of New Risk Management Measures (RMMs)

Responses to these questions are in part linked to those given above with respect to changes in the classification of substance. For example, in response to the new classification of two of its substances as reprotoxicants, one company referred to above is adopting more stringent risk management measures within its own production facilities to ensure reduced worker exposures. As this company is a manufacturer under REACH, it has similarly specified more stringent risk management measures in its extended Safety Data Sheet for the substance.

Across the manufacturers and importers that were interviewed, the results and experiences of preparing the chemical safety assessment were evaluated as follows:

- There was little time to work on the safety assessment of uses;
- Information from downstream users was in most cases not helpful (e.g. too detailed regarding uses) for use in the chemical safety assessment;
- In most cases, ECETOC TRA or EUSES were used applying generic information and assumptions to derive the conditions of safe use;
- Due to the high degree of conservatism regarding both the PNECs/DNELs and the assumptions on uses, the resulting RMMs were much more severe than those implemented before REACH;
- These stricter RMMs are not always regarded as useful, as no “real risk is expected” given that they are often based on default values. As a result, some interviewees indicated that the stricter RMMs are also unlikely to be implemented in practice;
- In other cases, RCRs exceeding 1 were accepted in order to get the registration done; and
- Registrants are now starting to update their dossiers to improve the assessments.

Consequently, the process is seen as difficult and complex and at the same time too general; hence no meaningful results are stated to have been derived in many cases. The high number of uses of substances makes it difficult for the registrants to provide good quality assessments in the available time. Nevertheless, three consultees mentioned that the CSA is useful, because it forces them to adopt a different perspective on the uses and to consider the RMMs along the supply chain and that this leads to better advice to customers.

In contrast to the above consultees, one interviewee stated that the CSAs did not lead to changes in how to handle substances or to the identification of new RMMs. The RMMs and operating conditions as well as occupational exposure limit values were known previously. The only new information was when to actually apply the measures; consequently, the CSR did not lead to the identification of new information on operating conditions, RMMs but to a better targeting of their application. (This is of course not unexpected as REACH was not expected to lead to significant changes across the set of higher tonnage substances.)

The interviews give the impression that the classification of substances is a more important trigger for the recommendation of new RMMs than the chemical safety assessment.

The derivation of DNELs and PNECs was seen as critical by many consultees: the hazard information was observed as having “not been used correctly” (no explanation of what went wrong) and the resulting values contradict e.g. OELs (DNELs were higher or lower). Furthermore the safety factors are regarded as leading to too low values and hence too conservative assumptions on risk. Particular difficulties were reported for UVCB substances, where guidance is lacking and opinions of Member States have been found to vary significantly.

With regard to the environment, registrants and downstream users stated that the chemical safety assessment resulted in the derivation of very low use amounts rather than in the identification of risk management measures.

Better Targeting of Information

The approach to group working for classification purposes described above by the precious metals representative to group working for classification purposes was also credited with enabling the formalisation of risk management measures already in place in all facilities pre-registration (although most facilities already had in place rigorous worker protection controls). This included allowing for more harmonized actions in terms of packaging and transport of substances. The representative believes that there was value in this exercise as it helped ensure that all companies were adopting the same types of measures to reduce exposures, with this particularly important for those substances that have not yet been registered under REACH.

Another manufacturer noted that the requirement to provide downstream users with formal recommendations on risk management measures was an important element of REACH, and a requirement which did not exist previously. Although most of its downstream users already had appropriate measures in place (e.g. local exhaust

ventilation or personal protective equipment), at least one customer was making changes to its existing worker protection measures and now recognized that this was needed. This manufacturer has taken a proactive approach to ensuring that its downstream users understand the information provided in the exposure scenarios included in the eSDS, meeting with customers individually. At these meetings, they also discuss other additional actions that companies could and should undertake for both worker and environmental protection reasons, including increased monitoring for example.

Issues Surrounding eSDS

As discussed in Section 5 on supply chain communication, there is concern that some of the benefits arising from changes in recommended RMMs are being lost or are even being negated at present due to problems surrounding SDS. Many downstream user consultees expressed the view that the SDS are not very readable or user friendly; although best practice is evolving there is a long way to go for them to become the tool that was desired. This view would appear to be shared by respondents to CSES' Competitiveness and Innovation Surveys.

Although respondents noted that a potential way of better targeting SDS towards downstream users would be the use of electronic supply systems, they also highlighted the legal liability issues associated with ensuring that the DU actually downloads and reads the SDS for demonstration of compliance. Thus, consultees believe the conflict between ease of access for downstream users versus placing a legal obligation on manufacturers and importers to ensure information is received needs to be addressed. On the other hand, it was noted that electronic versions may not be readily available on the 'shop floor' to workers and thus not accessible when there is a query or an issue in the workplace. However, greater use of electronic versions may make it easier for formulators to develop more targeted SDS for their customers.

Up-dates of RMMs

One association highlighted the fact that it is not clear what part of the registration number should go on an SDS, etc. Because of this, and the lack of a central system where such data is registered for use by Inspectors and Customs officials, it is easy for a free-rider to just take the number from someone else and use it; in other words, people other than the registrant have access to the numbers and there is a threat of mis-use. Where such free-riding occurs, there may also be the potential that recommended risk management measures are not as stringent as those proposed by the legitimate registrants, or that RMMs are not up-dated as new information becomes available.

A related issue concerns how it can be guaranteed that all suppliers will up-date information on exposure scenarios and risk management measures in response to up-dates of dossiers or to the findings of new testing. Where letters of access to a dossier have been issued, the share of registration costs indicated in the letter may either not be sufficient to cover the costs of additional testing requirements as determined by ECHA or cover the costs of any additional works stemming from Evaluation. Unless

ECHA releases a new ‘token’ number for the registration, there is no way for the lead registrant to force those who previously paid for a letter of access to gain a new letter or to pay for the additional testing. Similarly, there is no way of ensuring that all original registrants up-date their exposure assessments and risk management measures to take into account test results.

4.3.5 Responses to Other Consultations: Impacts on Competitiveness and Innovation

CSES Competitiveness Survey

Manufacturers

The CSES survey on Competitiveness⁸ asked respondents a series of questions about the level of contribution of REACH to different types of benefits for their business. Manufacturers in general responded negatively with respect to the extent to which the different benefits have been realized, with the majority indicating that they did not believe that significant benefits had yet occurred (Table 4.8).

Benefit	Manufacturers/ Importers
Increased confidence of consumers	7%
Increased knowledge on properties and/or possible uses	23%
Improvement in risk management procedures in own business	13%
Reduction of the costs and damages related to occupational health and safety	3%
Total number of respondents	296
<i>Source: Based on raw data from CSES Survey on Competitiveness</i>	

To a degree, some of the responses to the CSES Competitiveness Survey are not surprising. Substances registered in the first round of REACH will have been those for which the greatest level of data was already available, either due to their CMR or highly aquatic toxic properties or due to the fact that they had been subject to data collection and assessment under other regimes such as the OECD HPV Programme. Thus, one would not have expected there to be a significant increase in knowledge on properties, and hence changes in risk management or reduction in occupational health and safety risks for this set of chemicals. Such benefits are much more likely to be realised in relation to chemicals yet to be registered.

Some of the industry comments summarized in Section 4.3.4 regarding eSDS are mirrored by the responses of manufacturers to the CSES Competitiveness Survey. For example, 233 out of 295 manufacturers/importers responding to the CSES survey indicated that the information requirements for the eSDS were difficult to fulfill (agreed or strongly agree); while 276 responded that eSDS are long and complex

⁸ CSES (2011): Impact of REACH on single market and competitiveness, draft report to DG Enterprise, December 2011.

(agree or strongly agree)⁹. Interestingly, 239 indicated that there was not enough time to develop eSDS before the deadline of 1st December 2010.

Responses from formulators were similar, with 82% indicating that information requirements were difficult to fulfill, 88% indicating that they were long and complex, but only 59% indicating that there was inadequate time to develop these before the December 2010 deadline. Unsurprisingly, distributors also noted the same issues, with 79% indicating the data requirements were difficult to fulfill, 81% that they are overly long and complex and 74% indicating that there was inadequate time to prepare these before the 1st December 2010.

CSES Innovation Survey

The most relevant question from the CSES Innovation Survey¹⁰ to this study is that on whether:

“REACH-related factors such as in Chemical Safety Reports or Safety Data Sheets, or other communication throughout the supply chain lead to any changes in work organisation (e.g. production processes or material handling) at your firm?”

Out of the 577 respondents to the survey, 182 indicated no while 152 indicated yes (with the remainder either leaving the question blank or responding with ‘don’t know’). Scanning through the responses of those that said yes, indicates the following types of measures were taken as a result:

- Changes in RMMS, for example confining particular substances, changes in handling activities, etc.;
- Changes in production processes;
- Changes in information provided to employees, increases in staff training;
- Greater awareness of potential dangerous consequences associated with particular chemicals;
- Investment in know-how, software and hardware for SDS, changes in archiving systems; and
- Changes in monitoring of emissions within the workplace.

Others noted that their changes had led to reduced flexibility, to an increase in costs, and to an increase in compliance checks.

4.3.6 Linkages to Other Pathways and Benefits

There are clear linkages between the classification of chemicals and the registration requirements of REACH in terms of the delivery of benefits to health and the

⁹ This analysis, as well as that for the Innovation Survey, was carried out on the raw survey data provided by CSES to RPA. RPA alone remains responsible for the analysis of the data and its interpretation.

¹⁰ CSES (2011): Impact of the REACH Regulation on the innovativeness of the EU chemical industry. Draft Final Report to DG Enterprise, December, 2011.

environment. The need to notify classifications under CLP has led to some changes in classification on its own, while the generation of new information through REACH is also leading to changes in classifications. As noted above, this includes changes in classification which include both more and less restrictive classifications against certain end-points. Indeed, more than one interviewee highlighted that the change in classification had implications for harmonised classification and labelling in Annex VI of CLP. REACH and CLP are acting together to impact on the types of risk management measures being recommended in extended SDS, and hence in the actions being taken by manufacturers, importers and downstream users of chemicals. However, the interviewees also noted that, where classifications become less restrictive, this should be picked up through changes to other legislative requirements, such as in occupational exposure limits at the national or EU level.

There are also clear linkages between registration as a driver and requirements regarding the communication of information through the supply chain. These are picked up in more detail in Section 5.

4.3.7 Conclusions

The general hypothesis examined here is that the requirement placed on registrants to prepare a Chemical Safety Assessment as part of the Chemical Safety Report, where this applies, should lead to benefits through a reduction of unsafe uses. The above discussion generally supports this hypothesis.

- There are some cases where uses are being “advised against” in the registration dossiers and associated SDS, although few such cases have been identified to date. It is more common for an eSDS to not cover all existing uses, with downstream users then having to notify their uses to their suppliers (see also Section 5).
- It is clear that through the new information being generated for registration purposes, the classifications of substances are changing and this in turn is leading to recommendations for more stringent risk management measures. However, in some cases, the RMMs are also becoming more stringent as a result of adopting default assumptions being adopted in the exposure assessments being carried out for the CSA, with this leading to overly stringent measures.
- It has also be hypothesized that by collecting information on uses, manufacturers and importers will learn more about uses and can better target their information provision towards reducing risks. There is currently more limited support for this hypothesis, as there is less evidence that the anticipated exchange of information has occurred, with communication up the supply chain (from users to suppliers) considered less successful (see Section 5 for a fuller discussion). However, downstream users are notifying their suppliers of uses not covered by exposure scenarios, with this leading to an up-date of CSA and the identification of risk management measures.

- With regard to advice on waste management becoming more specific so as to ensure safe disposal, it is too early to tell whether this will create benefits as most interviewees noted that work on this aspect is still underway or has only recently been completed.

Overall consultees agree that the requirement for CSAs will deliver benefits, particularly for substances registered at between 10 and 1000 tonnes and that formal recommendations on risk management measures are of value to downstream users. They also agree that there is value in ensuring that all users are adopting the same types of measures, or at least the same level of control (e.g. for local exhaust ventilation and on emissions to the environment), to reduce human and environmental exposures.

4.4 Registration and Substance Withdrawal

4.4.1 Pathway to Benefits and Associated Indicators

Prior to REACH it was argued that the registration provisions, as well as the requirement to demonstrate the safe use of chemicals, may lead to some substances being withdrawn from the EU market for economic reasons. This may result in either reduced tonnages of substances with hazardous properties being placed on the market, or the overall withdrawal of substances having particular properties of concern (e.g. carcinogens, highly toxic substances, PBTs, etc.). Withdrawn substances (regardless of the reason for withdrawal, as many may be withdrawn to rationalise product portfolios) may be substituted by less hazardous alternatives. This substitution may take place across all uses or be only partial, with withdrawal affecting only certain uses; for example, a substance may be registered for use as an intermediate but not registered for professional uses where the latter may give rise to human health or environmental risks. This is one of the pathways through which REACH benefits are expected to arise: due to lower exposures to hazardous substances risks to human health and the environment should be reduced.

As an indicator of benefits, substance withdrawal where accompanied by a move to less hazardous substances may therefore be linked to three potential benefit drivers:

- Registration requirements, and in particular the generation of data on intrinsic properties of substances;
- The need to demonstrate safe use of a chemical, as part of the chemical safety assessment (with this further linked to provisions regarding the development of exposure scenarios and the need to identify risk management measures (RMMs) to ensure safe use); and
- The provisions regarding authorisation, as the potential for candidate listing and prioritisation of substances which may meet the criteria for being Substances of Very High Concern, may have an impact on the future marketing and use of a substance.

4.4.2 Expectations Prior to REACH

The Revised Business Impact Assessment (Revised BIA, prepared in 2003 by RPA)¹¹ provided estimates of the total number of chemical substances that might be withdrawn from the EU market as a result of REACH, with these findings based on consultation with industry and the findings of the earlier BIA work. Table 4.9 below presents the estimated number of phase-in chemicals placed on the market, together with the estimated percentages and corresponding numbers of substances that might be withdrawn from the market by tonnage over the course of REACH implementation (i.e. from adoption to 2018).

Tonnage	No. of chemicals on market	% withdrawn	No. of chemicals withdrawn from the market (rounded)
>1,000 t/y	4,338	0%	0
>100 t/y	3,014	5%	150
>10 t/y	5,846	10%	600
>1 t/y	18,696	15%	2,850
Total	31,894	11%	3,600

Source: RPA (2003): Revised Business Impact Assessment for the Consultation Document, prepared for DG Enterprise, October.

The Revised BIA was only one study which examined the potential for substance withdrawal. Several other studies were carried out by industry organisations which predicted much higher rates of withdrawal from the market, mainly for economic reasons, with this predicted as leading to impacts on the manufacturing sector as reflected by losses in gross added value and jobs¹². The Commission carried out its own assessment in response to these concerns, which used a microeconomic model to predict the reaction of the chemical manufacturers and downstream users to the additional costs to test and register the substances (Canton and Allen, 2003¹³). It concluded that while some substances might be withdrawn from the market, their number would be limited¹⁴. Through the model, the authors simulated the increase in chemical costs arising from testing and registration: these costs would be passed to downstream users in the form of higher prices of chemicals and costs stemming from the need to substitute those chemicals withdrawn from the market. The results of the

¹¹ RPA (2003): Revised Business Impact Assessment for the Consultation Document, prepared for DG Enterprise, October, p.27.

¹² ADL (2003): Economic effects of the EU substances policy, Supplement to the report on the BDI research project dated December 2002, August 2003 and Mercer Consultants (2003): Study of impact of European Chemicals Policy, March 2003.

¹³ Canton and Allen (2003): A microeconomic model to assess the economic impacts of the EU's New Chemicals Policy, prepared for DG Enterprise, November 2003.

¹⁴ Extended Impact Assessment of REACH (2003): *"REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants" – Extended Impact Assessment*, Commission staff working paper, 2003, p. 15.

model indicated that even under a “higher substitution costs” scenario, just 1-2% of all substances would have been withdrawn from the market.

Thus, based on such findings, one could suggest that if significant levels of substance withdrawal are identified, these may be more due to hazard and risk considerations than economic reasons alone. Where substances with hazardous properties are withdrawn, their substitution by less hazardous substances may lead to health and environmental benefits.

4.4.3 Indications on Withdrawals from an Assessment of Registration Data

In response to the Directors Contact Group, ECHA has published (21 September 2011) a note reporting on the gap between pre-registration intentions and actual registrations within the first deadline, which indicates that there is a gap of about 1500 substances, or roughly 30% of all the intentions. This note sets out the list of those substances that were identified to be registered by the first registration deadline but have not been registered yet.

Unfortunately, ECHA was unable to mandate that companies indicate why they were not registering their substances within the first deadline; furthermore the categorisation system used by ECHA does not specifically identify whether there was a health or environmental hazard reason for not registering. However, it is possible to analyse the data presented in the spreadsheet to some degree. Key statistics on these circa 1500 substances are as follows (bearing in mind that itself ECHA notes that explanations exist for the majority but not all substances):

- 34 substances were indicated as being “dropped” (no market / other reason);
- 274 substances were not registered as they were later identified as being “exempt from registration / not in the scope of REACH”;
- 551 substances were not registered for “reason unknown”;
- 395 chemicals were “registered with different EC / List No.”;
- 485 chemicals had their “registration postponed”; and
- 1 substance was registered instead as a “special mixture”.

Those substances most likely to be of interest to this study are those that were “dropped”, those not registered for “reason unknown” and possibly those which had their “registration postponed”. These categories, and in particular substances that were “dropped”, are most likely to include those substances which were withdrawn due to their hazardous properties, although it is also clear that some of these substances may not have been registered for economic reasons (i.e. no longer a market or the financial costs of registration are greater than the anticipated future value of sales).

Substances Withdrawn – No Market or Other Reasons

The list of substances that were “dropped” has been reviewed and a number of these are on Annex VI of the CLP Regulation EC (No) 1272/2008, have been withdrawn from use under other legislation (e.g. pesticides, cosmetics), are on the SIN 2.0 list produced by NGOs, or have had supply chain restrictions placed on their use. Table

A1.1 provided in Annex 1 to this report provides the list of such substances. Although not authoritative, Table 4.8 sets out our judgement as to the status of the 34 substances and hence the potential reasons why they may have been “dropped” from registration.

As can be seen from the Table 4.10, thirteen of the substances that were “dropped” were CMRs (Category 1a or 1b) listed on Annex VI of CLP (previously Annex 1 of Directive 67/548/EC) or have otherwise been identified as having CMR properties, and another four were listed in Annex VI of CLP for their health and environmental hazard properties. A further five of the substances have had their use restricted under other legislation, including the Biocides directive, the Plant Protection Products directive and the Cosmetics directive (although controls under this are tighter on some types of substances than REACH so it may not be a strong indicator).

Table 4.10: Potential reasons for dropping substances from Registration	
Potential reasons	No. of substances
Possible health concern (Annex VI or CMR)	13
Possible health concern (restricted under other legislation)	1
Possible health and environmental concerns (Annex VI or CMR)	4
Possible health and environmental concern (restricted under other legislation)	3
Possible environmental concern (Annex VI)	0
Possible environmental concern (restricted under legislation)	1
Potential reasons identified (total)	22
Reasons unidentified	12
Total	34

For the 22 substances highlighted in Table 4.10, REACH may have acted as a trigger for the final withdrawal of these substances from the market if pre-registration can be interpreted as indicating that there was an intention to continue placing these substances on the market. However, it may also be the case that those substances which are restricted under other legislation would have been withdrawn from the market in any case. It is less clear why the other 12 out of the 34 substances were “dropped” for either having no market or for other reasons, as we have not identified any particular hazardous properties that might make them subject to authorisation nor do they appear to be regulated under other legislation. It is therefore difficult to draw any conclusions concerning these substances.

Substances Not Registered – Reason Unknown

Table 4.11 below sets out a list of the substances that were not registered and where no reason was provided by the pre-registrant. As can be seen from this table, these substances fall into three groupings. The first group (provided in the top portion of the table) are substances which have a CMR Cat 1a or 1b classification under the CLP (Cat 1 or 2 under DSD). Ten of the 45 substances fall into this group. These substances should have been registered by December 2010 to comply with REACH requirements. It is therefore assumed here that these substances have effectively been withdrawn from the EU market either due to their properties or due to the lack of a market; this lack of market may itself be due to the substance’s properties. Indeed, in the case of lead chromate, there may be a link between non-registration and its being placed on the candidate list for authorisation (at the time when the registration would have been due).

The second group of substances is composed of those which are highly aquatic toxic and thus should have been registered by December 2010 if they are placed on the market at greater than 100 t/y. Thus, it is less clear whether these substances have been withdrawn from the market, as they may be produced at a volume lower than that which would have triggered the need for early registration.

The final group of substances are oil based substances. The classification of these substances as carcinogens is related to a possible content of benzene. If the substance does not contain benzene above a certain limit, then the substance should not be classified as carcinogen.

Table 4.11: Substances Not Registered for Unknown Reasons			
EC / List No.	CAS RN	Substance Name	DSD Annex 1 Classification
Cat 1 or 2 Carcinogens, Mutagens or Reprotoxins			
200-028-5	50-32-8	Benzo[def]chrysene	Carc. Cat. 2; R45 Muta. Cat. 2; R46 Repr. Cat. 2; R60-61 R43 N; R50-53
202-039-0	91-08-7	2-methyl-m-phenylene diisocyanate	Carc. Cat. 3; R40; T+; R26; Xi; R36/37/38; R42/43; R52-53
203-839-2	111-15-9	2-ethoxyethyl acetate	Repr. Cat. 2; R60-61 Xn; R20/21/22
211-076-1	629-14-1	1,2-diethoxyethane	F; R11; R19; Repr. Cat. 2; R61 Repr. Cat. 3; R62; Xi; R36
219-006-1	2312-35-8	Propargite	Carc. Cat. 3; R40; T; R23; Xi; R38-41; N; R50-53
231-846-0	7758-97-6	Lead chromate	Carc. Cat. 3; R40 Repr. Cat. 1; R61 Repr. Cat. 3; R62 R33 N; R50-53
232-287-5	8001-58-9	Creosote	Carc. Cat. 2; R45
244-077-0	20845-01-6	hydroxylammonium phosphate (3:1)	E; R2; Carc. Cat. 3; R40 Xn; R21/22-48/22; Xi; R36/38 R43; N; R50
274-724-2	70657-70-4	2-methoxypropyl acetate	R10 Repr. Cat. 2; R61 Xi; R37
271-084-6	68515-42-4	1,2-Benzenedicarboxylic acid, di-C7-11-branched and linear alkyl esters	Repr. Cat. 2; R61 Repr. Cat. 3; R62
Highly aquatic toxic substances			
203-486-4	107-39-1	2,4,4-trimethylpent-1-ene	F; R11; N; R51-53
203-508-2	107-64-2	dimethyldioctadecylammonium chloride	Xi; R41; N; R50-53
203-523-4	107-83-5	2-methylpentane	F; R11; Xn; R65; Xi; R38; R67; N; R51-53
205-293-0	137-42-8	Metam-sodium	Xn; R22 R31 C; R34 R43 N; R50-53
215-657-0	1338-02-9	Naphthenic acids, copper salts	R10 Xn; R22 N; R50-53
219-006-1	2312-35-8	Propargite	Carc. Cat. 3; R40 T; R23 Xi; R38-41 N; R50-53
233-307-5	10112-91-1	Dimercury dichloride	Xn; R22 Xi; R36/37/38 N; R50-53
Other Substances			
263-072-4	61789-60-4	Pitch	Carc. Cat. 2; R45
266-023-5	65996-88-5	Benzol forerunnings (coal)	Carc. Cat. 2; R45
266-025-6	65996-90-9	Tar, coal, low-temp.	Carc. Cat. 1; R45
270-738-8	68477-55-4	Distillates (petroleum), steam-cracked, C5-10 fraction, mixed with light steam-cracked petroleum naphtha C5 fraction	Carc. Cat. 2; R45 Xn; R65
271-418-0	68555-24-8	Tar acids, cresylic, residues	Carc. Cat. 2; R45

Table 4.11: Substances Not Registered for Unknown Reasons			
EC / List No.	CAS RN	Substance Name	DSD Annex 1 Classification
284-896-0	84989-07-1	Tar acids, 3,5-xyleneol fraction	Carc. Cat. 2; R45
284-898-1	84989-09-3	Distillates (coal tar), naphthalene oils, naphthalene-low	Carc. Cat. 2; R45
284-898-7	84989-10-6	Distillates (coal tar), upper, fluorene-free	Carc. Cat. 2; R45
292-611-6	90640-89-4	Distillates (coal tar), naphthalene oils, alk. exts.	Carc. Cat. 2; R45
295-304-5	91995-42-5	Distillates (coal tar), heavy oils, pyrene fraction	Carc. Cat. 2; R45
295-312-9	91995-51-6	Distillates (coal tar), pitch, heavy oils	Carc. Cat. 2; R45
295-313-4	91995-52-7	Distillates (coal tar), pitch, pyrene fraction	Carc. Cat. 2; R45
302-693-8	94114-57-5	Distillates (coal), solvent extn. hydrocracked hydrogenated middle	Carc. Cat. 2; R45
308-713-1	98219-46-6	Naphtha (petroleum), light steam-cracked, debenzenized, thermally treated	Carc. Cat. 2; R45 Xn; R65
309-889-2	101316-87-4	Tar oils, coal, low-temp.	Carc. Cat. 2; R45
309-971-8	101794-90-5	Distillates (coal tar), light oils, neutral fraction	Carc. Cat. 2; R45
310-165-3	121620-46-0	Distillates (coal tar), benzole fraction, distn. residues	Carc. Cat. 2; R45

Source: ECHA (2011): Substances identified for 2010 deadline but not registered, available from website.

4.4.4 Classifications of New Substances versus Phase-In Substances

At this point in time, an exhaustive analysis of the properties of substances registered so far is not possible. ECHA has published a list of all the registered substances¹⁵ for which the IUPAC name was **not** claimed confidential under Article 119(2)(f) or (g). This list does not include NONS substances for which no dossier has been disseminated. The last update of the list was on the 3rd of November 2011: 5,181 substances were registered of which 3,908 were publishable.

Table 4.10 shows the number of registered substances by source:

- 2,894 substances were already classified under the previous inventories established by past regulatory frameworks;
- 1,014 substances appear to be “new”, meaning that the ECHA system was not able to find a correspondent EC number.

¹⁵ Available at this Internet site: <http://www.echa.europa.eu/web/guest/information-on-chemicals/registered-substances>

As a further explanation, the substances listed with an EC number starting with 2 or 3 were included in EINECS, so they were on the European market between the 1st of January 1971 and the 18th of September 1981. The substances listed with an EC number starting with 4 were included in ELINCS, so notified and placed on the market after the 18th of September 1981 and up to 31st of May 2008. The substances listed with an EC number starting with 5 are included in the NLP list, meaning that these substances were considered to be polymers under the reporting rules for EINECS but were no longer considered to be polymers after the implementation of the new definition in the 7th amendment of the 67/548/EEC.¹⁶

When an EC number is not specified in a technically complete submission, the REACH-IT system set up by ECHA assigns automatically a list number, although this has no legal validity. It is actually possible that different list numbers are assigned to the same substance for which different identifiers were used or that a new list number is allocated to an EINECS, ELINCS or NLP list substance. When the submission provides a CAS number not linked to any EC number or other list number already allocated by ECHA, a list number starting with 6 is assigned. When the submission does not provide any CAS number, the system allocates a list number starting with 9. The substances listed with a number starting with 7 are non-phase-in substances for which a verification of the substance identification was performed.¹⁷

Unfortunately, since the C&L inventory was not available at the time of writing, it has not been possible to carry out a comparison of the hazard properties of the registered substances (phase-in and non-phase-in substances). If the C&L inventory were available and provided reliable information, it would be possible to compare the properties of new substances with those of substances withdrawn from the market. This might provide some indication of the degree to which the market is shifting towards the use of less hazardous substances or not.

EC Number	Source	No. of substances
2xx-xxx-x 3xx-xxx-x	EINECS (European Inventory of Existing Commercial chemical Substances) List	2,741
4xx-xxx-x	ELINCS (European List of Notified Chemical Substances) List	96
5xx-xxx-x	NLP (No-Longer Polymers) List	57
List Number	Source	No. of substances
6xx-xxx-x	ECHA Automatic system	347
7xx-xxx-x	ECHA Substance ID Team	277
9xx-xxx-x	ECHA Automatic system	390
Total		3908

¹⁶ ECHA (2011): Guidance for identification and naming of substances under REACH and CLP, Version 1.1, November 2011, p.10.

¹⁷ ECHA (2011): Guidance for identification and naming of substances under REACH and CLP, Version 1.1, November 2011, p.11.

4.4.5 Discussions with Industry

In order to gain a better understanding of industry's views on substance withdrawal, consultation was undertaken as part of this study with a range of manufacturers and importers, as well as distributors (relevant questions were also asked as part of the CSES survey; these are discussed in Section 4.4.5). These consultees were asked the following types of questions:

- Has the substance been withdrawn from only some uses or across all uses? If only for some uses, what are these (consumer, professional etc.)?
- Has the substance been withdrawn from the market because:
 - the hazards of the substance suggested an exposure and risk assessment would show unacceptable risks or high RMM needs for many intended uses?
 - risks were newly identified (no safe use possible; adequate control requires too strict RMMs, new classification is expected to discourage customers)?
 - risks were already known but these had not been taken into account in recommendations for downstream uses (responsibility for safe use and need for clear communication triggered by REACH)?
 - the use identification showed that the substance is used in unsafe uses that the manufacture / importer did not intend; M/I realized that it cannot control the market and hence does not want to take the responsibility?
- For which types of substances (hazards/classification) has withdrawal taken place?

- Depending on the responses from those contacted, a follow-up consideration was the degree to which there may be differences between large companies and SMEs with respect to substance withdrawal, and the reasons for it.

As will be seen from the discussion that follows, responses from interviewees were not fully unanimous which may be due to the fact that each company only oversees its own range of products and market segment.

Economics Considerations as a Driver for Substance Withdrawal

Many interviewees stated that no substance withdrawal as a result of REACH was observed in the first registration phase. This is attributed to the fact that many of the substances falling under the first registration phase were commodities that had already been assessed under previous programmes. It was also suggested by interviewees that the specific registration costs are comparatively low for these substances because of the high number of SIEF participants for many of the substances (see also Section 4.4.5 below on responses to the CSES studies). Most interviewees supported the view that decisions on whether or not to register a substance are driven only by economic reasons and in many cases are driven more by a desire to rationalise product portfolios than the costs of registering the substance itself. However, they also noted that if the actual expected registration costs will exceed the future market expectations for an individual supplier, then no registration is carried out.

For example, one manufacturer stated that 25 pre-registered substances were not registered because production ceased. This was not due to REACH but a general decision of the company. Many downstream users have indicated that their suppliers have given the same reason for substance withdrawal, i.e. that product portfolios have been rationalised in response to registration requirements, and they confirm the view that the hazardousness of the chemicals is not the issue with some non-hazardous substances also being withdrawn.

More generally, downstream users noted that they have experienced some suppliers stopping the sale of certain substances as they decided the volumes were too low for them to support (i.e. from a financial perspective it was not worth their while to register the substance). These consultees also noted that they have always been able to find an alternative supplier of the substances – generally a larger company – with this resulting in reduced competition within the market place rather than the loss of a substance. When asked, those suppliers who do stop supplying have been reluctant to give reasons as to why they have stopped supply, generally they put it down to the complexity and expense of registration if they are willing to provide a reason.

Hazardous Properties as a Driver

Most interviewees said that the difference in efforts and costs for the registration of hazardous and non-hazardous substances (potential additional testing and exposure assessment) is too small to be important in the registration decision. Thus, they suggest that there is no clear link between substance properties and decisions on whether or not to register a substance for the first phase of registrations.

The views of substance suppliers on the relevance of hazardousness with regard to the size of markets also differ: while some companies see labelling with “skull and cross bones” as a major obstacle to maintaining and entering markets, others do not see this as so relevant, as long as the chemical’s function is wanted by customers and risks can be managed so as to ensure safe use.

One manufacture did indicate though that the listing of a substance on the Candidate List for its properties of very high concern was the reason for not registering the substance. The company produces an alternative with a similar hazard profile which it also offers on the market. The search for an alternative with less hazardous properties has started but has not yet been successful. Another interviewee identified a case where a candidate substance was only registered as an intermediate and not for other industrial/professional use. Downstream users also expressed the fear that Candidate substances may not be registered in the future, even though there are uses of such substances which are safe.

One of the manufacturers consulted indicated that the costs of registration together with declining market demand due to the hazardous properties of one of its substances is likely to lead to the substance being withdrawn from the EU market. This substance was not due to be registered within the first REACH deadline, so is not included in the ECHA statistics. The substance has carcinogenic and reprotoxic properties (Cat 2) and downstream users have started moving away from it already due to health concerns. Thus, REACH on its own cannot be said to have resulted in

the loss of market for the substance, although it may be the final driver for its withdrawal from the EU market. The manufacturer notes though that the substance will remain on the market outside the EU and thus can continue to be used professionally and in the manufacture of goods for import into the EU.

An industry association consultee noted that substances are beginning to be withdrawn from the market due to their properties. In the consultee's view, this is due to the fear of authorisation in the future and manufacturers making the decision that it is not worthwhile supporting a substance through registration. This perspective is shared by other associations, which expect the fear of authorisation to lead to more substances being withdrawn from the EU market. Interestingly, an importer also indicated that it supported a substance through registration at the request of its downstream users but now wishes that it had not, as it is a likely candidate for authorisation.

Additional Drivers for Substance Withdrawal for Lower Tonnage Substances

All interviewees were of the opinion that substance withdrawal would be an issue for the next registration phase; this is substantiated by several observations and considerations:

- SMEs are currently discussing whether or not to register;
- There is less data on hazardous properties available for the lower volume substances than for the high volume substances, with this indicating that more testing is likely to be required, increasing the costs of registration;
- The expertise in the (SME) companies, which are expected to be represented in larger numbers in the next and last registration phase, is lower. There are therefore fewer people with the necessary knowledge and expertise to undertake registrations;
- Current communication in SIEFs and the general levels of activity for registration are considered to be comparatively low, with the exception of the existing consortia that collaborated for the 2010 deadline; and
- It is expected that there will be a bottleneck in the capacity of testing laboratories in the next registration period, limiting the ability of registrants to produce the information needed for their dossiers.

As the registration decision is taken before any assessment is performed, the chemical safety assessment – and potentially identified risks or required risk management measures - were not mentioned as a trigger for not registering by any interviewee. However, there have been cases where the registration itself only covered a sub-set of the identified uses due to risk considerations, with other uses being advised against.

It must also be remembered that only a sub-set of all phase-in substances have been registered to date.

4.4.6 Responses to Other Consultations: Impacts on Competitiveness and Innovation

REACH Competitiveness Survey

Manufacturers

As shown in Table 4.12, the CSES survey on Competitiveness asked manufacturers whether they had decided to withdraw any chemical substances from the market as a result of REACH¹⁸. Out of a total of 301 respondents, 76 said that they have withdrawn substances a result of REACH, with a further 72 indicating that they may in the future. Out of these, 23 had withdrawn only 1 substance, 37 had withdrawn between 2 to 5 substances, and only 11 had withdrawn more than 6 substances from their portfolios (Table 4.13).

Table 4.12: One of the main concerns of users of chemicals is that REACH will lead to the withdrawal of chemical substances. In your business, have you decided to withdraw any chemical substance from the market as a result of REACH?				
Business size	YES	NO, and we do not expect to do so in the future	NO, but we are considering doing it in the future	No experience
Micro (1-9 employees)	1	7	3	1
Small (10-49 employees)	8	20	9	2
Medium (50-249 employees)	23	43	23	5
Large (more than 250 employees)	44	54	36	20
Business size unknown	0	1	1	0
Grand Total	76	125	72	28

Source: Based on raw data from CSES Competitiveness Survey

Table 4.13: How many substances has your business withdrawn?					
Business size	Don't know	1	2-5	6-10	>10
Micro (1-9 employees)	0	0	1	0	0
Small (10-49 employees)	0	4	3	1	0
Medium (50-249 employees)	3	7	11	1	2
Large (more than 250 employees)	1	12	22	4	3
Business size unknown	0	0	0	0	0
Grand Total	4	23	37	6	5

Source: Based on raw data from CSES Competition Survey

¹⁸ Note that CSES kindly provided RPA with its raw survey data. Thus the analysis presented here was undertaken by RPA; any mis-calculation or mis-interpretation is therefore our responsibility.

When asked about the reasons for substance withdrawal (Figure 4.2), the main reason given by respondents to the survey was cost, with this being cited by 58 respondents; 19 respondents indicated that a substance being placed on the Candidate List was a driver for withdrawal, while six respondents indicated that this was the case for a substance placed on the list of restricted substances. It is clear that some respondents indicated more than one reason applied across their set of withdrawals (i.e. there were 83 responses in total by manufacturers to this question but only 76 indicated previously that they had withdrawn substances from the market).

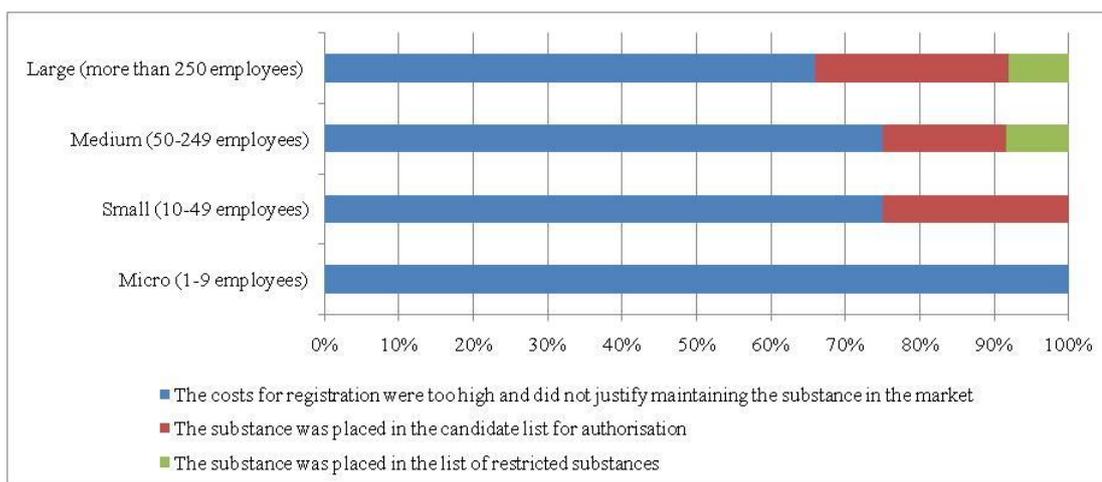


Figure 4.2: What were the reason(s) that led you to withdraw a substance from the market (Source: Based on raw data from CSES Competitiveness Survey)

It is important to note that no inferences can be drawn from these survey data as to the number of substances which have actually been withdrawn from the EU market, as a substance withdrawn by one supplier may have been registered by another.

Formulators

In total, five formulators noted that they registered a substance because if they did not it would have been withdrawn from the market – this included micro, medium and large enterprises. When asked about the withdrawal of critical substances (Table 4.14), 105 formulators indicated that a critical substance had been withdrawn. Unfortunately the CSES survey data provides no indication of how many formulations may have been affected. Most companies responding to the survey indicated that between two to five critical substances had been withdrawn (Table 4.15), with the resulting actions indicated in Figure 4.3.

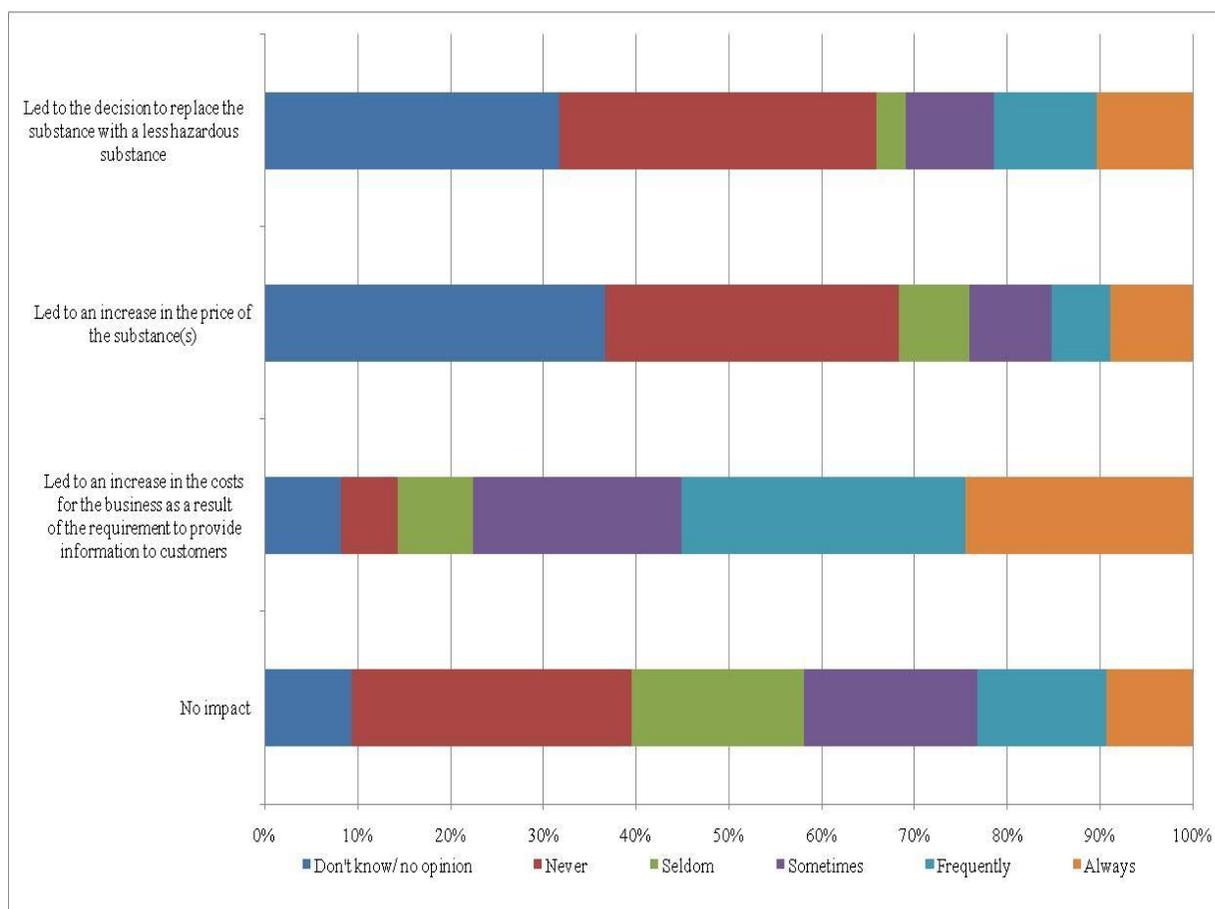


Figure 4.3: What has been the result of the entry of one or more substances you use in your formulations in the candidate list for authorisation?
 (Source: Based on raw data from CSES Competitiveness Survey)

Table 4.14: One of the main concerns of business is that REACH will lead to the withdrawal of chemical substances. In your business, have you experience the withdrawal of one or more of the critical substances used in the production of your formulations as a result of REACH?

Business size	YES	NO, and we do not expect this to happen in the future	NO, but we are expecting this to happen in the future	No experience
Micro (1-9 employees)	2	3	1	0
Small (10-49 employees)	36	7	15	4
Medium (50-249 employees)	33	3	21	6
Large (more than 250 employees)	34	1	13	0
Business size unknown	0	0	0	0
Grand Total	105	14	50	10

Source: Based on raw data from CSES Competitiveness Survey

Table 4.15: How many substances have been withdrawn? (Question to Formulators following from the question asked in relation to Table 3.8)

Business size	Don't know	1	2-5	6-10	>10
Micro (1-9 employees)	1	0	1	0	0
Small (10-49 employees)	8	9	19	3	0
Medium (50-249 employees)	5	4	18	1	5
Large (more than 250 employees)	3	3	19	3	4
Business size unknown	0	0	0	0	0
Grand Total	17	16	57	7	9

Source: Based on raw data from CSES Competitiveness Survey

Unfortunately the CSES survey did not ask companies whether they knew why substances had been withdrawn, except in relation to candidate listing. 64 formulators indicated that one of the substances that they use in their formulations/mixtures is included in the candidate list of SVHCs for authorisation, with a further 41 suggesting that this has led to their suppliers withdrawing the substance from the market (seldom to always) and 43 indicating that this led them to make the decision themselves to replace the substance. Similarly, the CSES survey did not ask what the impact of withdrawal was in terms of the number of formulation affected.

Article Producers

Out of the 103 producers of articles who responded to the CSES survey, 51 said that they had experienced the withdrawal of chemical substances from the market as a result of REACH and 52 said that they had not (see Table 4.16). When asked how many substances have been withdrawn (Table 4.17), 13 producers of articles said that only one substance had been withdrawn, 21 said that two to five substances had been

withdrawn, five said that six to ten substances had been withdrawn and one producers of articles said that more than ten substances had been withdrawn.

Table 4.16: One of the main concerns of business is that REACH will lead to the withdrawal of chemical substances. In your business, have you experienced a withdrawal of any chemical substance from the market as a result of REACH? (Producers of Articles)

Business size	Yes	No
Micro (1-9 employees)	1	2
Small (10-49 employees)	10	12
Medium (50-249 employees)	10	16
Large (more than 250 employees)	30	22
Business size unknown	0	0
Grand Total	51	52

Source: Based on raw data from CSES Competitiveness Survey

Table 4.17: How many substances have been withdrawn? (Producers of Articles)

Business size	Don't know / no opinion	1	2-5	6-10	>10
Micro (1-9 employees)	0	0	0	1	0
Small (10-49 employees)	4	3	3	0	0
Medium (50-249 employees)	2	2	5	1	0
Large (more than 250 employees)	4	8	13	3	1
Business size unknown	0	0	0	0	0
Grand Total	10	13	21	5	1

Source: Based on raw data from CSES Competitiveness Survey

When asked by the CSES survey what their response has been to the withdrawal of the substance, 17 producers of articles said that they had (frequently to always) substituted the product with other substances with less hazardous properties, eight said that they had (frequently to always) switched to another supplier based in the EU, one producer of articles said that they had (frequently) switched to another supplier based outside the EU and three said that they had (always) decided to register the substance themselves, as it was critical for their product.

End Users

As shown in Table 4.18, from a total of 113 end users responding to the CSES survey, 28 said they had experienced the withdrawal of one or more critical substances and 42 responded that they are expecting this to happen in the future.

Table 4.18: One of the main concerns of business is that REACH will lead to the withdrawal of chemical substances. In your business, have you experienced the withdrawal by your supplier of one or more critical substances used in your business as a result of REACH?

Business size	YES	NO, and we do not expect this to happen in the future	NO, but we are expecting this to happen in the future	No experience	Other
Micro (1-9 employees)	0	2	0	0	1
Small (10-49 employees)	10	5	17	4	2
Medium (50-249 employees)	9	9	15	3	5
Large (more than 250 employees)	9	7	10	4	1
Business size unknown	0	0	0	0	0
Grand Total	28	23	42	11	9

Source: Based on raw data from CSES Competitiveness Survey

When asked about their response to the withdrawal of the substance, 17 end users responded to the CSES survey that they had substituted the product with other substances with less hazardous properties (seldom to always), 10 said they had switched to another supplier based in the EU, six said they had switched to another supplier based outside the EU and one said they had decided to register the substance themselves. These results are illustrated in Figure 4.4.

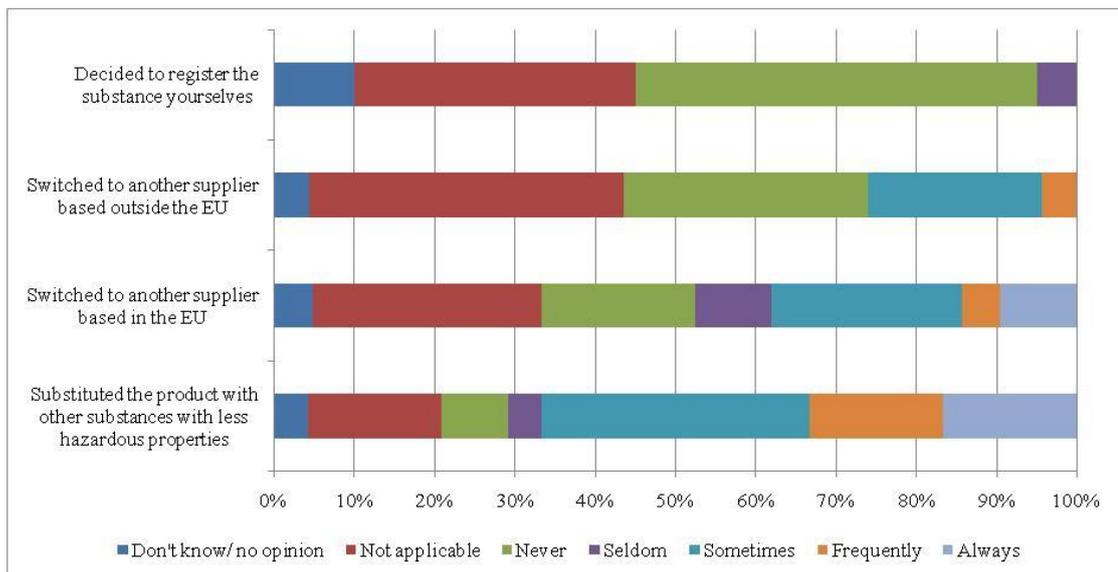


Figure 4.4: What has been your response to the withdrawal of the substance? (Source: Based on raw data from the CSES Competitiveness Survey)

As with other questions, respondents could provide more than one answer, and it is unclear therefore whether the responses relate to intentions or actual actions. Based on the responses provided, the data suggest that in half of the cases, withdrawn substances were substituted by safer alternatives (i.e. 17 out of 34 responses); 16 of the responses suggest that withdrawal may have been carried out for economic reasons as supply within the EU or by importers to the EU continued; while the last

case suggests that although manufacturers or importers may not have been willing to support the substance, its criticality led to it being registered by the end-user.

REACH Innovation Survey

Only one question from the CSES Innovation Survey is of relevance to the issue of the human health and environmental benefits of REACH, rather than impacts on innovation. In response to the Innovation Survey carried out by CSES, 124 out of 577 respondents indicated that they had withdrawn a substance from their product portfolio in response to a substance being placed on the candidate list. Out of the 124 respondents who indicated that they had withdrawn a substance, 44 were manufacturers of chemical substances and 35 were formulators (mixers) of chemical substances or mixtures. A summary of the type of respondents who indicated that they had withdrawn a substance from their product portfolio is given in Table 4.19. Again no information is available from the survey on the number of formulations or articles that may be impacted from substance withdrawal, for example due to a substance being placed on the Candidate List.

Table 4.19: Type of respondents who indicated that they had withdrawn a substance from their product portfolio	
Respondent type	Number of responses
Distributor / retailer of chemical substances	5
End user	2
Formulator (mixer) of chemical substances or mixtures	35
Importer of articles that contain chemical substances	2
Importer of chemical substances or mixtures	12
Manufacturer of chemical substances	44
Other role	7
Producer of articles that contain chemical substances	12
R & D org	4
No answer	1
Grand Total	124
<i>Source: Based on raw data from CSES Innovation Survey</i>	

4.4.7 Linkages to Other Pathways and Benefits

The example of substance withdrawal given in Section 4.4.5 by one of the companies interviewed for this study listed is linked to the interactions of REACH with other legislation. In this case, the real driver underlying the loss of market was identified as the Carcinogens and Mutagens Directive (2004/37/EC), and the emphasis it places on substitution or replacement of the substance to reduce risks to workers, even though the substance is not a Cat 1a or 1b substance. This was the initial trigger for the movement away from the substance and to the use of substitutes. In this respect, the example provides an indication of the way in which REACH is helping to reinforce some of the objectives of other EU legislation.

4.4.8 Conclusions

The hypothesis underlying registration as a driver of benefits through substance withdrawal is based on the proposition that, where a substance is no longer supported due to its hazardous properties there may be benefits to health and the environment. In this respect a series of pathways were proposed to the generation of benefits:

- There will be a reduction in the tonnage of hazardous substances entering the market, with this leading to reduced exposures to hazardous substances;
- Uses which may have posed risks to people or the environment in the past are no longer supported; and
- Where withdrawn substances are substituted by less hazardous alternatives, there are clear reductions in exposures and hence benefits.

The above discussion highlights that, at this point in time, it is difficult to draw clear conclusions on the degree to which registration has led to the withdrawal of hazardous substances and their replacement with less hazardous substitutes.

There is clear evidence from ECHA's note on the gap between pre-registration intentions and actual registrations that substances have been "dropped" from the market or otherwise not registered. It is less clear why these substances were dropped: there is evidence to suggest that at least a small set (possibly 17) may have been "dropped" due to their properties (i.e. CMRs), while this may also apply to a further set which were not registered for "unknown" but also have CMR properties. Discussions with industry (manufacturers, importers, distributors and downstream users) suggest that substance withdrawal has mainly been for economic reasons and, in many cases, downstream users have been able to find other suppliers or have decided to act as importers themselves. Others have cited a few cases where withdrawal has been partial, with particular uses not covered by the CSA and CSR.

More generally, to date there is little evidence that where substances have been withdrawn, they have been replaced by a less hazardous alternative. In some cases, manufacturers are offering instead alternative substances of a similar hazard profile.

4.5 The Number of Newly Identified PBTs and vPvBs

4.5.1 Pathway to Benefits and Associated Indicators

As noted above, REACH includes requirements for substances manufactured and produced above 10 tonnes per year to provide data which would enable an assessment of a substance's persistence, bioaccumulation and toxicity (PBT) potentials. The chemical safety assessment of these chemicals is to include a PBT assessment. For substances under 10 tonnes per year, such data should be provided in the registration dossier where it is available.

As a result of this registration related driver, REACH should enable the identification of currently unknown chemicals which fulfill the criteria for being PBTs or for

meeting the criteria for being classed as very persistent and very bioaccumulative. This in turn can help ensure that action to reduce the environmental risks (or potential risks) associated with the continued use of these substances is taken in a timely fashion through the need for manufacturers and importers to be able to demonstrate safe use and later, if included, through the authorisation provisions under REACH.

4.5.2 Expectations Prior to REACH

Prior to the introduction of REACH a number of different entities tried to estimate the number of substances meeting the PBT and vPvB criteria (as set out in Annex XIII). The PBT Working Group provided a figure of around 70 (similar to the number of 79 in the OSPAR list), but these are the substances produced at over 1,000 tonnes per year. In order to consider the lower volume PBT and vPvB substances that might be identified through REACH, a non-governmental organization suggested a number of around 500 as a reasonable guess. RPA (2003)¹⁹ adopted the estimate of 2,000 PBTs developed by the Danish EPA using a QSAR based approach that led to a prediction of roughly 2% of the more than 100,000 substances listed in EINECS meeting the criteria to be classified as PBT or vPvB. Applying the same percentage of PBTs in high production volume substances across all the tonnage bands of phase-in substances and intermediates (70 out 2,500 HPV substances is 2.8%) a figure just over 2,000 is obtained.

4.5.3 Data from an Analysis of Registration Data

Data available to the study team has been evaluated for a limited number of substances. For these substances, the following conclusions can be drawn on their status as identified PBT-substances:

- There are five substances fulfilling PBT criteria according to EU European chemical Substance Information System (ESIS);
- Of these only one is assessed as a PBT substance in the registration dossier; and
- Of the five substances, one substance is classified with R52/53 (harmful to aquatic organisms, may cause long term adverse effects in the aquatic environment) and one substance with R53 (may cause long term effects). The remaining 3 substances are classified with R50/53 (very toxic to the aquatic environment, may cause long term effects).

4.5.4 Discussions with Industry

Consultees were asked whether the explicit requirement to carry out a PBT assessment as part of the chemical safety assessment had impacted on any substances within their portfolios. In particular, they were asked whether this led to the new identification of substances with such properties. They were also asked whether they believed that this requirement would be important in terms of identifying substances which may prove to be of Very High Concern in the future.

¹⁹ RPA (2003): Revised Business Impact Assessment for the Consultation Document, prepared for DG Enterprise, October 2003, p.80.

Although manufacturers and importers (including distributors acting as importers) were consulted on the potential impact of the need to undertake a PBT assessment, no examples were identified where this had led to the new identification of a PBT.

One registrant responded that the assessment could be performed fairly quickly, as the data are available from the information requirements. In contrast, another response was that the data were not sufficient to make a final decision on whether or not a substance fulfills the PBT criteria or not. In this latter case, a testing proposal submitted to ECHA with the aim of generated the missing data, with a decision on this still pending. None of the consultees stated that they had newly identified a PBT/vPvB so far.

4.5.5 Linkages to Other Pathways and Benefits

In theory, the need to consider whether a substance is a PBT or a vPvB as a potential pathway to trigger benefits is linked to the pathways of substance withdrawal and authorisation. However, as can be seen from Section 4.4, it is not clear yet whether the PBT assessment aspect has resulted in any substance withdrawals, with the potential exception of this being linked to the non-registration of nonylphenol by at least one manufacturer which pre-registered at greater than 1000 t/y (however, it must be noted that other manufacturers may still register it at lower tonnages or indeed it may be registered for its use as an intermediate by others).

4.5.6 Conclusions

The findings of an evaluation of registration data suggests that registrants have not yet fully responded to the need to provide a clear assessment of PBT and vPvB properties, and thus that more work on this aspect may be required across the first tranche of registration dossiers.

More generally though, those substances registered to date will be the set for which the most data were available pre-REACH. As a result, it is not surprising that few substances were newly identified as having PBT or vPvB properties.

It is likely that this requirement will become more important in the next registration phases, as the lower volume substances have less data available on their properties as required by REACH than those registered in the first phase and thus less consideration will have been given to date as to whether they fulfill the PBT and vPvB criteria.

However, it is unlikely that 2,000 such substances (as assumed in the Revised BIA – see above) will be identified based on the current registration requirements. For example, the identification and assessment of PBT and vPvB properties is required as part of a CSA as set out in Article 14, but a CSA is not required for 1 to 10 tonne substances. The other reference to PBT and vPvB properties is in respect to their communication in the supply chain via SDS (Article 31 and Annex II), which in this case does apply to 1 to 10 tonne substances. A PBT/vPvB assessment would therefore need to be carried out but this could be limited to assessment of the information requirements for 1 to 10 tonne substances against the screening criteria

set out in Annex XIII²⁰. A positive match to the screening criteria may then require a registrant to consider obtaining additional data (test data or otherwise) to fully determine whether or not, and to what extent, their substance has PBT/vPvB properties.

In addition, there is no requirement to undertake a PBT/vPvB assessment for intermediates. Only available physicochemical and (eco) toxicological information is required for the registration of isolated-intermediates (in most cases). However, for transported isolated intermediates manufactured and/or imported in quantities greater than 1,000 tonnes per year, per registrant, the information requirements are extended to cover those required for the registration of non-intermediate substances in the 1 to 10 tonne per year range, as set out in Annex VII.

The only conclusion that can be drawn at this stage, therefore, is that the number of new PBT/vPvB substances will be somewhere between 70 and 2000, with the figure of 500 probably not being too bad an estimate.

²⁰ An interpretation supported by ECHA.

5. INFORMATION THROUGH THE SUPPLY CHAIN AND DOWNSTREAM USERS REQUIREMENTS

5.1 Overview of Supply Chain Communication

5.1.1 Pathways to the Realisation of Benefits

As discussed in Section 4, manufacturers and importers are required to provide hazard, exposure and risk management information to their recipients, primarily via SDS and in some cases extended Safety Data Sheets (eSDS). In particular, Exposure Scenarios (ES) must be communicated via eSDS wherever an exposure assessment has been undertaken (Article 31, see also Annex II). This should provide enhanced guidance to downstream users on the control of risks to human health and the environment. ES are not to be included for uses for which adequate control could not be demonstrated and these uses should be explicitly advised against. Downstream users may not use a substance for an application that falls outside the ES supplied to them, unless they apply RMM which are equivalent or stricter or if use outside the ES²¹ takes place for only a short period of time (i.e. 6 months or less). Thus, such uses should cease, unless a downstream user produces a Chemical Safety assessment (Annex XII) or his supplier provides him with an ES on his use demonstrating that any risks can indeed be adequately controlled.

As indicated in Figure 5.1, there are also provisions in REACH requiring companies to communicate information up and down the supply chain (see also Table 5.1 for further details):

- SDS should be communicated down the supply chain (Article 31) together recommendations on appropriate measures to adequately control risks;
- Where SDS are not required, companies are still required to communicate hazard information down the supply chain (Article 32) if the substances are subject to restriction, authorisation or require specific risk management;
- New hazard information or information questioning the validity of risk management measures must be communicated up the supply chain; and
- Suppliers of articles that contain chemicals identified as Substances of Very High Concern (SVHCs), which are on the Candidate List for inclusion in Annex XIV or are already on Annex XIV, have obligations to provide information available to them down the supply chain and to consumers, to enable safe use of those articles (at a minimum the name of the SVHC). This information must be available to consumers, on request.

²¹ They may also use a substance outside the conditions described in the exposure scenario if they fall under any of the cases described under Article 37(4).

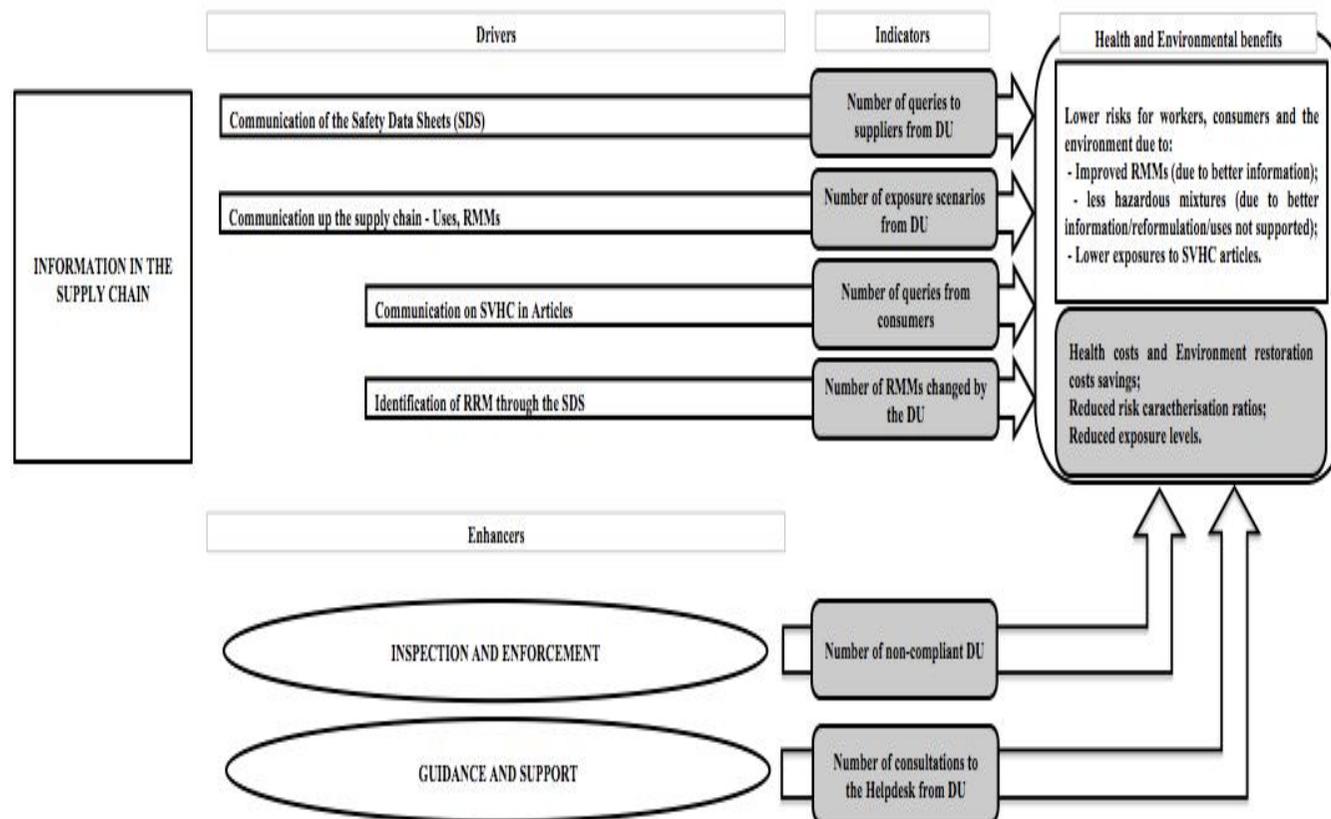


Figure 5.1: Flow Chart of the Drivers under Title IV “Information in the Supply Chain” and Title V “Downstream users”

Table 5.1: List of the Key Provisions by Duty-holders, Drivers and Benefits for Information in the Supply Chain				
Article	Key Provisions	Duty-holders	Pathways	Human health and Environmental Benefits
31(1)	Requirement on a supplier of a substance or a mixture to provide recipient with a SDS compiled in accordance with Annex II.	M, I, D	Communication of the Safety Data Sheets (SDS)	Enhanced guidance to Downstream Users on the control of risks to human health and the environment
31(2)	Requirement on any actor in the supply chain who has been requested to perform a CSA to ensure that information in the SDS is consistent with the information in the assessment.	M, I, D		
31(3)	Requirement on a supplier to provide a SDS when requested for a mixture which falls within paragraph 3.	M, I, D		
31(4)	Requirement on a supplier to provide downstream user or distributor with a SDS when requested for a mixture or dangerous substance which is offered or sold to the general public.	M, I, D		
31(5)	The SDS shall be provided in the language of the Member State concerned.	M, I, D		
31(6)	The SDS shall contain the information listed in article 31(6).	M, I, D		
31(7)	Requirement on actors in the supply chain to place the relevant exposure scenarios in an annex to the SDS.	M, I, D	Communication up the supply chain - uses, RMMs	Lower exposure due to the improvement of Risk Reduction Measures
	Requirement on a downstream user to include the exposure scenarios in their own SDS for identified uses.	DU		
	Requirement on a distributor to pass on relevant exposure scenarios and use other relevant information from the SDS when compiling his own data sheet.	D		
31(8-9)	The SDS shall be provided free of charge either electronically or on paper.	M, I, D	Communication	Enhanced guidance to

Table 5.1: List of the Key Provisions by Duty-holders, Drivers and Benefits for Information in the Supply Chain				
Article	Key Provisions	Duty-holders	Pathways	Human health and Environmental Benefits
	Requirement on a supplier to update the SDS and provide it free of charge to all former recipients.	M, I, D	of the Safety Data Sheets (SDS)	downstream users on the control of risks to human health and the environment
32 (1)	Requirement on a supplier of a substance who does not have to supply a SDS to provide the recipient with the information in paragraph (1).	M, I, D		
33(1 and 2)	Requirement on a supplier of an article to provide the recipient with sufficient information to allow safe use, including as a minimum the name of that substance.	M, I	Communication on SVHC in Articles	Lower exposure to SVHC
	Requirement on a supplier of an article to provide a consumer on request with sufficient information to allow safe use, including as a minimum the name of that substance, free of charge and within 45 days of the request	DU, R		
34	Requirement on every actor (including distributor) in the supply chain to communicate the information on new information or any other information that might call into question the appropriateness of the risk management measures to the next actor or distributor up the supply chain.	M, I, D, DU, R	Communication up the supply chain - uses, RMMs	Lower exposure due to the improvement of Risk Reduction Measures
35	Requirement on an employer to provide workers and their representatives with access to information received in accordance with articles 31 and 32 in relation to substances or mixtures which they may use or be exposed to in the course of their work.	M, I, DU, D, R	Communication of the Safety Data Sheets (SDS)	Enhanced guidance to downstream users on the control of risks to human health and the environment
<i>Downstream Users Only</i>				
39	Article 39 states that downstream users shall comply with the Article 37 obligations at the latest 12 months after receiving a registration number.	DU	Identification and application of	Lower exposure due to the improvement of Risk

Table 5.1: List of the Key Provisions by Duty-holders, Drivers and Benefits for Information in the Supply Chain				
Article	Key Provisions	Duty-holders	Pathways	Human health and Environmental Benefits
37(5)	Requirement on downstream user to identify and apply appropriate measures to adequately control risks identified in (a) an SDS supplied to it; (b) its own chemical safety assessment or (c) any information received in accordance with article 32. Requirement on downstream user to recommend, where suitable, measures to adequately control the risks identified in (a) an SDS supplied to it; (b) its own chemical safety assessment or (c) any information received in accordance with article 32.	DU, M, I, D	RRMs	Reduction Measures
37(2)	Requirement on a downstream user to have the right to make a use known in writing. Requirements on distributors to pass on such information to the next actor up the supply chain.	DU, D, M, I	Communication up the supply chain - uses, RMMs	Lower exposure due to the improvement of the Risk Reduction Measures
37(4)	Requirement on a downstream user to prepare a CSR in accordance with Annex XII for any use outside either the conditions described in an exposure scenario or a use and exposure category in a SDS or for any use his supplier advises against.	DU	Identification and application of RMMs	Lower exposure due to the improvement of Risk Reduction Measures
37(6)	Requirement on a downstream user to identify and apply appropriate risk management measures needed to ensure that the risks to human health and the environment are adequately controlled.	DU		
37(7)	Requirement on downstream users to keep their chemical safety report up to date and available.	DU	Communication up the supply chain - uses, RMMs	Lower exposure due to the improvement of Risk Management Measures
39	Article 39 states that downstream users shall comply with the Article 38 obligations at the latest 6 months after receiving a registration number.	DU		
38(1)	Requirement that downstream user reports information in article 38(2) to ECHA before commencing or continuing with a particular use of a substance that has been registered by an actor up the supply chain.	DU		
38(2)	Requirement that a downstream user includes the information listed in article 38(2).	DU		

Table 5.1: List of the Key Provisions by Duty-holders, Drivers and Benefits for Information in the Supply Chain				
Article	Key Provisions	Duty-holders	Pathways	Human health and Environmental Benefits
38(3)	Requirement that downstream users update the information provided in article 38(2) without delay in the event of a change in information.	DU		
38(4)	Requirement that a downstream user reports to ECHA if its classification of a substance is different to that of its supplier.	DU		

Title V of REACH presents the duties of the downstream users to identify, apply and recommend risk management measures and their obligation to report information.

The mandatory communication of safety data throughout the supply chain and the responsibilities for the quality of those data that are placed on the various actors are expected to be a major driver for the reduction of harmful impacts on human health and the environment. Safe conditions of use are defined and are communicated and implemented along the supply chain.

This may result in exposure reduction where more stringent measures are recommended. The process of identifying and implementing risk management measures regarding workers, consumers and the environment by industry should take place more quickly due to the exchange of information along the supply chain. A shorter time period between the identification of risks and their actual control leads to benefits through earlier exposure reduction and hence lower adverse consequences. Furthermore, the number of substances subject to a risk assessment is much higher than that which could have been assessed by authorities under the previous legislation due to the fact that the risk assessment is now performed by industry.

5.1.2 Work Hypotheses for the Main Pathways

Based on the above principles, three main work hypotheses have been developed to reflect the different mechanisms through which supply chain communication requirements should deliver benefits. These are as follows.

- 1) **Safety Data Sheets and Conditions of use:** The communication of information through SDS and eSDS creates benefits because: new information is received by Downstream users that requires all actors to check their handling and use of chemicals in general; the SDS provides information on unsafe uses which are explicitly identified as “uses advised against”; formulators use information on recommended Risk Management Measures (RMMs) and Operating Conditions (OCs) to derive their recommendations for end-users within their safety data sheets; and formulators and end-users implement recommended RMMs and OCs thereby ensuring safe use.
- 2) **Communication of information upstream as well as downstream:** The requirement to communicate information upstream, if inappropriate recommendations on operating conditions or risk management measures are received, creates benefits because: new and appropriate RMMs are identified and included in the up-dated safety assessments provided by suppliers; new information on hazardous properties is received and taken into account, where relevant, in particular from company practices (e.g. monitoring of workers’ health); and the overall quality of safety data sheets is improved.
- 3) **Communication on SVHCs in articles:** The need for article manufacturers to communicate the presence of an SVHC within an article leads to benefits by (see also Section 6 on authorisation): helping to ensure the safe use of articles; triggering requests from retailers for the phase-out of SVHCs in articles because they want to avoid communicating any SVHC content in articles; and

enabling consumers to take the presence of an SVHC into account in their purchasing decisions.

These three work hypotheses are explored in more detail in the remainder of this section.

In addition, ECHA's provision of Guidance Documents may act as an enhancer of the benefits delivered through the first two of the above pathways in particular. This is because such documents increase different actors' understanding of the overall communication mechanisms within REACH and facilitate such communication through standardisation.

5.1.3 Indicators of Benefits

In addition, potential indicators of benefits have been identified to act as proxies for the impacts that the communication of safety data may have in terms of realising health and environmental benefits. These include:

- The extent to which ES set out more stringent use conditions (operational conditions and/or RMM) to be implemented by Downstream Users in their processes;
- Queries and information provision to suppliers from Downstream Users;
- The number of Downstream User chemical safety assessments (although it may be too early for there to be many of these); and
- Queries from consumers about the content of substances of very high concern in articles.

5.2 Safety Data Sheets, Conditions of Use and Supply Chain Communication

5.2.1 Pathways to Benefits and Associated Indicators

As discussed in Section 4, a key assumption underlying REACH is that the provision of new data on the hazardous properties of chemicals will lead to improvements in risk management, through the new requirements for exposure scenarios to be attached to the SDS provided to downstream users. In addition, as there is a duty on downstream users to communicate information up the supply chain, manufacturers and importers should have a better understanding of how a chemical is used and thus should be more able to identify the operating conditions corresponding to safe use.

For these benefits to be delivered, however, there needs to be effective communication throughout the supply chain. Furthermore, the ES assumed in the eSDS need to be detailed enough and of sufficient quality to act as real guidance on how to achieve safe use and provide information on this down the supply chain. Thus, in this case, the research has focused on addressing the propositions put forward in the first work hypothesis detailed above.

However, the second hypothesis is also closely linked to the first one regarding the role of eSDS and OCs in generating benefits. This is that the requirements placed on downstream users to communicate upstream if inappropriate information has been received creates benefits because:

- New and appropriate RMMs are identified and included in the safety assessment of suppliers;
- New information on hazardous properties is received and taken into account, in particular from company practice (workers' health); and
- The overall quality of safety data sheets is improved.

As a result, we have combined the discussion of both hypotheses into this one section.

5.2.2 Expectations Prior to REACH

There were no detailed predictions prior to the introduction of REACH as to the extent to which new information would lead to downstream users changing the risk management measures in place to reduce worker or environmental exposures.

Assumptions on such aspects are implicit in a number of the benefit studies, however. For example, Pickvance *et al*²² (2005) base their analysis of the potential reduction in levels of occupational dermatitis and asthma on arguments concerning the improved information on safe use that will be generated by REACH. They argue that both the more reliable classification and labeling of chemicals and the provision of eSDS will provide workers with better information on the safe handling and use of chemicals. This in turn will enable both employers and workers to take further action to reduce exposures, even though employers already have obligations under the Chemical Agents Directive (Council *Directive* 98/24/EC). Indeed, these arguments are the bedrock of their analysis, as they include consideration of exposures to known sensitisers and other such chemicals from the set of chemicals and disease endpoints over which benefits are estimated. In other words, better information on the safe use of hazardous chemicals will deliver benefits even in relation to those substances which are currently known to pose hazards.

Following an approach which involved calculation of the burden of occupational disease across the EU, Pickvance *et al* (2005) derived estimates of the percentages for the diseases they considered that could be attributed to exposures to substances that would fall under the scope of REACH. This resulted in estimates of the number of future cases per year that might be avoided as a result of REACH, equivalent to 40,000 for asthma, 10,000 for chronic obstructive pulmonary disease and 40,000 for dermatitis. These reductions in disease burden were then calculated as representing benefits in terms of reduced health service costs, reduced losses in productivity and improved health related quality of life of €3.5 billion over a 10 year time period, and €90 billion over a 30 year time period.

²² Pickvance, S *et al* (2005): The impact of REACH on occupational health with a focus on skin and respiratory diseases, Final Report to ETUI.

It is also interesting to note a common problem that arose under the Existing Substances Regulation, with assessments being undertaken both to assess the risks associated with the use of the substances under consideration as well as to identify appropriate risk management measures. Repeatedly, the transition from the risk assessment to the development of risk reduction measures led to the identification of previously unknown and un-assessed uses of substances. This issue arose as the risk assessments were based on information provided by manufacturers, with no obligation for downstream users to feed information into the risk assessment process conducted by Member States. When in the scope of the assessment under the Existing Substances Regulation downstream users were then consulted on the costs of different risk reduction options, new uses as well as different exposure scenarios regularly came to light. Even then, not all uses could be identified. This problem is illustrated by the fact that the risk assessment for nonylphenols and their ethoxylates, as well as the associated risk reduction strategy, identified that use of around 5% of the total volume placed on the EU market was unaccounted for. Other examples are given by the need for the Commission to introduce last minute derogations into marketing and use restrictions for other substances, as previously unidentified but safety critical uses were tabled by industry at the last minute; where there were well justified reasons for such uses to be continued, derogations were given. This was the case, for example, when restrictions on the use of pentabromodiphenyl ethers were being finalised, with a derogation agreed very late in the day for their continued use as a flame retardant in airplane emergency exit slides for safety reasons.

5.2.3 Discussions with Industry

Views of consultees on the degree to which they believe that supply chain communications have been successful are mainly negative. Discussions with both individual downstream user companies and with sector associations representing downstream users have identified problems with respect to both the degree to which eSDS are being provided to downstream users and the quality of the current eSDS.

Availability of eSDS to Downstream Users

Most consultees, including distributors, noted that they are not receiving as many eSDS as they expected. Several downstream users have indicated that they thought that they would have seen more eSDS by now, but realise that many of their suppliers may not face such obligations yet due to the volumes at which they are supplying. Others noted that they have not been getting eSDS from their distributors; they are not sure why not in all cases, although these downstream users do indicate that they always ask whether there is a new eSDS for the substances. More than one downstream user noted that it was unclear whether formulators had to communicate exposure scenarios to their customers and felt that this lack of clarity was being used by some formulators to avoid providing eSDS to their customers, where this may require them to undertake a significant level of work.

From their side, formulators have indicated that eSDSs have been “dripping in” over time and there has not been a peak of new SDSs directly after the registration

deadline. Based on the discussion at a national workshop on eSDSs²³, none of the article producers present at the meeting had yet received an extended safety data sheet.

Importers/distributors and manufacturers, as well as consultants, stated that there are three main reasons for eSDS for substances not yet being supplied by the registrants:

- Lack of time and resources in general;
- Lack of standardised formats and IT-Tools and unwillingness to provide something “self-made” to the customer which is expected to require updating, once harmonized information formats are available; and
- Unwillingness to provide information to customers which is regarded as too extensive, not understandable and not helpful.

The last reason is supported by many of actors interviewed who have responsibility for implementation of REACH, because they believe that information that really contributes to safe handling is hidden or lost in the ESs and communication of “nonsense” or bad information is not intended by REACH. They also fear that such communication will lead to downstream users responding by a failure to pay attention to any future information. This was a common view across manufacturers, distributors (acting as importers or formulators), as well as formulators.

Another reason given as to why some formulators would appear not to be forwarding eSDS down the supply chain is the difficulty that they may face in doing so at the present time. For example, one company noted that it buys in a lot of formulations and makes some formulations itself. It argues that guidance on producing eSDS is for substances and is not really correctly focused for mixture manufacturers; it is too complex and technical for smaller mixture manufacturers who do not have the same expertise as the substance manufacturers. As a result, in the absence of appropriate IT tools, there is a lot of confusion on how to prepare eSDS for mixtures and the company noted that it is tremendously complicated to bring the information together from a large number of substance eSDS when one has some data for some chemicals but not for others, and some CLP classifications but not all. For both themselves and, based on discussions with some of their suppliers and customers who are also formulators, it is taking a disproportionate amount of time and effort to develop mixture eSDS.

Other formulators are providing, or are planning to provide, ESs with the SDSs of their mixtures, regardless of whether or not this is legally required. However, in addition to the difficulties related to the consolidation of information for mixtures, some of these formulators have not yet started developing ESs (some mixtures only contain one substance with an ES) because they have a lot of clarification needs

²³ This was a workshop of the so-called “REACH Hamburg Network”, a group of companies and authorities in the city that regularly meet to discuss REACH related issues. This workshop was a specific activity and approximately 50 participants took part. Further information is available in German at: [http://www.reach-hamburg.de/index.php?id=information&tx_ttnews\[tt_news\]=213&tx_ttnews\[backPid\]=17&cHash=d5689c4b68e48bf182dff9147e0d0252](http://www.reach-hamburg.de/index.php?id=information&tx_ttnews[tt_news]=213&tx_ttnews[backPid]=17&cHash=d5689c4b68e48bf182dff9147e0d0252)

regarding the information they receive. Until such issues are clarified, they believe that no eSDS should be forwarded. At the level of formulators, the argument that “nonsense” should not be forwarded is hence strongly supported.

From the above it can be concluded that communication via eSDSs is only just starting to take place. A large share of registered substances would appear to be being placed on the market with updated main bodies of the SDS but not yet with ESs attached. Reasons for this are to some extent the difficulty in extracting the relevant information from a CSR to the ES (content), the lack of standardisation and tools, and the lack of time and resources. There is also an increasing awareness amongst registrants that the information from ESs should be shortened and processed in order to be useful for the DU. The length of eSDSs reported ranged from 20 to an average of 30 pages; however, many cite 100 pages as being common and there are cases reported of eSDS with more than 1000 pages. Respective updating is on-going, and some argue that best practice is beginning to emerge but will take some time yet.

Quality and Value of eSDS

One manufacturer notes that it is important to step back and learn from the difficulties that have arisen to date in preparing eSDS. In particular, there is a need to consolidate what is being recommended to downstream users to make sure that it is clear what they should do and why. This is partly an issue arising from the language required in producing exposure scenarios and eSDS, but also due to the language that the authors of these documents like to use and which is not easily understood by non-experts.

From the perspective of downstream users, quality issues in the eSDS that have been received would appear to arise from:

- A lack of supply chain communication prior to the development of the exposure scenarios;
- A lack of understanding on how to apply the use descriptor system and the huge amount of meaningless information communicated for the “identification of uses”;
- The failure of manufacturers, formulators or distributors to seek information on how customers are using chemicals;
- The practice of registrants which involves copying information straight from the CSR into the SDSs without processing the information, due to time pressures and a wish to be compliant²⁴;
- The use of overly technical language within the eSDS, making them hard to understand for non-expert downstream users;

²⁴ One consultee stated that communication should not start with irrelevant and confusing information but that eSDS should be of good quality. Bad information is seen as counter-productive, because DUs would be quickly discouraged from using them. The timelines are regarded as too strict to allow learning and install interdisciplinary teams and to develop tools and structures in practice.

- Inclusion of information not relevant to the downstream user, making it hard for users to extract the information they actually need on appropriate risk management;
- Inclusion of wrong, contradicting, redundant and confusing information in the eSDSs triggering a lot of clarification requirements;
- Poor language translations (through the use of automatic SDS translators) which make it hard for recipients to understand what is actually being advised; and
- Confusion with respect to SDS and labelling due to the transition to CLP.

Although two downstream users noted that they have received information within eSDS which includes explicit advice on “uses advised against”, they also note that it can sometimes be much harder to determine whether or not a use falls within the exposure scenarios attached to the eSDS. This is a problem that affects both them and their customers, where they take the role of a formulator supplying mixtures for professional use. As described in Section 4, the explicit listing of uses advised against has been observed only in a very few cases. Registrants not supporting uses because of a suspicion or proof of an unsafe use are reported more frequently. However, none of the consultees could describe the status of the use pre-REACH (was a substance actually applied in this use, was it explicitly mentioned as an “allowed use” before REACH?).

Interviewees noted that there have been noticeable changes with respect to SDS, in particular in response to CLP. In 2006, the typical SDS was 4 – 6 pages long, with this increasing to 8 – 10 pages in 2009-10 pre-REACH. Since December they now see a typical SDS of 12 – 20 and sometimes many more pages. From their perspective, the SDS is no longer a tool for communicating risk and risk management but more a way for the manufacturer to document information on a chemical, with too much information being provided in order to ensure compliance with REACH. As a result, the SDS are of limited use to downstream users who are not specialists and who are looking for information on how to manage risks. This means that the SDS are essentially becoming unusable within the average workplace.

The over-riding fear is that as the eSDS are overly long, due to the large numbers of exposure scenarios relevant to the uses of the substance, downstream users may not read them. This is resulting in the necessary safety information failing to actually reach its target audience and thus for any potential health or environmental benefits to be realised (in essence, the potential benefits are being ‘diluted’ or as one respondent noted, “a worst case is that the current eSDS are a step backward, with potential increases in impacts on worker health and safety”).

There were several examples mentioned by consultees of the types of issues which are causing particular difficulties with regard to the supply chain communication. The most prominent quality issues raised by formulators and distributors are as follows.

- Overall structure and content: ES for the same substance from different suppliers differ significantly in terms of structure and content²⁵. Some ESs are not in any of the formats (9 or 4 headings) proposed by ECHA.
- Overview: An overview of the ES in the Annex and a clear structure is missing, therefore the reader loses track of which section/use they are reading. Pages are not numbered and the information is not provided electronically, hence, processing the information is manual, case-by-case work.
- Title sections of ES: it is not clear which uses and activities are actually covered. The wording to describe a specific use differs from supplier to supplier and also the understanding of what is covered and what isn't (c.f. above).
- Description of conditions of use: frequently the description is not well structured and lacks practical information; instead, reference to assessment tools or spERCs are given²⁶. The assumptions underlying the conditions of use being proposed are not always transparently communicated.
- Duration and frequency of use are sometimes mixed (e.g. 220 days per year for the environment or 330 days for workers health). This could already mean that an ES does not cover the use and the formulator should communicate information about it upstream.
- DNELs/PNECs: Some DNELs are (much) higher or lower than OELs. This creates confusion on what to communicate to customers and which values to apply. DNELs are reported to be useful for workplace RAs whereas the PNECs have no practical value for downstream users.
- Irrelevant and redundant information: ES contain irrelevant information, such as the ES for manufacture, DNELs for local effects, etc. Other information is redundant and occurs in several places.
- Some information is confusing: for example, if the safe use amount is given as well as a "normal use amount", this raises a question as to what was used as the assumption in the exposure assessment?
- Lack of a risk assessment: an environmental or human health risk assessment is sometimes not performed, although PNECs or DNELs have been derived.
- Conflicting approaches: in particular, conflicting approach to the assessment of local effects has been identified within the ES (e.g. eye irritation is assessed qualitatively, skin corrosion quantitatively).
- Questionable risk characterization ratios: by way of example, exposure levels for different PROCs were all the same in one ES.
- Scaling information: such information is hardly ever provided (< 10% of the ES).

²⁵ It was reported that the SIEF work ended with registration and therefore no harmonized supply chain communication was developed, although many consultees stated that the CSR was done jointly.

²⁶ One example from an unclear SDS: the supplier recommends an air exchange rate of 5. The actual workplace is in a large production hall, where such "wind" is not ensured. How should compliance be checked?

- Precautionary RMMs: It would appear that frequently RMMs are simply added for precautionary reasons, leading to unrealistic measures; in the area of worker safety, personal protective equipment is frequently recommended because it is “easy”, but no technical measures are taken into account. This results in conflicts with the hierarchy of measures in workers protection legislation.
- Amount rather than conditions of use: with regard to the environment, the main parameter used to iterate the assessment was often the use amount and, as a result, the use amount that is communicated as corresponding to the safe operating conditions of use is unrealistic²⁷.
- Information on waste: no new information on waste management is yet included in the eSDS.
- Failure to account for current conditions of use: it appears that the existing methods and approaches to worker, consumer and environmental protection have not been integrated into the CSRs; therefore already known and implemented conditions of use are not reflected in detail in the ES.

“Use Descriptors” and “eSDS” – A print company’s perspective

SMEs from within the print industry rely very much on receiving easy to understand advice to inform their chemical risk assessments. This advice primarily comes from the safety data sheets (SDS) that they receive from their suppliers. These short documents are currently less than ten pages in length and contain details of the hazards posed by the chemicals supplied to these companies, and guidance on safe use. These small print companies have staff that are experienced in using these simple SDS to inform their COSHH risk assessments. However, they are not likely to have staff dedicated to this task nor are they likely to have staff with a good, detailed knowledge of either REACH or CLP.

Under REACH the print companies now find that the SDS provided to them are increasingly in the new extended format required under REACH (eSDS). These are very much longer than they were previously, sometimes totalling hundreds of pages, and include new terminology such as “exposure scenarios” and reference to codes to describe the permitted use(s) of the chemical concerned (use descriptors). These terms can only be found with difficulty on the ECHA web site.

Once located, the use descriptor guidance is a 47 page PDF document which is moderately easy to understand; however, a reasonably high degree of knowledge of both REACH and CLP are assumed throughout. For a downstream user with little technical understanding of REACH, CLP or the theories of chemical risk management it can be bewildering. For example, nowhere in this document is the phrase “Exposure Scenario” defined or explained. There is no link in this document to the relevant guidance and the main title of this guidance “R12”, is as likely to be understood as referring to Risk Phrase R12 under DSD “Extremely flammable”, as section 12 of the guidance on information requirements.

Some of the formulators and distributors interviewed for this study and some attendees of the national workshop on eSDS²⁸ workshop reported the following approaches to forwarding information to their customers:

²⁷ One example: 10g of an aliphatic solvent may be used in the formulation of paints; practically, this means the product cannot be used any longer.

²⁸ This is the workshop of the REACH Hamburg Network cited above.

- No information is forwarded without processing²⁹;
- PNECs and DNELs as well as any new classification are included in the main body of the SDS;
- The formulator screens the relevant ES and communicates upstream or includes information in its own SDS if there is anything “surprising”. This includes checks on: coverage of user groups (professional / consumer), known uses with very high exposure levels (e.g. manual mixing, non-industrial spraying), existence of limitations on frequency and duration of use specific, very strict or extensive RMMs recommended;
- Only relevant changes in the risk management of substances are communicated in the main body of the SDS, including uses advised against (if there are any) and uses not supported; and
- A remark is included in the SDS that an ES can be obtained from the formulator on request.

Formulators noted that the above approach, although believed to be contributing to good supply chain communication, may involve taking over the responsibility from registrants on the identification of safe use, as the information they forward is selected from the information received.

Consultees also suggested that eSDS that have long lists of tables of supported uses and generic exposure scenarios in their current form are not really helpful, unless the recipient knows exactly what each applies to. Users want targeted information on whether their use is covered and what RMMs they need to adopt, rather than the current approach, which can result in an overload of information with everyone getting everything.

Several of these respondents indicated that they would prefer an approach, for mixtures at least, based on taking the worst case for each endpoint and then pulling together the SDS and providing guidance on use on this basis. Interviewees would also like to see the SDS more tailored, so that RMMs are specified for each classification end-point, rather than being broader exposure scenario based measures, or being recommended for each step within a processes (where the exposure scenario sets these out step-by-step).

Finally, one company from Eastern Europe indicated that it receives automatically translated eSDS that make no sense whatsoever. This problem has arisen across eSDS provided by a number of suppliers, who have no ability to check whether the translations into the Eastern European language are adequate or not. As a result, the company requests the eSDS in English and has to have it translated itself, in order to be sure that workers will actually have correct information on safe use and handling.

²⁹ Although one formulator and one distributor present at the workshop stated that they forward the ESs received “as they are” with their products.

Extent to Which Recommendations on OCs and RMMs Have Changed

To date, most consultees have indicated that there have been few changes in the operating conditions set out in exposure scenarios so as to ensure safe use, or in any of the associated RMMs being recommended to them. Since only few eSDSs have so far been produced, and even fewer have actually reached the article producers/final users of chemicals, this finding should be regarded as preliminary.

There are exceptions to this finding, though. For example, as discussed in Section 4, the act of registering one substance did lead a company to newly classify one of its substances as a reprotoxic, resulting in the recommendation of new measures to its downstream users.

These findings are not surprising in our view, as the chemicals which have had to be registered to date are either those substances already known to have CMR properties (and thus to be subject to requirements under the Carcinogens and Mutagens Directive as well as the Chemicals Agents Directive), or high volume substances for which there would have been the most data on hazardous properties pre-REACH. Thus, one would expect the impact of this driver to be greater in the future. As one consultee noted, the obligations to set out OCs and RMMs have not existed before, so they are bound to generate benefits once substances with less knowledge begin to go through the REACH process and information is provided to downstream users in a more usable format.

Communication up the Supply Chain

Information did not flow through the supply chain as anticipated pre-implementation. In particular, intentions regarding the identification of uses prior to registration were a failure, with this recognised by all parties. Manufacturers and importers could not cope with the huge volume of information received from downstream users, particularly where they did not refer to the use descriptors developed for this purpose. Downstream users were stated to have misunderstood the use descriptor system and therefore to have communicated unhelpful information upstream. However, from their perspective, downstream users expressed the view that manufacturers were not actively seeking information on uses. Thus, there is a view that no new knowledge on uses was generated, with manufacturers suggesting that this is the fault of downstream users and vice versa.

Downstream users and manufacturers both note that, in the early days, there was a lot of supply chain communication with manufacturers writing for information. Now communication tends to be limited to up-dates of the candidate list every time a candidate list is up-dated, with downstream users asking for information to see if they may be affected by possible future authorisation requirements or supply chain communication requirements.

Both types of consultees also indicated that downstream users are taking note of information coming down the supply chain, and responding to any new information that they receive. Both manufacturers and formulators stated that there have been some very proactive downstream users, particularly when they are concerned that

their use is not covered by the SDS. This has led to communication up the supply chain to clarify the understanding of ES, discuss inconsistencies and contradictory information and to ensure that either a use is covered or is added to the CSR. Consultees have indicated that such up-stream communication has led to a new use being added. One formulator reported that it is providing information on differences in classification to its suppliers. Other consultees reported, however, that when they have tried to communicate information up the supply chain, they received either no reply from the supplier, received a standard letter, or were told that the use would be considered but no updated SDS was received.

Other downstream users have communicated to their suppliers more reliable information on operating conditions (temperatures, quantities, descriptions of systems, etc.). This has allowed the suppliers to tighten up descriptions of conditions of use and has led to some further revisions in recommendations on risk management measures. An example where communication along the supply chain worked was reported by one consultee, and this is summarised in the box below.

An Example of Supply Chain Communications

According to the ES received, a substance used for brush or roller application should be used with exhaust ventilation or with the worker wearing a face mask. The substance is not severely hazardous and according to an authority it can be used safely without respiratory protective measures.

Feedback to the supplier on conditions of use and RMMS led to a reassessment and this resulted in the conclusion that no respiratory protection is needed.

The revised CSA was confirmed orally by the supplier to the company; the SDS has not so far been updated, however, and it is unclear why.

One downstream user association notes that there was a case where none of the uses of a chemical within its sector was included in the CSR. The association did not discover this until fairly late, suggesting that supply chain communication was not very effective in this case. However, the uses are minor within the context of other uses and the association accepts that it is very hard for manufacturers to reach out to all users in complex supply chains. This set of users notes, though, that it never saw an eSDS for the substance, just received information on the use codes. The association itself had to push to get the eSDS, and has still not received full eSDS from all suppliers.

More generally, downstream users (and others, including some manufacturers and distributors) are concerned that the process does not become overly administrative, as this would lead to a loss in the benefits that such communication can have. In particular, they would like to see guidance on how to minimise the box-ticking aspects of supply chain communications, so that the administration side of things can run more efficiently, and to ensure proper information is being communicated. In this regard, they would like to see better guidance on the use of websites as an acceptable means of communications. This would require guidance on what information has to be provided, length of time before up-dates are required, etc.

With regard to communicating and discussing eSDS once they are received, formulators stated that the following problems are arising:

- It is difficult to identify a competent contact person at the supplier and to receive an answer in due time;
- After making requests to suppliers, e.g. covering a use or providing clarification, suppliers often do not take action in response; and
- Some suppliers did not cover all downstream uses due to time (and potentially or resource constraints/financial reasons where a particular use is not a significant market for them and the aim has instead been to focus on core markets) but have indicated that they will consider them in the future (no actual activity yet); however, an unwillingness to update registration dossiers just to cover new uses has been observed.

When asked about the above problems as part of follow-up to the interview findings, manufacturers indicated that up-dates would take place over time, but that these were being planned so as to cover a number of requirements, not just the inclusion of a new use in the CSA. Those contacted also note that they do try to respond to the need for clarification but it is frequently difficult to provide this, due either to people being directed to work on other chemicals, consultants no longer being retained, etc. This suggests that on-going administration, on top of preparing for the next phase of registration, is proving difficult for some companies to manage.

Several registrants and formulators also indicated that downstream users are choosing not to request eSDS, in order to avoid triggering any new use requirements (i.e. new RMMs).

Several interviewees reported that the system of standardised use descriptions³⁰ and/or spERCs were helpful tools for supply chain communication, because they limit the amount of information registrants have to consider. For example, one company in the German construction sector reports that it asks suppliers whether or not a substance is covered by the generic “use reports” developed by the association, instead of evaluating the ESs provided by the suppliers.

A registrant noted that DUs have difficulty understanding eSDS and communicating with their suppliers. The registrant further specified that this is particularly obvious for the use descriptor system: many DUs simply notified all use descriptors as lists of relevant processes or product categories but failed to link them together. When receiving the eSDS, DUs are not able to recognise their uses in the title section of the ES, which is considered as an indication of the poor understanding by the registrant of how the combinations of use descriptors actually work.

³⁰ One formulator communicated identified uses with the DUCC system of grouping the most common conditions / uses. App. 10% of the suppliers answered they know the system (no eSDS received from them so far), app. 10% stated to use their own system and 80% did not react at all.

5.2.4 Responses to Other Consultations: Impacts on Competitiveness and Innovation

REACH Competitiveness Survey

Manufacturers

The CSES survey on Competitiveness³¹ asked manufacturers how the obligations posed by REACH have affected their relationship with customers. Out of the 304 responses to this question, 204 agreed that it had increased costs for the management of information along the supply chain and 160 agreed that it had led to the establishment of more advanced supply chain management processes. The responses to this question in the CSES survey, broken down by business size, are given in Table 5.2. It is not clear though how such improvements in supply chain management translate to health or environmental benefits, except to say that better information on uses is likely to help ensure that risk management recommendations are more realistic and focused.

Table 5.2: Based on the experience of your business, how have the obligations posed by the REACH regulation affected your relationship with your customers?							
Number of employees	Increased the costs for the management of information along the supply chain						
	Don't know/ no opinion	Not relevant	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
1-9	0	0	0	1	2	6	3
10-49	6	3	0	1	9	13	8
50-249	1	3	0	7	18	51	14
>250	7	6	3	9	23	77	31
Unknown	0	0	0	0	1	1	0
Grand Total	14	12	3	18	53	148	56
Number of employees	Led to the establishment of more advanced supply chain management processes						
	Don't know/ no opinion	Not relevant	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
1-9	1	0	2	3	1	3	1
10-49	5	5	4	5	10	10	1
50-249	2	8	3	31	27	21	2
>250	8	9	17	32	51	36	4
Unknown	0	0	0	1	0	1	0
Grand Total	16	22	26	72	89	71	8
<i>Note:</i> Based on raw data provided by CSES from the Competitiveness Survey. Data in this table refers to information given by manufacturers.							

³¹ CSES (2011): Impact of REACH on single market and competitiveness, draft final report to DG Enterprise, December 2011.

Formulators and Distributors

The CSES survey asked formulators and distributors whether they had submitted one or more chemical safety reports to the European Chemical Agency for uses of substances not included in the safety data sheets provided by their suppliers. Nine formulators indicated that they had. Out of these, four formulators had developed a chemical safety report for one substance and four formulators did not know how many substances they had developed a chemical safety report for.

In addition, formulators were asked in the survey to provide an estimate of the number of chemical substances for which they have developed a chemical safety report. Only eight formulators responded to this question, four answering 'one' and four answering that they did not know or that they had no opinion.

The majority of formulators and distributors responding to the survey indicated that the information requirements for eSDS were difficult to fulfill and that, in their view, they were too long and complex (around 80% or more of respondents to the CSES survey in both cases).

The CSES survey also asked formulators and distributors, based on their experience so far, to indicate the level of contribution of REACH to the following possible benefits:

- Increased confidence for consumers;
- Increased knowledge in relation to properties and or uses;
- Improvement in risk management;
- Reduction in health and safety damages;
- Help develop new less hazardous chemicals;
- Help identify potential new uses; and
- Led to improved cooperation.

In total, 118 formulators responded to this question. Of these, 30% agreed that REACH had led to an increased confidence of consumers in their products, 71% agreed that it had increased the level of knowledge in relation to the properties and/or the possible uses of chemical substances, 67% agreed that it had led to increased cooperation with suppliers, 62% agreed that it had led to an improvement of the risk management procedure within the business and 14% agreed that it had led to a reduction of the costs and damages related to occupational health and safety³².

Seventy six percent of distributors responded to this question that REACH had increased the level of knowledge in relation to the properties and/or the possible uses of chemical substances (22% agreeing very strongly/extremely), 70% agreed that REACH had led to an increase in cooperation with their suppliers, 70% agreed that REACH had led to an improvement of the risk management procedures within their business, 38% agreed it had led to a reduction of the costs and damages related to occupational health and safety and 38% agreed that it had helped identify potential new uses for existing chemical substances.

³² "agreed" includes all responses from "slightly" to "extremely".

Distributors

The CSES Competitiveness Survey asked distributors how easy they had found fulfilling the information requirements set by the regulation. Out of the 59 distributors who responded, nine said that they had found it easy or very easy and 39 said that they had found it difficult or very difficult; see Table 5.3.

Distributors were also asked about the problems they encountered related to the development and handling of the eSDSs, with the responses to this question indicated in Figure 5.2. Out of the 56 distributors who responded, 44 agreed or strongly agreed that the information requirement were difficult to fulfil, 37 distributors (out of the 56 who responded) agreed or strongly agreed that there was no standardized format for the provision of information, 52 (out of 58) agreed or strongly agreed that the development of the eSDSs required a lot of time and resources, 33 (out of 57) agreed or strongly agreed that the eSDSs were not available in their own language, 42 (out of 57) agreed or strongly agreed there was not enough time allowed to develop the eSDSs before the deadline of 1st December 2010 and 47 (out of 58) agreed or strongly agreed that the eSDSs are long and complex. Ten distributors agreed that they had encountered other problems.

Table 5.3: The implementation of REACH requires the exchange of information with your suppliers and your customers along the supply chain to get information on the uses of substances to include in the Safety Data Sheets. How easy did you find fulfilling the information requirements set by the Regulation? (Distributors)

Business size	No experience	Very easy	Easy	Neutral	Difficult	Very difficult
Micro (1-9 employees)	0	0	0	0	5	1
Small (10-49 employees)	0	0	5	6	5	5
Medium (50-249 employees)	0	2	0	3	9	5
Large (more than 250 employees)	0	1	1	2	6	3
Business size unknown	0	0	0	0	0	0
Grand Total	0	3	6	11	25	14

Source: Based on raw data from CSES Competitiveness Survey

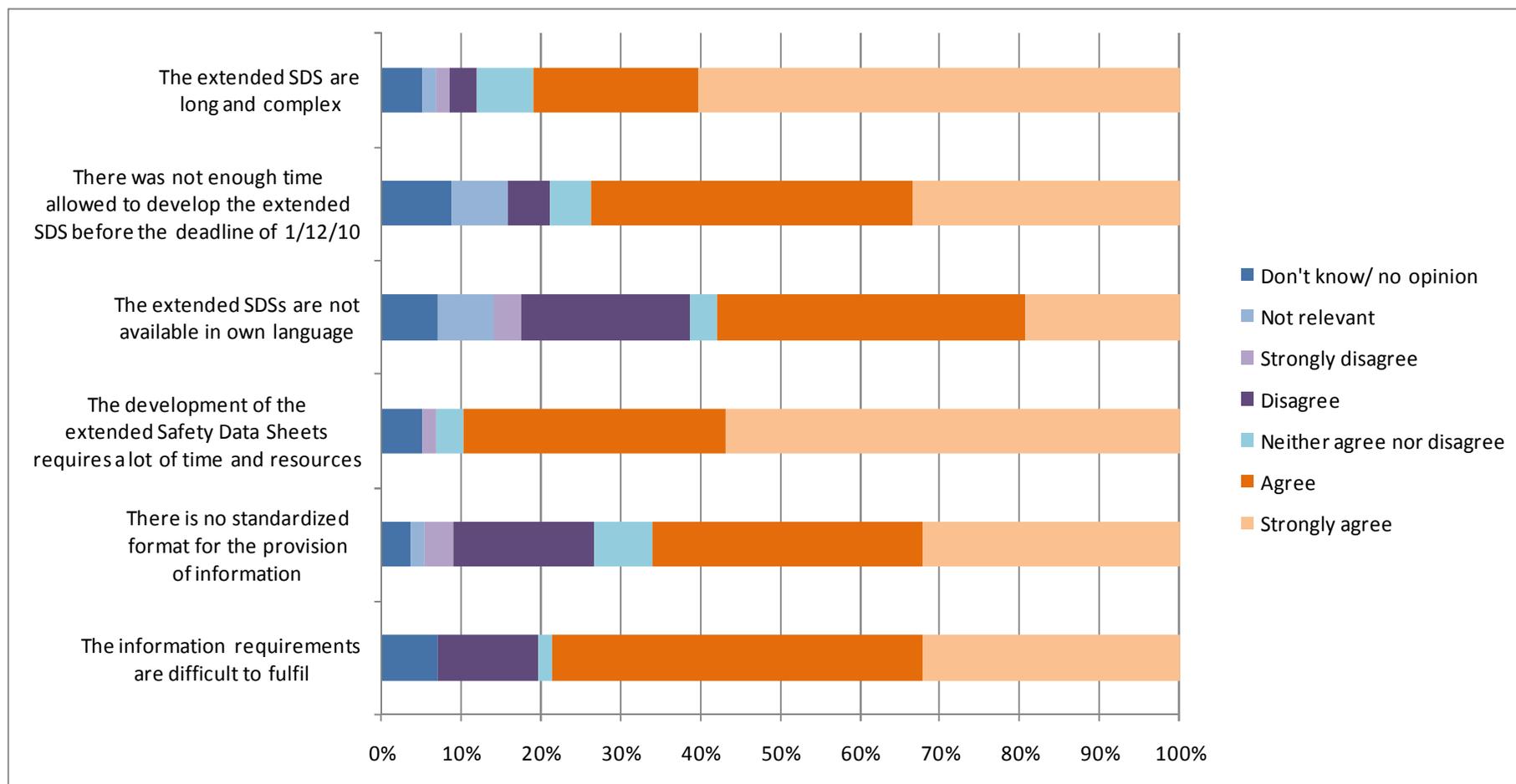


Figure 5.2: Are there problems related to the development and handling of the extended Safety Data Sheets as a result of REACH? How important are they? (Distributors) Source: Based on raw data from CSES Competitiveness Survey

Article Producers

With regard to article producers, 34% of respondents to the CSES survey agreed that REACH had increased the confidence of consumers in chemical products (unfortunately no information is provided on how this has been achieved), 36% agreed that it had led to improved cooperation with their downstream users, 53% agreed that it had led to an improvement of the risk management procedures within their business and 13% agreed that it had led to a reduction of the costs and damages related to occupational health and safety. However, only 1% of article producers agreed very strongly/extremely that REACH had led to a reduction of the costs and damages related to occupational health and safety. In total, 74% of article producers agreed that REACH had increased their level of knowledge in relation to the properties and/or the possible uses of chemical substances, 16% agreeing very strongly/extremely.

It is of note that no article producers indicated that they had submitted a CSR to cover the use of a chemical not included in the SDS provided by their suppliers. (Based on the above discussion, this could be because they had not yet received eSDS and thus do not know whether their use is covered or not). However, five article producers (out of a total of 137 respondents to this part of the survey) indicated that they had registered chemical substances or preparations included in the products that they produce in the ECHA database on substances intended to be released (with a further 16 saying they had not).

Article producers were asked whether they have prepared one or more chemical safety reports to cover uses of chemical substances that are not included in the safety data sheets provided by their supplier. Only five companies responded to this question, all answering 'no'.

End Users

The CSES survey asked end users whether they had submitted their own chemical safety reports due either to their desire to register a substance not covered by the SDS of their supplier or to avoid sharing confidential information with suppliers. Only eight of the respondents indicated that they had submitted their own CSR but none of these indicated it was for the above reasons.

The survey asked end users what their experience had been with respect to the exchange of information along the supply chain, including SDS. Interestingly, 38 out of 112 responses to this question indicated that their experiences had been negative, while only 22 indicated that they were positive (with 42 indicating it was 'moderate' and nine reporting no experience).

End users also perceive the eSDS information requirements as hard to fulfill. Perhaps more tellingly, over half agree that there is no standardized format for the provision of information in eSDS and that eSDS are long and complex (63 out of 97 respondents). However, only 21 out of 97 respondents indicated that the SDS were not available in their own language (although 15 did not know or had no opinion on this).

In total, 76% of end users responding to the CSES survey agreed that REACH had increased the level of knowledge in relation to the properties and/or the possible uses of chemical substances (14% agreeing very strongly/extremely), 52% agreed that it had led to increased cooperation with suppliers, 49% agreed that it had led to an improvement of the risk management procedures within their business, 12% agreed that it had led to a reduction of the costs and damages related to occupational health and safety and 26% agreed that REACH had contributed to identifying new uses for existing chemical substances. Only 1% of end users agreed very strongly/extremely that REACH had led to a reduction of the costs and damages related to occupational health and safety.

REACH Innovation Survey

Only limited questions from the CSES survey on innovation are of relevance to this study, and only the aspects related to human health and environmental benefits are considered here (i.e. innovation in general is not considered here unless it is clear that this is resulting in health or environmental benefits).

The CSES survey on innovation asked whether REACH has led to increased access to and scrutiny of information about chemical substances, and if it had, whether individual companies had benefited from this increased access. Out of 577 responses to this question, 320 respondents indicated that REACH had led to increased access on information about chemicals; however, only 82 respondents then noted that this has led to benefits in terms of having better information on the properties of chemicals. Sixty-one respondents noted that these benefits stemmed from information through their own supply chain. This suggests that eSDS have been more effective communication tools than is credited by our consultation responses.

However, at the same time, 115 respondents to the survey indicated that supply chain communication costs would have a negative impact on their decisions to invest in the development of new products or services, with a further 27 indicating that these costs would have a very negative impact on such activities. It is not clear from the survey responses why this should be the case.

The other relevant question from the CSES Innovation survey is that also discussed in Section 4, on whether CSRs, SDS or other communication throughout the supply chain had led to any changes in work organisation (e.g. production processes or material handling). Out of the 577 respondents to the survey, 182 indicated that REACH-related factors had not led to any changes in work organisation (i.e. it did not impact on production systems or material handling arrangements), while 152 indicated that it had (with the remainder either leaving the question blank or responding with 'don't know'). Out of the 152 respondents who said that it had, 56 were manufacturers of chemical substances, 36 were formulators (mixers) of chemical substances and 17 were importers of chemical substances or mixtures. A breakdown of the business types who answered yes to this question is given in Figure 5.3.

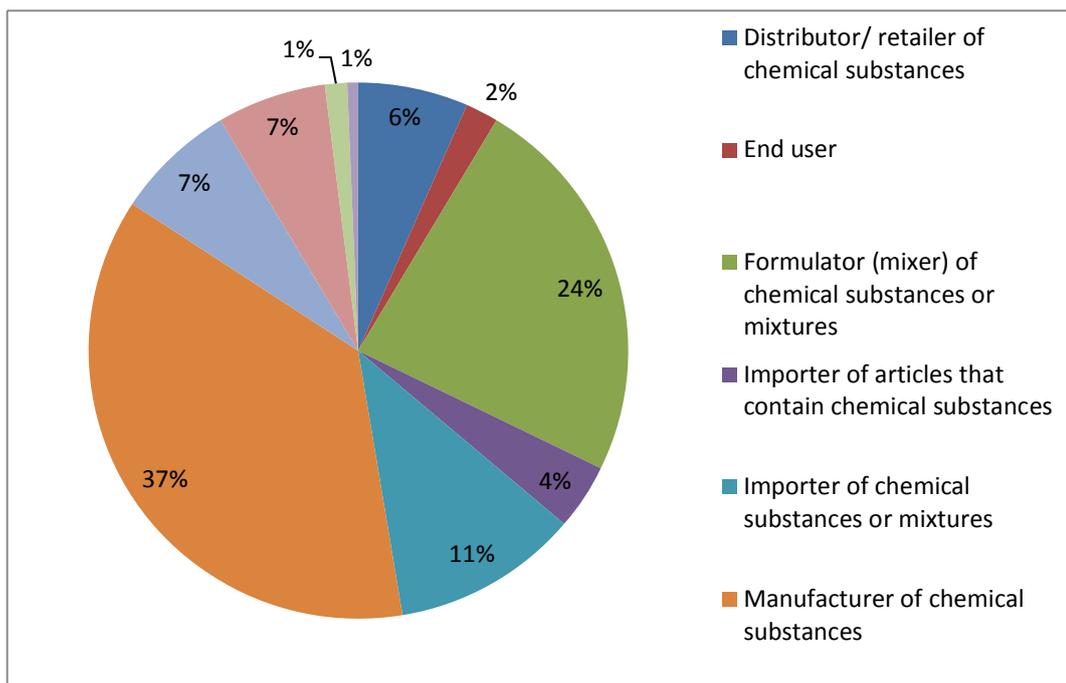


Figure 5.3: REACH-related factors have led to changes in work organisation within our business (based on raw data provided by CSES - breakdown by business type)

Scanning through the responses of those that said REACH-related factors had led to changes in work organisation indicates that respondents to this survey undertook the following types of measures:

- Changes in RMMs, for example confining particular substances, changes in handling activities, etc.;
- Changes in production processes;
- Changes in information provided to employees, increases in staff training;
- Greater awareness of potential dangerous consequences associated with particular chemicals;
- Investment in know-how, software and hardware for SDS, changes in archiving systems; and
- Changes in monitoring of emissions within the workplace.

However, others noted that their changes had led to an increased inflexibility, an increase in costs and an increase in compliance checks.

5.2.5 Linkages to Other Pathways and Benefits

The preparation of SDS, particularly eSDS, and of information on safe conditions of use and associated risk management measures as a pathway leading to benefits is clearly linked to all the different registration pathways. This includes the generation of new information on the properties of substances, classification of substances for

their hazardous properties and preparation of the chemical safety assessment and its associated exposure scenarios.

Of particular importance is the fact that the eSDS and the OCs and RMMs are the tools through which key information is actually communicated. Thus, unless these are implemented efficiently and act as effective communication tools, some of the benefits that could be created through the different pathways associated with registration as a driver will not be realised. This is important given the significant issues highlighted above with regard to the extent to which eSDS are being communicated and the concerns over the quality of the information that is being communicated.

5.2.6 Conclusions

Two related work hypotheses have been assessed in the above discussion. These are that:

- the communication of information through SDS and eSDS creates benefits by setting out information on risk management measures and identifying “uses advised against”; and
- the requirement to communicate information upstream if inappropriate recommendations on operating conditions or risk management measures are received creates benefits as new and appropriate RMMs are identified, new information on hazardous properties is received and taken into account, and the overall quality of safety data sheets is improved.

From the above discussion, it is clear that the quality of SDS has improved because the information on classification and labeling contained within them is regarded as more reliable (c.f. Section 4 on classification and labeling). In addition, the information being provided on DNELs is considered to be useful for workplace safety assessments and could therefore contribute to better targeted RMMs. As one consultee noted, these types of obligations (to set out OCs and RMMs) have not existed before, so they are bound to generate benefits for both health and the environment once substances with less knowledge about them begin to go through the REACH process and information is provided to downstream users in a more usable format.

However, the first work hypothesis is not supported by the following findings: the reliability of DNELs and PNECs is questioned and contradictions with the existing OELs are seen as confusing. PNECs in particular are not regarded as helpful as they reflect environmental concentrations rather than allowable quantities discharged into the environment; in this regard, PNECs will be of more use to authorities than to industry actors.

The issue with regard to DNELs differing from OELs has been identified by others as potentially leading to confusion (Kayser, 2007³³), and such differences are considered likely given the basis for their respective derivations. OELs are intended as specific occupational health and safety instruments while DNELs primarily define what risk management measures are necessary (Kalberlah, 2007³⁴). This illustrated by a recent comparison of 88 OELs produced by SCOEL with their corresponding worker DNELs under REACH that showed safety margins for DNELs were overall about six-times higher than for the OELs, though ranging between 0.3 and 58 (Schenk and Johanson, 2011³⁵). Over the period of phase-in of REACH and until such time as the apparent differences between the regulatory significance of OELs and DNELs can be clarified, it is likely that industry may be subject to some confusion.

More importantly, concerns over the quality of eSDS are viewed by many as leading to a reduction in the usefulness of the documents to downstream users. This is due to the large amount of information contained in the eSDS that is either not relevant, not useful or confusing and “hides” or “dilutes” the information necessary to ensure safe handling. Indeed, some actors fear that the safety data sheet as a whole is being discredited in the long run. This has led to some actors not circulating eSDS, where they believe that they will not be understood by downstream users, and may lead to the basic safety information being ignored.

It is important therefore to step back and learn from the difficulties that have arisen to date. In particular, there is a need to consolidate what is being recommended to downstream users to make sure that it is clear what they should do and why. This is partly an issue arising from the language required in producing exposure scenarios and eSDS, but also due to the language that the authors of these documents like to use and which is not easily understood by non-experts.

These findings are mirrored by responses to the CSES survey results. For example, as reported above, the majority of formulators and distributors indicated that the information requirements for eSDS were difficult to fulfill and in their view were too long and complex. A significant percentage of end users (around one third) also indicated that they had either had no experience or a negative experience with respect to the exchange of information along the supply chain. End users also perceive the eSDS information requirements as hard to fulfill and not based on realistic use and operating conditions. Perhaps as tellingly, over half agree that there is no standardized format for the provision of information in eSDS and that eSDS are long and complex. This means that the realisation of benefits related to the preparation of eSDS largely

³³ Kayser M (2007): DNEL: multiple values for identical substances? Lecture at Occupational Limit Values for Hazardous Substances – Health working conditions in a global economy. Conference under the German Presidency of the European Council, Germany, May 7-8, 2007.

³⁴ Kalberlah, F (2007): Harmonising OELs and DNELs at European Level: a position paper reflecting the results at the OEL conference in Dortmund. Lecture at Occupational Limit Values for Hazardous Substances – Health working conditions in a global economy. Conference under the German Presidency of the European Council, Germany, May 7-8, 2007.

³⁵ Schenk L and Johanson G (2011): A Quantitative comparison of the Safety Margins in the European Indicative Occupational Exposure Limits and the Derived No-effect Levels for Workers under REACH. *Toxicol. Sci*, 121, 408-416.

depends on the quality of the eSDS communicated downstream and the standardisation of information (resources), as well as the competence of the actors. This has implications for the degree to which the potential health and environmental benefits that should be delivered by REACH are actually being realised.

Furthermore, it is clear from the interviews that there are severe issues affecting the effectiveness of supply chain communication:

- Processing of registration information to produce an amount and content that is relevant and helpful to the DUs and that can be supplied as ES has not yet been carried out in many cases;
- The clarification of questions and the inclusion of new uses in a CSR requires work and resources on both sides, by registrants and DUs, which is not practicable at present;
- The content of the feedback and the consequences with regard to the quality of eSDS cannot yet be clearly described, because this process has only just started and remains rare. However, it is clear that there are issues regarding the degree to which eSDS are being up-dated after newly identified uses are communicated to suppliers; and
- In addition, it appears that some suppliers may have taken a decision not to cover some uses in their CSAs so as to reduce the burden of meeting all of their first round registration obligations. As a result, some identified uses still need to be included within the exposure scenarios and thus communicated in the eSDS.

To a degree, these findings are also supported by responses to the CSES surveys. For example, registrants indicated that REACH has increased the costs of managing information along the supply chain, with a large proportion indicating that it has led to the establishment of more advanced supply chain management processes. Although it is not exactly clear how this improved management translates to health and environmental benefits, most formulators and distributors agreed that there has been an increased level of cooperation with suppliers, and an improvement in risk management procedures within their businesses.

Although article producers were less positive on the above two issues, most agreed that REACH had increased their level of knowledge on the properties and/or the possible uses of chemical substances. This can only have been the result of supply chain communication requirements. The same is true for end-users, who responded to the CSES survey that REACH had increased their level of knowledge in relation to the properties and/or the possible uses of chemical; roughly half also felt that it has led to increased cooperation with suppliers. Both of these aspects should help ensure that potential benefits to consumers, the general public and the environment associated with emissions to the environment, dispersive uses of chemicals and the presence of hazardous chemicals in articles are realised through safer use.

Responses to the CSES Innovation Survey also indicate that most respondents believe REACH has led to increased access on information about chemicals, even if only

around a quarter of those expressing this view believe that this includes better information on the properties of chemicals or benefits stemming from better information through their own supply chain; again this is relevant not only to worker protection but also consumers, the general public (i.e. exposures of man via the environment) and the environment. This suggests that eSDS may have been more effective communication tools to date than credited by our consultation responses.

5.3 Communication on SVHCs on the Candidate List for Authorisation

5.3.1 Pathways to Benefits

The need to communicate information on the presence of a SVHC³⁶ in a mixture or in an article is linked to two potential pathways of effect. The first is the removal of hazardous substances through supply chains due to the “announcement effect”, which may in turn result in benefits for both human health and the environment where there is a reduction in risk. The second relates to the communication of information down to end-users of articles, as it is hypothesized that this could lead article recipients to avoid articles containing SVHCs or, as a minimum, ensures the communication of information on safe use and disposal as a waste.

These potential benefits are linked to the following drivers:

- The identification of a substance as an SVHC and candidate listing (with this being one of the key drivers within REACH); and
- The requirement for the provision of information on SVHC in articles contained in concentrations above 0.1%.

Although it is early in the process for there to be much information on these issues, it is clear that the candidate listing process has had an effect on some supply chains. Given that the number of actors that can be consulted on this aspect is limited at this point in time, there are also limits on the conclusions that can be drawn at this stage.

Similarly, although the larger retailers may be responding to the candidate list by recommending to suppliers that they remove listed SVHC from their products, it is too early to draw conclusions on how suppliers are dealing with this issue across the range of retailers that they supply.

Finally, given the substances placed on the list to date, there are only limited cases where consumers may have taken into account the presence of an SVHC in their purchasing decisions.

5.3.2 Expectations Prior to REACH

In 2007, Oekopol carried out a study for DG Environment which examined the potential role of supply chain communication in promoting a shift away from the use

³⁶ A SVHC is a substance classed as a CMR cat 1a or 1b, a PBT or vPvB according to Annex XIII of REACH, or a substance of equivalent concern meeting the criteria set out in Article 57 of REACH.

of SVHCs in consumer articles. Two of the key factors identified by that work included (Oekopol, 2007):

- Market pressure towards substitution. Downstream users and retailers producing and selling consumer products are especially sensitive to hazardous substances, and particularly SVHCs, and require their suppliers to exclude them from their products. However, others may not be aware of the substance in the products they use or are not involved because they are outside EU.
- NGO campaigns can influence consumer behaviour. Thus companies selling consumer products and brands show increasing openness in communication and willingness to exclude SVHCs from their products. By publishing company policy statements and product policies, they demonstrate awareness and responsibility.

These factors are also clearly relevant to the announcement effect driver discussed in Section 6.

The Oekopol study of 2007 found that market actors in the EU are quite aware of CMRs, but less aware of PBTs, vPvBs and substances of equivalent level of concern. A number of indicative lists existed at the time, referring not only to legal requirements, but also to upcoming requirements for substances of which the use should be limited in order to reduce the risks to people and the environment. These lists were (and remain) widely used by companies to deal with the challenges of substance related risk reduction. All experts consulted at that time expected that the candidate list would be used in a similar way as the existing indicative lists. In particular, companies representing the end of the supply chain noted that they were highly interested in an EU wide harmonised list of substances regarded as being of high concern.

With regard to the different roles in the supply chain, the Oekopol study concluded that it would be mainly the task of formulators to substitute SVHC in their preparations and that they will often react to a strong demand by their customers. This hypothesis was confirmed for consumer articles, by interviews conducted for the 2007 study with retailers and owners of consumer brands indicating that they would demand SVHC-free products from their suppliers to ensure product safety and give NGOs no reason for criticism (e.g. to avoid NGOs running campaigns against a particular consumer brand producing goods containing a high profile chemical or retailers selling such goods). In addition, for suppliers, it was expected that there would be increased pressure to provide information on SVHCs contained in articles (according to Art. 33), at least for the supply of article parts which are further processed inside EU.

The study also revealed from the interviews that some retailers were worried that the candidate list could be too large to be manageable for supply chain communication and in particular for checking compliance through product and supplier inspection. With regard to this problem, the KEMI expert proposed to include information on uses in the candidate list to enable companies to focus on substances relevant for their specific applications and some retailers identified the need to group their products

according to the probability of the presence of specific substances. It was not clear, though, whether this would be of much assistance to retailers dealing with very large numbers of product lines to be checked.

On the other hand some interviewees consulted in the Oekopol 2007 study were doubtful whether the article requirements could be implemented for imported articles. Retailers noted at the time of the study that many Asian suppliers normally agree to the supply commitments regarding substances and concentration limits, but often do not take them seriously and the products which they then provide do not comply with the restrictions/limits. This has been illustrated more recently by the presence of banned substances in imported toys (e.g. paint used on toys, phthalates).

The Oekopol study (2007) concluded that as enforcement can be difficult, there was a danger that retailers without sensitive brands or reputation issues might continue their business without making additional efforts and that this would remain undetected (although this obviously highlights the importance of enforcement of Articles 7 and 33).

5.3.3 Discussions with Industry for this Study

Many of the predictions from the Oekopol study (2007) appear to be substantiated by findings from the consultation carried out in the context of this study with formulators, article producers and retailers. They were asked for information on the following types issues, to the degree appropriate:

- To what extent and how is the candidate list used as communication instrument?
- Is there pressure from the market to avoid candidate substances in mixtures or articles? How is the pressure exerted?
- What exactly triggers action: threat of authorisation, communication requirements with articles, fear of loss of company reputation due to use of SVHCs?
- What information is communicated with articles containing SVHC and in which form?
- Is the information provided believed to promote safe handling of the article? If yes, was the information available before?
- Do consumers / recipients of articles request information on SVHC in articles? What is their reaction if they are made known of a SVHC content?
- What role does the communication on SVHC in articles play in the decisions to supply an article?

All consultees agreed that the authorisation candidate list is a powerful instrument triggering actions on SVHCs in the supply chain. Many actors confirmed that a notification of an intention is already a signal to the market. (See also Section 6 on the announcement effect of authorisation).

Pressures within the Supply Chain

The overall perception of a substance on the candidate list is that it is very hazardous and should be avoided. This is viewed by some as a concern, since some uses of such substances may be safe – an example was given of a substance used as reactant in polymers which is fully integrated into a product matrix and not released as such during the lifecycle – and provide overall environmental benefits compared to alternatives (e.g. lower environmental impacts in lifecycle analyses). Although other uses may not be safe, the concern is that candidate listing on its own will force substitution in those uses which are safe, even if the alternatives do not deliver the same technical performance or result in significant cost impacts.

There is also a concern that substitution may be with alternatives that are not better from a health or environmental perspective (i.e. and/or are not suitable in the context of Article 55 of REACH) because some of the properties that result in their being classed as a SVHC (e.g. persistence) are necessary to their technical functions. Indeed, the discussion provided in Section 4 highlighted that one manufacturer has withdrawn a candidate list substance from production but is now supplying another substance for use in its place which has very similar properties.

Interview responses suggest that registrants may refrain from registration of a substance placed on the candidate list because of expected decreasing markets. However, this would still be a case-by-case decision and registration may also continue despite a listing. An active search for alternatives was not mentioned as a prominent business strategy of registrants; however many companies do offer alternatives from the same group (and, as suggested above, substitution with these may lead to an equal level of concern/risk). This suggests that it may be important to consider groups of substances used to deliver a specific function when identifying potential candidate substances, at least in terms of classification and labeling. As indicated below, this might produce strategic benefits for article producers, as it could reduce their costs over the medium to longer term of identifying, testing and moving to less hazardous chemical inputs.

Formulators have reported that they start looking for alternatives as soon as a substance has been included in the candidate list. This is conducted together with registrants and downstream users. From the formulators' perspective, substitution efforts are preferable to considering an application for authorisation, due to the fact that authorisation is regarded as a very cumbersome and expensive process and there is insecurity about the success. Formulators are also concerned with the long term availability of the substance on the market, as candidate listing may trigger substance withdrawal/reduction of the supply.

Brands, retailers and article producers request that SVHCs are phased out as soon as they are included on the candidate lists. The most common approaches are the request for confirmation that no SVHCs are used by their suppliers, and an on-going checking of the entire candidate list. Sector- and company specific blacklists all contain the candidate substances. Many of these actors also carry out measures to control their suppliers. The article producers and retailers interviewed for this study have put in place or are putting in place IT-systems to ensure compliance with the

SVHC provisions. They have had a dialogue with their customers on these issues and are asking their own suppliers about reformulation.

One article producer stated that substitution is the preferred option to react to a candidate listing, because communication or notification obligations, as well as problems with a potential authorisation, can be avoided and compliance with other legislation (e.g. RoHS) is supported. This company initiates substitution discussions within its supply chain between formulators and parts manufacturers to develop solution proposals, which are communicated to the article producer, who takes a decision. These processes are on-going and have been started by different companies in the sector in parallel; hence, the solutions being developed and applied by the article producers are frequently similar.

A consultee also stated that a major challenge with substitution is that frequently substances which are well tested are being replaced with substances for which less information is available³⁷. Hence, companies do not fully know if the solution is sustainable and actually leads to a risk reduction. The availability of information for alternatives is not yet seen as having improved due to REACH.

Other consultees reported that the SVHC criteria are being implemented into routines for product development and purchasing decisions.

Communication Issues

In general, interviewees indicated that they feel there is a lack of understanding of the information flow for SVHCs (although this could be interpreted instead as reflecting differences in strategies towards dealing with or managing SVHC issues). In particular, there is a large variation in customers' and others' understanding and knowledge of the SVHC requirements. Industry associations appear to communicate some information on SVHCs (whether well informed or not) to their members, who then go to suppliers to seek information on whether or not a SVHC is present in the products being provided to them. But one downstream user noted that the way in which they are approached varies considerably, from a number of questions on their strategy with respect to substitution, to requesting confirmation that there no SVHCs are present in a mixture/article, to asking for future commitments regarding SVHCs. The requests that they receive suggest that many downstream do not understand what the obligations for communicating information are.

The need to communicate on SVHCs has delivered some benefits, in that it has made companies more aware of their products. However, some have found it quite difficult to gain sufficient information from some of their overseas suppliers or to ensure that the information being provided is valid. To a degree, this has hardened their attitude to making sure that suppliers are complying with the company's own standards. This

³⁷ As discussed in Section 4, the generation of new information through REACH is expected to newly identify a large number of substances as having currently unknown hazardous properties, including CMR, PBT and vPvB properties, and properties of equivalent concern such as endocrine disruption. Given the numbers predicted, e.g. 450 newly identified CMRs category 1 or 2 in accordance with Directive 67/548/EEC (as included under Article 57 of REACH), this means that such substances will continue to be identified over the next phases of REACH.

leads to another issue – companies have to decide whether they trust the information that non-EU companies are providing them with, whether they will take action to enforce company standards or whether they should revert to greater use of EU manufacturers (at a cost and possible market share penalty). All of these act as triggers for encouraging article producers to look at the ease of replacing SVHCs so as to minimise issues.

It is also argued, though, that the above makes it harder for EU manufacturers than for non-EU manufacturers, as there is a real lack of transparency in relation to non-EU goods. If a non-EU manufacturer declares that his goods are compliant, then they will be imported and used by other article producers, which could be to the advantage of unscrupulous suppliers. As a result, there is no level playing field for EU producers.

This is both an issue which is intrinsic to REACH and one of enforcement.

1. One of the intrinsic problems relates to the 0.1% concentration threshold in articles and ECHA's/COM's interpretation which means that, for many "final" articles, the 0.1% will not be exceeded for the imported goods but that it may be exceeded for the individual parts produced in the EU. In addition, the existence of different interpretations of the threshold creates confusion in the market. But this is not the focus of the issue raised above, which is that there is no legal requirement for exporters to pro-actively provide information to the importer but the importer has to generate it.
2. The enforcement issue is that if there was a better enforcement and "real" penalties within the supply chain and from authorities, the playing field would be more level than it is right now. However, the 0.1% issue is difficult to enforce due to the large diversity of articles, complex supply chains, etc.

Several end of chain mixture manufacturers/article producers indicate that they have not yet had any information coming down the supply chain on SVHCs; the communication is only up the chain so they are having to ask for information. This is true in terms of information requests to both EU suppliers who have a legal obligation to communicate such information and non-EU suppliers. As a result, these end of chain actors regularly ask their suppliers about SVHCs under REACH and may also refer to the SIN list.

Article producers also indicated that a real problem for them is in trying to understand whether an SVHC will be contained in the types of products that they sell. They note that the Annex XV reports may highlight typical uses, but there may be others or the way in which uses are described is too general. As a result, they have to think about whether the types of uses could be relevant to their products. Thus, one of their key recommendations would be for ECHA to provide more information on what types of end-products/articles may be of concern so that downstream supply chains can fulfil their obligations.

This recommendation would seem reasonable at a general level, as article producers are the actors that know the least about substances and thus need the most support and help in focusing what to look for may be of value in this regard. The difficulty is that

ECHA may not have such precise information. It will not be available from registration, although it may be provided from the notification requirements placed on article producers. While the Annex XV reports do generally try to describe uses as far as possible, it has to be realised that it can occasionally be very difficult to take information on first and second uses through to the article level. For example, assume that the SVHC is used as a pigment. In such cases, it may be relatively easy to identify the end articles in which the pigment is used. In other cases, e.g. a SVHC used in anti-corrosive applications, providing a complete list of articles in/on which the substance may be found could be unrealistic. This does not mean, however, that such efforts could not be made to outline the likely broad article categories (and their end-uses) which may contain the substance.

Addressing the Complexity of Supply Chains

One major multinational retailer noted that it is trying to assist its suppliers in understanding REACH obligations and has been developing and giving them tools for this purpose. This includes a tool that looks at different products and flags up what types of chemicals may be in that product, so that their suppliers can check whether they have the chemical in theirs.

The need for this type of activity was also identified by another retailer, which confirmed that one of the key problems from its perspective is that article producers will buy parts from other producers and then put these together to form the article. These article producers will themselves rely on several different suppliers as sources for parts – e.g. cables. If they do not manage their own supply chain and purchasing decisions, then they cannot guarantee that the end articles do not include SVHCs. For example, this was an issue with respect to phthalates and their use in PVC cabling. For retailers, it is hard to work out what might be in a finished product, so they have to decide what to look for and what analyses to undertake themselves to identify the presence of SVHCs. Thus retailers may carry out some analytical testing of products to check whether an SVHC is present in a product and, at one point in time, find that none are present and then 6 months later find that they are within the same product; this is an additional and new cost to these operators. Retailers fear that as the number of substances entered onto the candidate list increases, their ability to manage such product checks will decrease.

A recurring comment from article producers is that they currently face difficulties in the implementation of REACH, due to the frequency with which the candidate list is being up-dated. They expect this to become an increasing problem as the number of substances on the List increases. This issue is considered further in Section 5, where the request from consultees for a more spaced ‘batch’ versus ‘trickle’ approach is highlighted.

Impacts on SVHC Use

None of the consultees was able to specify whether or not substitution has already happened to a large extent and whether or not the alternatives are less hazardous than the substances on the candidate list. There appears to be a tendency to select alternatives from substances within the same family, as they will have the properties

required to deliver the technical function for which the SVHC was chosen in the first place. Therefore, as indicated above, one consultee suggested that SVHC identification and inclusion in Annex XIV should consider listing groups of substances, to prevent an outcome where analogous substances are selected for substitution. This would give more security for (long term) planning and the search for alternatives.

The above type of approach might be of particular value where there is a risk that candidate listing could lead to a substance not being registered, yet there are no currently identified substitutes

According to a number of consultees, the listing of phthalates was found to have triggered more awareness of imported products (e.g. gloves, tablecloths) which still contained the substances and is providing an incentive for actors to phase-out the remaining uses. However, such substitution efforts were in place prior to the candidate listing of the phthalates, with listing only further reinforcing the final phase-out.

The situation is different for HBCDD, where it seems that no alternative is available yet for some building applications. Hence, three consultees expect problems in the future and have no information on whether an application for authorisation is currently being prepared.

Chromates are viewed as a case where the conditions of use implemented in the UK and Germany, for example, are understood as delivering a “high quality and high protection level”. Thus, further controls may not be required in these countries; other countries do not necessarily have such stringent controls and additional measures may be necessary in those countries to protect worker health. In this respect, authorisation should lead to health benefits, however, there is a fear that even where the risks are well controlled and regulated the use of these substances and associated production activities will be lost to the EU.

The discussion provided in Section 4 on substance withdrawal also highlighted that some manufacturers are deciding not to register a SVHC placed on the candidate list based on the view that it is too risky financially to incur the associated costs for a substances that has an uncertain future. This may cause real problems for downstream users, however, where there is not known alternative at the present time. This is leading to downstream users either considering taking on the burden of registration themselves (based on the import of the substance) or agreeing to share the financial costs of both registration and authorisation. As a worst case, it has been suggested by one interviewee that it is leading to a shift of production activities outside the EU.

Queries from Consumers

The core motivation to substitute SVHCs on the candidate list is to avoid future authorisation requirements; hence, it is understood from the consultees that candidate listing is considered equal to being placed on the list of substances for authorisation. For formulators and article producers, communication on SVHCs (labelling of chemical products, explicit mentioning of SVHC content) is avoided to maintain a

good company image. In the case of mixtures, formulators substitute because markets demand products which do not hold specific classifications and thus where labelling for SVHC content is not required.

This raises questions as to whether the duration of the process for agreeing that a substance is a SVHC (from a classification perspective) plays a role in decisions to substitute and whether the prioritisation criteria for inclusion on the authorisation Annex are checked prior to substitution. No interviewee raised the classification process as leading to early efforts for substitution, and only one interviewee (an industry association) raised the prioritisation criteria in the discussions. In this case, it was expressing the view that some of the chemicals being placed on the List do not appear to meet the criteria; for the association, consideration of the criteria was not a good guide toward whether or not prioritisation would occur. Instead, in most cases, it appears that the mere fact that there is a possibility of authorisation is what is important. The classification of a substance may play a role in prioritising the substitution sequence inside a company, but there are also many other factors. The result is that substitution is started – if feasible – once a substance is on the candidate list (and possibly even when it is placed on the Registry of Intentions). The duration of agreeing on SVHC properties or CL or the severity of CL are not important. Neither are the prioritization criteria.

The request for information on SVHCs in articles is reported as relevant mainly in business to business communication; only very few requests have been received from consumers. One article producer mentioned that the SVHC content is not regarded as an important factor influencing a consumer's purchasing decision (supplier of electronic equipment). The information communicated with articles in the cases reported by the consultees was stated to be limited to the legal minimum (name of the substance).

UK retailers have indicated that they have not yet had a “single true consumer”³⁸ asking for information on whether or not an article contains a SVHC. The only requests for information that they have received have been from environmental NGO activists or journalists. Nevertheless, the retailers have put in place systems to handle such requests when they do arise. However, they note that, if they were asked whether a SVHC is in a product, then they would probably have to test that product rather than rely on their suppliers' information (at least at this stage) in order to guarantee compliance with REACH. This approach was cited by three retailers as being essential at this point in time. As there have been so few queries, carrying out such testing itself is not an issue. If more queries were to occur, then it would become financially prohibitive to carry out such testing and analysis. This poses a real dilemma given the difficulties in developing information within the complex global supply chains which currently exist, as also cited above by the article producers themselves.

However, retailers may not be able to just sit back and wait for an Article 33 request if they have trade customers. In these cases they are supposed to inform their customers

³⁸ Someone not motivated by lobbying, political or job related reasons for asking, e.g. a general consumer. See also Section 5.3.4 on the research carried out by BEUC on this issue.

of the presence of an SVHC and have to carry out labelling of such information on the products themselves. This has happened in relation to expanded polystyrene insulation panels (articles) which contain HBCDD; one retailer noted that it has had to add information on the packaging to ensure that this information is communicated.

Retailers have also noted that there are inconsistencies across the EU in how an ‘article’ is being defined and that this is causing problems. In most countries, the end item as a whole is the article, while a few others are adopting an approach based on all parts essentially being defined as a separate article (anything that started life as a separate item is an article in of itself). The second approach increases the level of detail required and has created problems in terms of the weight issues as to when ‘substances in articles’ provisions come into effect. It is particularly difficult for multinationals to address this problem as it also acts as a market barrier to intra-EU trade. One such retailer did note, though, that in its opinion the separate article approach may have advantages, in that a consumer may be exposed to the part that has the SVHC but which does not have to be labelled due to the overall weight of the product.

This can be illustrated by considering an article that contains a part with a SVHC above 0.1% and which the article user would have contact with:

- Case 1: the entire article is relevant for checking the threshold: the substance is diluted so there is no notification/communication. In such a case there is no incentive to look at exposure at all.
- Case 2: the parts are considered: in this case, notification and communication is triggered, theoretically exposure must be assessed, because conditions to allow safe use must be communicated (Art. 33). In such a situation, the lack of exposure could be used to avoid notification by claiming the exemption of “no exposure” but not to avoid the communication.

One company communicates on SVHCs in its articles on its web-site: all articles provided are listed in a pdf document. In a table, for each item, either the name of the SVHC contained above 0.1% is given (and CAS number), or the statement “no SVHC”. No information on safe use is provided. Other consultees also noted that there are arguments for companies creating repositories of information so that all customers can draw on them. They also indicated that this may give rise to legal issues regarding who is liable for the quality of such information, what information should actually be provided, how often does it have to be up-dated, etc.

The main actions identified by consultees that would help in addressing the current problems they are facing are:

- Improved information on where individual SVHCs are likely to occur – in particular whether this is in consumer articles, and then the likelihood of substances being found in different types of products.
- Information on ECHA’s website of the above nature which could be easily searched by article producers and retailers and which would ensure some consistency across the EU.

5.3.4 BEUC Research on Consumers Right to Know

BEUC, the European Consumers' Organisation, together with a series of national consumer organisations, tested the degree to which retailer and producers were aware of and able to fulfil their obligations concerning consumers' rights to know about the presence of SVHCs in their products or packaging (BEUC, 2011)³⁹. Letters were sent in nine EU countries for 34 categories of products to different producers to assess the communication methods being adopted, the language of the reply, the length of time taken to reply (and whether this was within the 45-day deadline), the comprehensiveness of the answer, the content of the reply, who made the reply (retailer or producers) and their knowledge of the candidate list and the ChemSec SIN List. In total, 25 letters were sent out in each country asking for information on 75 products per country. All requests were sent electronically.

They concluded that the vast majority of companies fall short of meeting their obligations, with the following needing to be addressed:

- Insufficient knowledge and awareness of REACH obligations;
- Insufficient information flow between the different economic operators involved; and
- The need to provide more specific and comprehensive answers.

As a result, they raise questions over the practicability of the "Right to Know" provisions (i.e. Article 33(2)) within REACH. For example, they note that few of the respondents referred to the latest version of the candidate list, with this raising questions over the accuracy of the responses. They also note that keeping up-to-date this will be a growing challenge for companies as the list continues to grow, as additional substances are added.

BEUC conclude that consumers' Right to Know is not currently working well enough to create the pressure helped for to achieve pressure by retailers on their suppliers to phase out the use of SVHC. More concrete recommendations include the following (paraphrased from BEUC, 2011):

- Different means of communicating a request for information should be allowed: letter, fax, email
- Web-forms should be designed so that consumers are able to send in meaningful requests (sufficient space);
- Websites should contain dedicated information on chemicals policy and how consumers can exert their Right to Know;
- Replies should be in the same language as the consumer request;

³⁹ BEUC (2011): Chemicals, Companies & Consumers: How much are we told?, The European Consumers' Organisations, Brussels.

- Sanctions should be put in place when action is not taken to provide a reply to consumers within the 45 days (whether the delay is due to producers' failure to provide information or retailers failure to respond);
- Mechanisms need to be built into the supply chain to enhance information flow between retailers and producers so that both are able to fulfil their obligations;
- Information should be adapted to the needs of consumers and relate to the specific information request;
- Market surveillance organisations should monitor experiences with the operation of Article 33(2) information requests and take enforcement action when appropriate, with this including joint actions across member States; and
- Training and awareness raising are needed for retailers and manufacturer to enable them to provide better answers to consumers.

5.3.5 Responses to Other Consultations: Impacts on Competitiveness and Innovation

REACH Competitiveness Survey

Manufacturers

When asked whether any of the substances they produce are included in the current candidate list of substances of very high concern for authorisation, 40 manufacturers responded that they had (with 35 out of these 40 being large firms with more than 250 employees) (Figure 5.4) Out of these, 20 manufacturers agreed that the result of entry in the candidate list for authorisation had (sometimes to always) been an increase in the costs for the business as a result of the requirement to provide information to customers, 19 agreed that it had led to a reduction in the demand for the specific substance, 10 agreed that it had led to the decision of their suppliers to remove the substance from the market and 11 agreed that it had led to the decision of their suppliers to replace the substance with a less hazardous substance. Fourteen manufacturers said that it had had no impact.

Formulators

Formulators were also asked whether any of the substances they use in their formulations/mixtures are included in the current candidate list of substances of very high concern for authorisation. Out of the 144 responses (see also Figure 5.5), 64 formulators (44%) said yes. Seventy eight percent of formulators agreed that entry in the candidate list for authorisation had (sometimes to always) led to an increase in the cost for the business as a result of the requirement to provide information to customers, 24% agreed that it had (sometimes to always) led to an increase in the price of the substance(s), 24% agreed that it had led to the decision of their suppliers to remove the substance from the market and 31% agreed that it had led to the decision to replace the substance with a less hazardous substance.

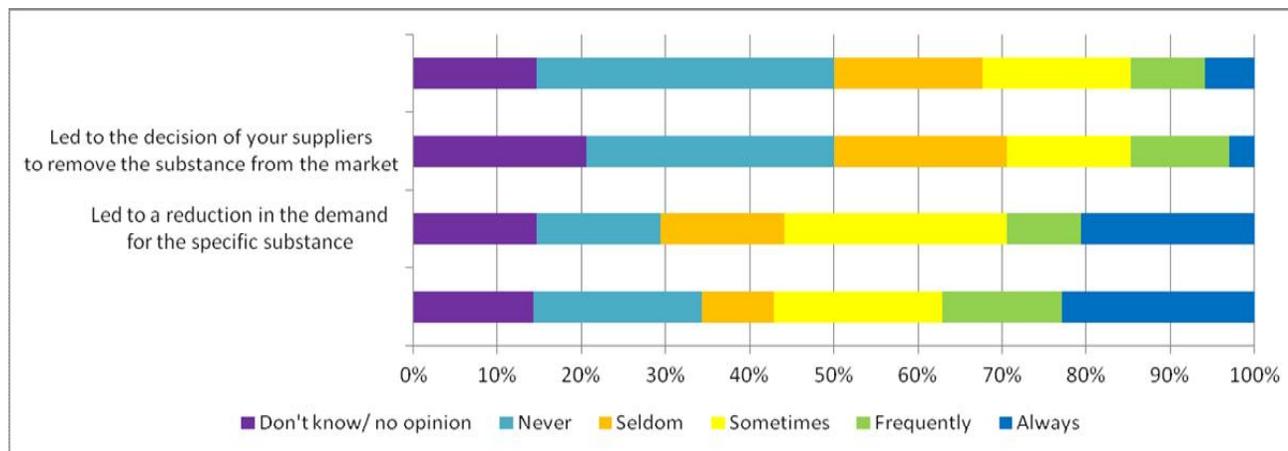


Figure 5.4: What has been the result of the entry of a substance you produce in the candidate list for authorisation? (manufacturers of chemicals)

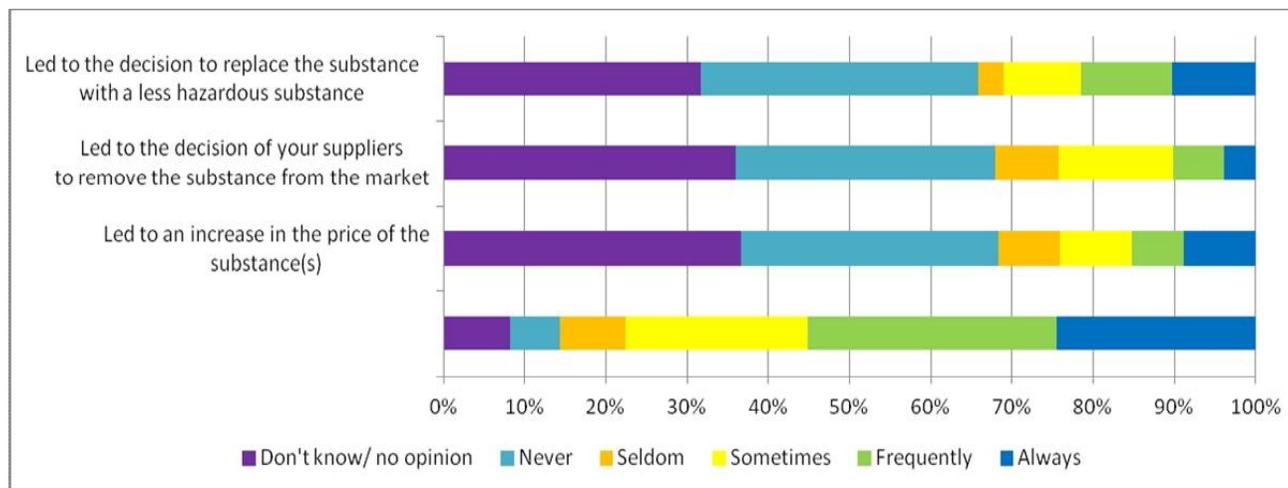


Figure 5.5: What has been the result of the entry of one or more substances you use in your formulations in the candidate list for authorisation? (formulators)

Distributors

Out of the 58 distributors who responded to the survey, 33 have substances on the candidate list for authorisation. Out of these, ten are small businesses employing between 10 and 49 employees, 12 are medium size businesses (50-249 employees) and 11 are large businesses with more than 250 employees. When asked about their response to the entry of a chemical substance used in the products they distribute/sell in the candidate list for authorisation, three businesses said that they had asked their supplier not to supply any products that include the specific chemical substance and ten said that they had asked their supplier to ensure that no products supplied include the specific chemical substances. Twenty four distributors said they had made no specific response.

Article Producers

In total, only three article producers responding to the CSES survey indicated that any of the substances they use in the articles they produce are included in the candidate list of substances of very high concern for authorisation. These three article producers were all large companies with more than 250 employees. Of these, only one company agreed that entry into the candidate list for authorisation had frequently led to an increase in the costs for the business as a result of the requirement to provide information to customers, two companies agreed that it had sometimes led to a reduction in the demand for the specific substance, two companies agreed that it had sometimes led to the decision of their suppliers to remove the substance from the market and two companies agreed that it had sometimes led to the decision of their suppliers to replace the substance with a less hazardous substance.

Out of the 137 producers of articles who responded to the CSES survey, 23 said that they manufacture one or more articles that contain chemical substances intended to be released from the article (i.e. within the context of Article 7 obligations) and 114 said that they do not. See Table 5.6 for further details.

Table 5.6: Do you manufacture one or more articles that contain chemical substances intended to be released? (Producers of Articles)		
Business size	Yes	No
Micro (1-9 employees)	1	2
Small (10-49 employees)	5	25
Medium (50-249 employees)	6	29
Large (more than 250 employees)	11	56
Business size unknown	0	2
Grand Total	23	114
<i>Source: Based on raw data from CSES Competitiveness Survey</i>		

Out of the producers of articles who responded to the CSES survey that they do manufacture “one or more articles that contain chemical substances intended to be released”; three said that they only placed “one article that contains chemical substances intended to be released” on the market in 2010; six said they had placed two to ten articles “containing chemical substances intended to be released from articles” on the market in 2010; while one said they had placed 11-50 articles that “contain chemical substances intended to be released” on the market in 2010; two said they had placed 51-100 articles that “contain chemical substances intended to be released” on the market in 2010, three said they had placed 101-1,000 articles that “contain chemical substances intended to be released” on the market in 2010 and one said they had placed >10,000 articles that “contain chemical substances intended to be released” on the market in 2010, as indicated in Figure 5.4.

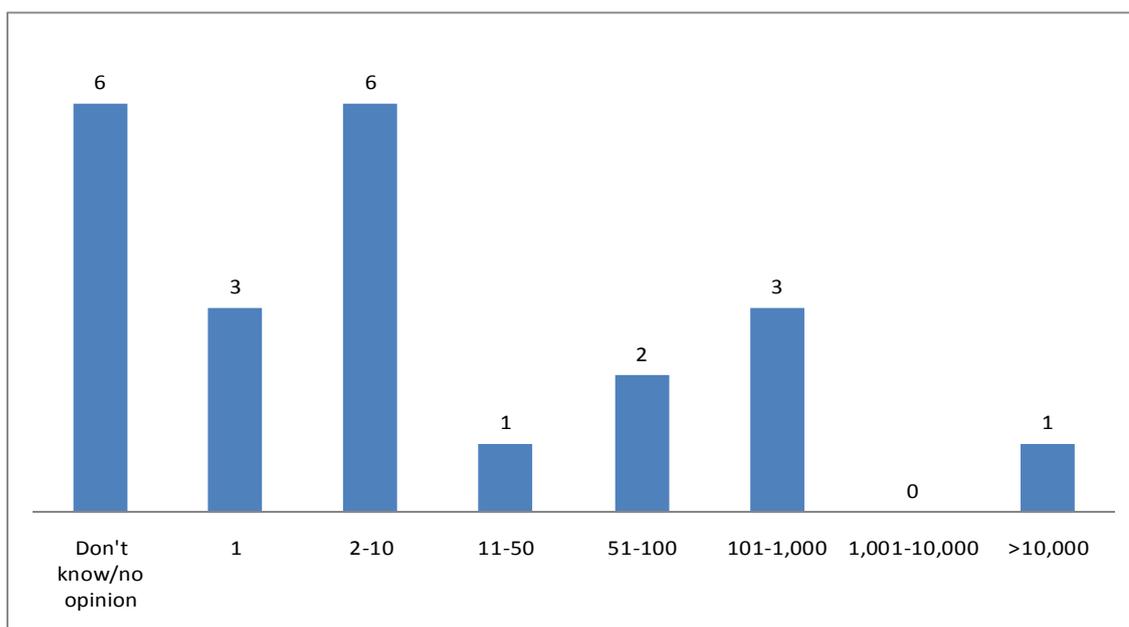


Figure 5.4: How many articles containing chemical substances intended to be released did you place in the market in 2010 (Producers of Articles). *Source: Based on raw data from CSES Competitiveness Survey*

End Users

Only three end users indicated that any of the substances they use in their products are included in the candidate list of substances of very high concern for authorisation. These were all small companies with between 10 and 49 employees.

Innovation Survey

When asked in the CSES survey on innovation what the effect had been of placing substances on the candidate list for innovation at their firm, 11% of respondents said that they had launched initiatives to develop new substances to substitute them, 28% said that they had launched initiatives to find alternative formulations of existing substances to substitute them, 21% agreed that they had withdrawn them from their product portfolio, 23% said they had requested substitution of those substances by their suppliers and 14% said they had taken no special action.

Perhaps more interesting, though, in relation to the impact of the Article 33 requirements, are some of the more detailed additional comments provided by respondents. These include the following, extracted from the survey data:

- “Most of our suppliers are also downstream users. They have rejected any kind of responsibility and have relegated it to the importers and manufacturers [of substance].”
- “We inform our employees and customer about this substance and the background of the candidate list. It generates additional costs.”
- “We have never used substances in the candidate list, they were still hazardous beforehand. We have to process thousands of inquiries about substances we do not even know and which we would never have allowed near our company. A mass of data for nothing, absolutely nothing.”
- “We have cancelled products and/or withdrawn products from the EU market. Has not led to innovation due to cost and availability of alternatives.”
- “Providing guidance and support to our clients in sourcing alternatives or considering authorisation.”
- “More communication to customers was needed.”
- “We advised customers on analyses to be performed on their articles and possible substitutions.”
- “We had to coerce our suppliers to use other substances.”

5.3.6 Linkages to Other Pathways and Benefits

There is a clear link between the pathways to benefits discussed above and those identified under authorisation as a driver (see also Section 6). As the above discussion has also highlighted, there are links between the above pathways and registration as a driver and more specifically substance withdrawal. These links are demonstrated by numerous of the comments made by interviewees, but also by the findings of the CSES surveys.

5.3.7 Conclusions

The starting hypothesis for the analysis presented above is that the following REACH requirements will deliver human health and environmental benefits.

- The identification of a substance as an SVHC and candidate listing (with this being one of the key drivers within REACH): the “announcement effect” associated with the candidate listing of SVHC will result in the removal of such substances from the market, which may in turn result in benefits for both human health and the environment where there is a reduction in risks.

- The requirement for the provision of information on SVHC in articles contained in concentrations above 0.1%: the communication of information to end-users of articles, as it is hypothesized that this could lead article recipients to avoid articles containing SVHCs or, as a minimum, ensures the communication of information on safe use and disposal as a waste.

Both the interviews carried out for this study and the responses to the CSES surveys would appear to support the above propositions. Candidate listing is leading to early action towards substitution by formulators and demands for substitution within their supply chains by article producers. Thus SVHCs are gradually being withdrawn from use, particularly from supply chains that produce end-consumer goods. It is not clear that substitution is taking place to the same extent where use of the SVHC is in an industrial process and where the substance is not present in the final good. Indeed, some consultees asked why such SVHCs are being considered at all at this stage, given that there is extensive worker protection and environmental legislation to regulate exposures from such activities.

There are concerns, though, that substitutes are not necessarily always better from a human health or environmental perspective. There is also concern that candidate listing leads to pressure for substitution even in those applications which have been assessed as being safe and for which there may be no feasible or suitable alternatives. In other words, all applications are blacklisted even if they do not pose a real risk. Although this is one of the stated aims of the authorisation provisions, it has potential implications for both costs and human health and the environment if it results in shifts to alternatives (substances, techniques or materials) which present their own risks. It is therefore important that consideration is given to the risks from substitution with alternative chemicals or processes vis-à-vis the risks from continued use of the candidate list substance and whether there would be a net reduction in risks with substitution.

It can also be concluded that the need to communicate on SVHCs has delivered some benefits, in that it has made companies more aware of raw materials in their products. In the longer term, this will lead to much greater awareness throughout the supply chain of chemicals management issues and the replacement of SVHCs in articles; however, in the short term it is proving difficult for EU article producers and retailers to put in place the necessary information management systems.

Article producers and retailers are worried that, as the candidate list increases in size, it will become impossible for them to manage the necessary supply chain communication and in particular to undertake the necessary compliance checks through product and supplier inspections. To address this issue, it has been proposed that information on the uses of substance placed on the candidate list is published by ECHA to enable companies to focus on substances relevant for their specific applications. This would also help producers and retailers to group their products according to the probability of the presence of specific substances. It is not clear, though, whether this would be of much assistance to retailers dealing with very large numbers of product lines to be checked.

Retailers noted that, if asked whether a SVHC was in a product, they would probably have to test that product rather than rely on their supplier's information (at least at this stage) in order to guarantee compliance with REACH. This is not yet a problem given the low level of queries, however, if more queries were to occur then retailers indicated it would become financially prohibitive to carry out such testing and analysis. This poses a real dilemma given the difficulties in developing information within the complex global supply chains that currently exist.

6. AUTHORISATION AND RESTRICTION

6.1 Overview

6.1.1 Pathways to the Realisation of Benefits

The authorisation provisions within REACH are aimed at assuring that risks from substances with properties of very high concern are properly controlled, with this including the progressive phasing out of their use. The authorisation process involves the following steps:

- Identification of SVHCs on the basis of the criteria contained within Article 57 of REACH and evaluation of these by ECHA (with the outcome of this presented in an Annex XV report);
- Their listing on the Candidate list for consideration as priority substance for eventual inclusion in Annex XIV of REACH;
- The prioritisation of listed substances to Annex XIV with defined sunset dates after which the substance may no longer be placed on the market or used;
- Application for an authorisation for the continued use of the substance in defined applications by the manufacturers/importers and/or users 18 months prior to the sunset date;
- Review procedures of applications by ECHA and its Risk Assessment and Socio Economic Analysis Committees, leading to opinions on an application;
- Approval procedures for the granting or refusal of an application by the Commission based on the opinions from ECHA and its supporting Committees, together with the time limited review of authorisations that have been granted.

Substances subject to authorisation are those that have been identified as having specific hazardous properties, where these include CMR properties, PBT or vPvB properties or other properties of equivalent concern. The need for controls on such substances is therefore hazard based and not risk based, although prioritisation does take into account factors such as production volumes and whether there is wide-dispersive use of the substance as proxies for potential risks. The burden of proof to justify the continued use of a SVHC falls on industry rather than the authorities and, importantly, the European Commission may only approve an application should either the risks from the use of such substances be “adequately controlled”, or the socio-economic benefits of continued use outweigh the human health and environmental risks. As illustrated in Figure 6.1 and Table 6.1, this process should act to significantly control exposures to substances of very high concern and thus the risks posed by them to human health and the environment.

REACH also includes a separate provision allowing restrictions (Title VIII) to be placed on the manufacture (or import), placing on the market or specific uses of either a substance, mixtures and/or articles (subject to some exemptions), where these can be

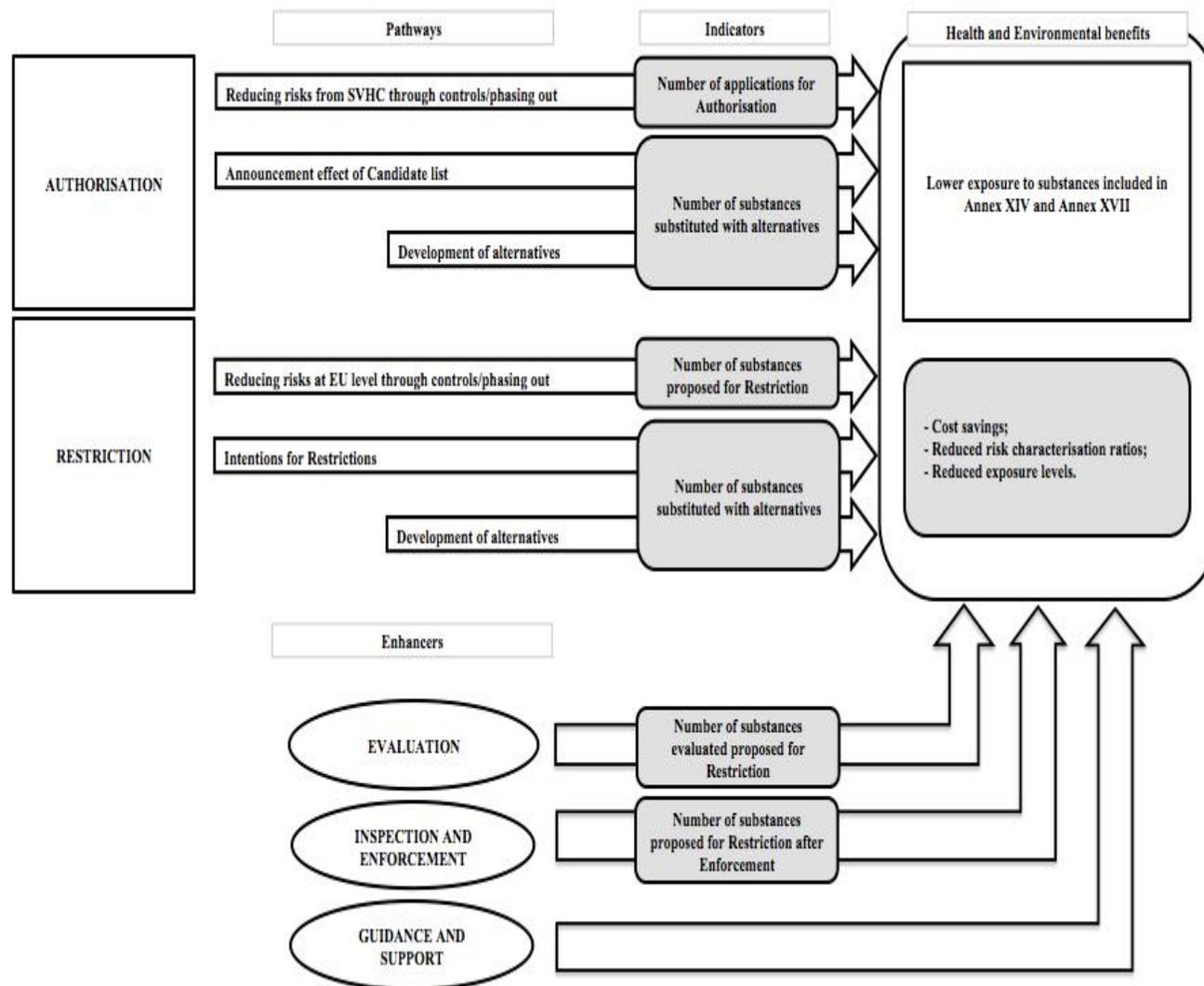


Figure 6.1: Flow Chart of the Drivers under Title VII “Authorisation” and Title VIII “Restriction”

Table 6.1: List of the Key Provisions by Duty-holders, Drivers and Benefits for Authorisation and Restriction				
Article	Key Provisions	Duty-holders	Pathways	Health and Environmental Benefits
Authorisation				
55	Requirement on all manufacturers, importers and downstream users applying for authorisations to analyse the availability of alternatives and consider their risks, and the technical and economic feasibility of substitution.	M, I, DU	Reducing risks from SVHCs through controls/phasing out	Lower exposure to substances included in Annex XIV
56(1)	Requirements on manufacturers, importers or downstream users not to place a substance on the market for a use or use it itself if that substance is included in Annex XIV unless sub-paragraph (a), (b), (c), (d) or (e) are satisfied.	M, I, DU		
56(2)	Requirements on downstream users not to use a substance otherwise than in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use.	DU		
60(8)	Requirement to ensure the respect of the conditions linked to the authorisation.	M, I, DU		
60(10)	Requirement on a holder of an authorisation to ensure that the exposure is reduced to as low a level as is technically and practically possible.	M, I, DU		
65	Requirement on a holder of an authorisation and downstream users to include the authorisation number on the label before they place the substance or mixture on the market for an authorised use.	M, I, DU		
66(1)	Requirement on a DU using a substance in accordance with article 56(2) to notify ECHA within three months of the first supply.	DU		
Restriction				
67(1)	Prohibition on the manufacture, placing on the market or use of a substance on its own, in a mixture or in an article for which Annex XVII contains a restriction unless the manufacture, placing on the market or use of a substance on its own complies with the conditions of that restriction.	M, I, DU	Reducing risks from through controls/phasing out	Lower exposure to substances included in Annex XVII

shown to pose an unacceptable risk to human health or the environment that should be addressed at EU-wide basis. In the case of restrictions, the types of controls that may be placed on the use of a substance are wider in nature and include targeting of specific applications and its use in articles. In contrast with the authorisation process, the burden of proof falls on authorities rather than industry, and the authority must demonstrate that the restriction in terms of risk management measures is the most appropriate mechanism to control and reduce the risk.

As such, the REACH restriction provisions are not dissimilar to those established under the earlier combination of the Existing Substances Regulation (Regulation (EC) No 793/93) and Marketing and Use Directive (76/769/EEC, repealed on 1 June 2009) and, indeed, restrictions established under 76/769/EEC were carried over into REACH. Consequently, the pathways through which benefits to human health and the environment are delivered under a REACH restriction are similar to those under the earlier Directive. As for the “announcement effect” of candidate listing under authorisation, the publication of intentions to produce restriction dossiers may well also produce similar announcement effects.

A key aspect in establishing the extent to which the restriction process under REACH may provide overall greater benefits than the process for restricting the use of substances under the Marketing and Use Directive (76/769/EEC) concerns the length of time for the restrictions to be adopted and implemented. In particular, the focus on more targeted assessments under REACH is expected to result in a speeding-up of the process; this will stem in part from the fact that the mandatory registration of substances will ensure that the data on substance properties and exposures is already available to authorities rather than their having to generate this data.

6.1.2 Work Hypotheses for the Main Pathways

In order to assess the degree to which benefits have been realised to date, work hypotheses have been developed for both the authorisation and restriction procedures. These are as follows:

- Listing of SVHCs on the candidate list: as discussed in part in Section 5, candidate listing triggers benefits because: it discourages manufacturers from registration of listed substances; it triggers requests for phase-out by article producers; it triggers the reformulation of mixtures; it triggers the promotion/identification of alternatives by manufacturers (and may trigger innovation); and
- Restriction: Restriction helps ensure that risks are reduced at the EU level and triggers benefits because: the registry of intentions acts as a signal to manufacturers and downstream users to consider moving to or developing alternatives; by speeding up the process for risk management, benefits should be delivered more quickly than they were under the Existing Substances Regulation and Marketing and Use Directive. It also provides a mechanism for controlling the import of articles containing SVHCs from outside the EU ensuring that not only EU producers are impacted.

These two main pathways are discussed in more detail in the remainder of this section, following a summary of the potential indicators of benefits (which are likely to be more valuable as indicators in the future given the early stage of implementation of the authorisation and restriction provisions). A related and potentially stronger pathway, not examined in this study, is the listing of a substance on Annex XIV as this would have a stronger effect on the continued use of the substance and thus on the potential benefits of REACH. Linked to all of these is the role of evaluation in identifying substances for both of the above procedures (see also Section 7).

6.1.3 Indicators of Benefits

Based on the above, we have identified the following as potential high level indicators of benefits:

With regard to authorisation:

- Number of substances identified as meeting the criteria as a SVHC;
- Number of chemicals included in the candidate list (Art.58), and as a % of those meeting criteria as a SVHC;
- Number of substances (and % of all SVHCs) subject to authorisation (inclusion in Annex XIV);
- % of substances with SVHC properties listed in Annex IV of CLP and in Annex XIV compared to the total expected number of SVHCs;
- % of Annex XIV substances for which safe alternatives are introduced over specified time frames (e.g. first 10 years of REACH);
- Number of applications for the continued use of substances and the associated percentage of the total volume pre-candidate listing;
- Number of decisions taken regarding Article 60 using the adequate control route or the socio-economic route.

With regard to restriction:

- Number of restriction proposals introduced for substances, mixtures or articles;
- Number of new restrictions adopted on uses of substances and mixtures, and on articles;
- Average (and minimum/maximum) time taken to reach regulatory decision on a restriction proposal.

Evaluation and enforcement may also act as an enhancers of the main authorisation and restriction provisions, with these impacts potentially detected by the number of substances proposed for either authorisation or restriction after formal substance evaluation; the number of substances proposed for substances proposed for harmonised classification after formal substance evaluation; and the number of substances proposed for either authorisation or restriction as a result of enforcement activities.

At this stage in the implementation of REACH, it is not possible to assess performance against most of the above major or supplementary indicators. Where data does exist, it may also be misleading to use this at this stage as the basis for drawing conclusions given that both the authorisation and restriction mechanisms now in place under REACH are in their early stages of operation. As a result, the assessment is based on a more general consideration of the two pathways described earlier.

6.2 Placing SVHC on the Candidate List

6.2.1 Pathway to Benefits and Associated Indicators

Substances which are included on the “candidate list” must fulfil the criteria of REACH Art. 57 and must have been identified according to Art. 59. These substances of very high concern (SVHC) include CMRs 1a and 1b, PBTs and vPvBs and other substances which give rise to an equivalent level of concern (e.g. endocrine disrupting chemicals). Classified CMRs (as listed in Annex VI of the CLP Regulation) and substances already identified as PBTs/vPvBs (from the list developed by the pre-REACH working group) are expected to be entered onto the list. Additional substances identified by Member State Authorities and ECHA on behalf of the Commission will also be added to the list, based on registration data, substance evaluation work and other activities.

Substances placed on the candidate list are those which may be put onto Annex XIV and thus be subject to authorisation (Art. 58(3)). As part of this process, priority is normally to be given to substances with PBT or vPvB-properties, wide dispersive use or high volumes. The candidate list is also the basis for requirements concerning the notification of substances in articles according to Art. 7(2) and for the communication obligations discussed in Section 4.

The stated aims of authorisation is that substances of very high concern: “are eventually replaced by suitable alternative substances or technologies where these are economically and technically viable” (Article 55). In this respect, the candidate list has been identified as giving rise to potential ‘announcement effects’ (Oekopol, 2007). By listing the potential substances for authorisation beforehand, it is believed that producers and users of the substances will be incentivised to undertake substitution earlier.

Thus, the starting hypothesis is that the candidate list will trigger benefits because:

- It discourages manufacturers from registration (withdrawal);
- It triggers requests for phase out by EU article producers;
- It triggers reformulation of mixtures; and
- It triggers the promotion/identification of safer alternatives by manufacturers and downstream users, and may trigger innovation including both green chemistry or the move to more novel materials or techniques.

The degree to which such pressures have been experienced to date is summarised below, based on responses to the consultation carried out for this study and the responses to the CSES surveys on Competitiveness and Innovation. Position papers issued by some key organisations are also reviewed. First, we summarise some of the pre-REACH expectations of this work.

6.2.2 Pre-REACH Expectations

The study carried out by Oekopol (2007) for DG Environment on the degree to which the creation of a candidate list would encourage industry to develop safer alternatives and thus promote substitution concluded that there were a number of factors which may affect the speed at which substitution would take place as well as the extent of substitution as a result of the listing alone. Key factors identified then and which are also relevant here were reported to be as follows (text taken from Oekopol, 2007):

- **Market pressure towards substitution.** Especially downstream users and retailers producing and selling consumer products are sensitive to hazardous substances and require their suppliers to exclude them from their products (with this clearly also linked to the Communication driver - see Section 4).
- **Companies want to prevent damage to reputation.** This is a strong incentive for all actors in the supply chain to ensure product safety and to cooperate with NGOs in reducing consumer exposure to substance related risks. This is most relevant for owners of consumer brands and for enterprises, which demonstrate in their policy a high level of awareness with regard to environmental, health and social issues (with this holding for both EU producers and importers to the EU).
- **The availability of suitable alternatives.** Where alternatives are considered suitable, it implies a good performance of the resulting products and low additional costs for the substitutes and/or connected risk reduction measures and is of particular relevance for the formulators.
- **Acceptance of the identified risks in the sector:** e. g. companies may not agree with the risk conclusion, with this delaying the speed at which they move to substitutes.
- **Enterprises gain in company reputation and brand recognition if they provide ideal solutions for substance related risks:** This is also an incentive for substance manufacturers – both large and small – to search for alternatives.
- **A high level of risk management in the company/supply chain.** If risk reduction is already part of the management system and/or supply chain communication, risk based decision making and non-voluntary commitments are often easier to implement.

- **Legislative pressure drives action.** As legislative pressure is found to be one of the most powerful factors driving companies, the probability of actual limitations on future use will push companies towards substitution.

6.2.3 Progress with Candidate Listing and Prioritisation

As of mid-December 2011, 78 substances have had dossiers prepared regarding their identification of substances of very high concern (SVHC), with 12 of these prepared by ECHA at the request of the Commission. A further 33 intentions to produce such dossiers have been identified by Member States for 2012. Of the 78 substances, 73 substances had entered onto the candidate list as of January 2012, with 15 prioritised for authorisation in June 2009, 8 in December 2010 and a further 13 in December 2011 (total of 36 as of January 2012).

ECHA indicated publicly in early 2011 that there was still a long way to go to reach the European Commission target of 136 Substances of Very High Concern on the candidate list by the end of 2012. At the time, ECHA was encouraging EU Member States, especially those which have not yet been active in the process, to nominate substances to the candidate list. This is seen as the first step in achieving a target for all 'relevant' SVHCs to be put on the candidate list by 2020, with this expected to be around 400-500 substances. This is the number already identified by some Member States, although it has been suggested that up to 1200 substances will fulfil the criteria.

6.2.4 Discussions with Industry for this Study

Substance Withdrawal Because of Candidate Listing

Two industry associations indicated that, in their experience, candidate listing is leading to the withdrawal of a substance from the market, even where there may be good arguments for the continued use of the substance or where it may be possible to demonstrate adequate control. In other cases, suppliers have indicated that they are unwilling to register the substance for uses that may be subject to authorisation due to the costs of supporting an application and the risks of not being successful; instead they have indicated to their downstream users that they will have to do this and support any applications for authorisation should they wish to continue use of the substance. Although users have indicated that they may also support a substance through authorisation themselves, others have indicated that it is likely no downstream users will support uses of a particular substance with it then lost to the EU market (but remaining on the market outside the EU).

However, in other cases, manufacturers appear to be less willing to withdraw a substance from the EU market. Instead, they are arguing that their uses should be classed as 'intermediate' uses so that they fall outside the authorisation process, or are seeking exemptions for other reasons (e.g. use as medical packaging, use for military purposes, etc.). Thus, a range of responses can be seen at this stage, with only some responses corresponding to the announcement effect.

More generally, as reported in Sections 4 and 5, it would appear that there has been a greater level of substance withdrawal due to candidate listing than identified through consultation.

Although not directly relating to REACH (but highlighted as a likely impact of REACH), examples were given by more than two sectors to illustrate the unpredictable consequences that may follow the withdrawal of a substance from use. These related to biocides withdrawn from the EU market for economic rather than risk related reasons and focused on the consequences for companies of having to then undertake reformulation activities. For example, both a consumer product manufacturer and an adhesives manufacturer faced difficulties in continuing to offer certain water-based technologies due to increased rates of mould formation using alternative biocidal products; in both cases, the companies are having to consider a return to solvent-based technologies in order to be able to continue offering the end-products; in other cases, they are having to add back into the product another biocidal agent at a higher concentration than previously employed due to a change in the effectiveness of the replacement biocide being used. Such a change in the formulation to achieve adequate performance characteristics may inadvertently result in undesirable consequences due to the retrograde move away from water-based technologies with potential consequences with regard to wider environmental and safety aspects; cases such as this highlight the potential for the loss of a SVHC to result in negative effects on health or the environment.

Process of Identification of SVHCs

As part of the interview discussions, one of the associations noted that a key concern: once a substance is on the candidate list, it is not clear whether it could be removed when new data becomes available which would change the assessment of the level of hazard posed; this aspect is of particular importance to industry and, therefore, legal clarification on this issue by the Commission might be warranted. In addition, the listing is unspecific, hence any users of the substance regardless of whether or not an exposure is generally possible, are affected by a potential changes of supply.

Another association voiced concern that the current criteria used by Member States and the Commission are not entirely clear, when selecting specific substances out of all fulfilling Article 57 for identification as a SVHCs and thus for inclusion in the candidate list. It is also suggested that there is a lack of transparency on the decision-making that leads to a substance placed on the candidate list being moved to Annex XIV. Although the “general approach” set out by ECHA⁴⁰ includes consideration of factors for which criteria do exist (such as substance properties), it also involves a ‘verbal-argumentative’ component which is subject to interpretation and which not be applied consistently across substances. Another consultee argued that the nature of these criteria may even work against the intended effect of candidate listing, as it could lead to industry defence of substances where there is a suspicion that they are being put forward for candidate listing for political purposes rather than real concerns

⁴⁰ ECHA (2010): General Approach for Prioritisation of Substances of Very High Concern (SVHCs) for Inclusion in the List of Substances Subject to authorisation, May.

over the potential risks associated with their continued use; this aspect may work against the announcement effect being a trigger of benefits.

Consultees also noted downstream users may not necessarily be moving away from the use of substances placed on the candidate list at this point in time, as they are still are trying to understand the process and its implications for them.

Interviewees who were registrants and association representatives noted that the process for choosing what substances should be considered for formal identification as a SVHC (by Member States and the Commission), the prioritisation given to individual substances for review, and the criteria then adopted by the Commission for their own decision making as to whether a substance should be placed on Annex XIV are not clear. They would therefore ask for greater transparency.

Several downstream users also highlighted that there is a lack of transparency within the overall selection and decision process, and that consultations needed to be more transparent. In this respect, more of an early warning on when substances are selected was identified as being needed; consultees also noted that the timing for responding to a listing is too short, it can be difficult to organise inputs across a sector within the times allowed. This was particularly relevant for producers of complex articles.

Within some sectors, large percentages of their product portfolios change every year; for example, one consumer product manufacturer indicated that 20% of their products change annually. So by 2018 they will have a different set of products on the market than they do today. Managing such change means that they need to have some certainty in terms of their forward planning and product development in terms of what chemicals are likely to be available to them into the future (either as substances or in mixtures). There will undoubtedly be SVHCs within their products and their planning would gain from greater transparency in the processes and schedules for listing and prioritising candidate substances, and having set time periods for planning purposes. This is important as it takes years for supply chains to react and shift and companies cannot afford to find themselves in a process where they lose products and have to write-off stocks.

This lack of transparency was also raised with regard to the reasons why chemicals are being prioritised for authorisation (and selection of substances for harmonised classification and labelling, bringing forward proposals for restriction or for substance evaluation). Although these points would appear to concern process issues, they are relevant to the degree to which the anticipated benefits of the authorisation provisions are being realised. Because some of the downstream actors (and those further up the supply chain) do not understand the system, they are not necessarily reacting to it as predicted. The result of this may be a lower level of benefits being achieved from candidate listing than had been hoped.

Announcement Effect and Substitution

Following on from the above, therefore, downstream users noted that the extent of any ‘announcement effect’ is in part dependent on the manner in which substances are added to the candidate list. Two different types of comments were made in this

regard. The first is that the approach of adding just a few substances at a time, which then move slowly through the process for deciding if they are going to go onto Annex XIV, and which may then all have different sunset dates makes it (or will make it) hard for industry to manage its response; this will become more difficult over time. This set of downstream users would prefer more of a batch approach aimed at delivering more certainty, so that they can prioritise what substances they spend their money on replacing over the next few years.

The second comment is that the extent to which an announcement effect is actually occurring also depends on the pressure for substitution along the supply chain. Supplier declarations on SVHCs are part of this and it is clear that companies are putting in place processes and systems to ensure that they have information on the substances that are both within their formulations but also within articles. There is also on-going dialogue within supply chains on these issues, with this including pressure for reformulation. This includes pressure from article producers on distributors and formulators providing them with formulations, on other article producers (where complex articles are being produced) and from retailers seeking to ensure that the products they are placing on the market do not contain SVHCs. There is also concern that EU producers will be forced (whether by regulation or by market pressures) to move to alternatives which deliver reduced performances and thus affect product quality, while non EU producers are able to continue with the use of a substance in imported articles without incurring cost or quality penalties.

Dealing with complex articles is viewed as a major difficulty, with companies in some sectors working on the development of new substance-based information management systems; these will take considerable time and effort to develop but may be the only means for downstream users to understand what substances are in their products and to demonstrate compliance. These companies argue that until such systems do exist, and span across the global nature of supply chains, it is not clear that the potential benefits of the announcement effect will be realised (see also Section 6).

As discussed in Section 4, downstream users also note the huge variation in different actors' understanding and knowledge of the SVHC requirements. Consultees remarked that associations appear to communicate some information on SVHCs (whether well informed or not) to their members, who then approach their upstream suppliers. When these approaches are not well informed, they are just adding to confusion.

Several respondents noted that the candidate list is not the only list which may lead to announcement effects. The SIN lists developed by the various environmental NGOs are the most well known of these other lists and for many consumer product companies they have to respond to it in order to avoid adverse publicity and protests by NGOs. For example, the adhesives sector has noted that some unofficial 'lists' can cause problems (i.e. some of the NGO lists) particularly where there is inadequate data to reach conclusions as to the hazard potential of a substance let alone the risks associated with its use.

The same issues arise with consumer product manufacturers' lists as well as those of government funded bodies such as the list of chemicals to be reviewed by the UK Chemicals Stakeholder Forum. The entry of a substance onto these lists can cause pressure within supply chains. It was noted that within hours of substances being added to these lists – even if there is no data indicating a problem at the time of listing – customers may be in contact for further information. Interviewees cite cases where they receive queries as to the presence of a substance on the basis of news articles or journal articles which are based on incorrect information. Responses have to be provided to such queries, but the pressures being caused in supply chains are leading to increasing concerns about the loss of flexibility, particularly where substances are entered onto lists and not removed even if cleared of having the identified properties of concern; in a worst case scenario, the loss of some of the substances due to such pressures may result in less suitable alternatives being used as the basis for reformulation.

These interviewees would therefore like the Commission to make it clear that the candidate list is the official list of relevance within the EU, perhaps as part of providing greater transparency on how and why substances are placed on the list and then prioritised for authorisation. There may also be a further role for the Commission in educating downstream industry sectors, the public and the media of the role of the candidate list and its more authoritative standing compared to other un-official lists of less controlled scientific quality and accuracy. If reference to such lists leads to unfounded shifts in market demand, then it may also result in the adoption of substances which are not more suitable alternatives, having a negative impact on health and environmental benefits.

A complicating factor is the need for many article producers to understand the implications of REACH and SVHC status with respect to the other legal requirements they have to meet related to, for example, medical packaging, etc. Companies, particularly small and medium sized enterprises, are finding it very difficult to understand the linkages between these and thus to develop their own response scenarios. This suggests that there may be a need for the Commission to provide information on the linkages between REACH and other legislative requirements and how particular REACH outcomes (such as candidate listing) may impact on an actor's obligations under other legislation.

Finally, several of the consultees involved in manufacture of formulations noted that they tried to formulate out hazardous substances as a matter of principle. They move away from substances once effective alternatives are found and which are economically viable for both themselves and for their customers. As a result, they did not accept that, based on their experience, there were significant benefits from the announcement effect element of candidate listing.

Costs of Applying for Authorisation

One small company interviewee noted that the fees alone of making an application would place a huge burden on his company. When the costs of preparing the rest of the application are added to these, with this including the need to prepare a socio-economic analysis for the substance and use in question, then the total costs may

become prohibitive. From this company’s perspective, the use of the substance is already highly regulated by health and safety authorities and meets occupational exposure and environmental controls. As they are only one of a small set of EU producers for their specialist end-product, this may mean that the product will have to be imported into the EU in the future.

6.2.5 Responses to Other Consultations: Impacts on Competitiveness and Innovation

REACH Competitiveness Survey

All the relevant results from the CSES competitiveness survey are covered under Section 5.3.5.

REACH Innovation Survey

As shown in Figure 6.4, the CSES Innovation Survey asked participants what the effect has been of placing the substances on the authorisation list. In total 57 respondents said that they had launched initiatives to develop new substances to substitute them, 116 respondents said they had launched initiatives to find alternative formulations of existing substances to substitute them, 105 said they had withdrawn them from their product portfolio, 105 said they had requested substitution of those substances by their suppliers and 89 said they had taken no specific action. Table 6.2 gives a breakdown by business size of the respondents who answered ‘yes’ to the respective statements.



Figure 6.4: What has been the effect of the placing of substances on the authorisation list for your firm?

Table 6.2: What has been the effect of the placing of substances on the authorisation list for your firm

Business Size	We launched initiatives to develop new substances to substitute them	We launched initiatives to find alternative formulations of existing substances to substitute them	We withdrew them from our product portfolio	We requested substitution of those substances by our suppliers	We took no special action
(1-9)	4	6	9	9	4
(10-49)	8	19	27	20	18
(50-249)	21	43	29	34	22
(>250)	23	47	40	42	44
No answer	1	1	0	0	1
Grand Total	57	116	105	105	89

6.2.6 Conclusions

To date, 73 substances have been entered onto the candidate list⁴¹, with 14 substances now on the authorisation list and a total of 36 substances recommended for inclusion onto the list⁴². Clearly, in order to meet the target of 136 substances to be placed on the candidate list, further substances need to be selected to go through the procedures for formal identification as a SVHC and then listing and potential prioritisation. Should this target be met, one would expect that shifts to substitutes as described above, together with more general substance withdrawal from the market, will continue to take place. The level of health and environmental benefits that will be realised through this is difficult to predict at this point in time as it depends on several factors:

- The properties of the substance and the extent of current exposures to it.
- The level of use that currently takes place in the EU.
- The degree to which the alternatives are “suitable” in that they reduce risks to health or the environment.
- The outcome of the authorisation process and the degree to which applications for continued use are approved, and/or the time periods allowed for continued use prior to applicants having to move to alternatives (i.e. the periods agreed for substitution to take place).

⁴¹ <http://echa.europa.eu/web/guest/candidate-list-table>

⁴² <http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list>
<http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/1st-recommendation>
<http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/2nd-recommendation>
<http://echa.europa.eu/web/guest/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/previous-recommendations/3rd-recommendation>

In this respect, it should be noted that some of the substances currently on the list have fairly limited use in the EU (e.g. TCEP, diarsenic pentaoxide, and lead chromate). In other cases, the use profile of the substance is such that the reduction in risks are likely to be limited (e.g. use of lead chromates and 2,4-dinitrotoluene in explosives). In other cases, however, there may be far more significant impacts, e.g. the placing of the lead pigments on the list is likely to have contributed to their reduced production in the EU⁴³.

More generally, both the discussions with industry representatives and the CSES surveys (which actually asked questions about Annex XIV listing) indicate that candidate listing on its own is having the desired effect: substances placed on the list are being withdrawn from use (whether all uses or only partially across some uses) and downstream users are moving to substitutes where possible. Thus, this instrument within REACH is beginning to deliver its intended benefits of removing substances of very high concern from use in the EU, although as indicated above it is too early to establish the extent of these benefits in reality (e.g. how many future cancer cases would be avoided).

As discussed in previous sections as well as this section, substance withdrawal is taking place. This is in part for economic reasons, as manufacturers and importers are reluctant to bear the risks of registering a substance that may be subject to authorisation and, hence, lead to further costs associated with having to make applications for continued use. Experience with the Biocidal Products Directive is relevant here, with the costs of gaining approvals identified as leading to the withdrawal of products from the market⁴⁴. Where use of the substance is considered justifiable or important, manufacturers appear less willing to withdraw it from the market and downstream users also appear in some cases to be willing to support a substance through the authorisation process.

The concern amongst downstream users over the potentially unpredictable consequences that may follow from the withdrawal of substances placed on the candidate list may be justified. Only monitoring of such impacts over the next few years can establish whether their current fears are justified with respect to the degree to which the loss of some substances also leads to the loss of particular performance characteristics for which there are no good substitutes at present. Similarly, the degree to which substitution effectively becomes a process of moving from a listed substance to a similar non-listed substance should be monitored. This type of response has taken place in the past, for example, with restrictions on the use of short-chain chlorinated paraffins leading to an increased use in medium-chain chlorinated paraffins in leather fat liquors (which were assessed under the Existing Substances Regulation but remains the subject of only a transitional dossier under REACH).

⁴³ See for example: <http://www.cappelle.be/nl/nieuws%201>

⁴⁴ RPA, Hydrottox and Oekopol (2007): Study on Impact of the Implementation of Directive 98/8/EC concerning the Placing on the Market of Biocidal Products, Final report to the European Commission, DG Environment, October 2007.

Interviewees complained that the current process for identifying and prioritising SVHC are not entirely transparent (and selection of substances for harmonised classification and labelling, bringing forward proposals for restriction or for substance evaluation). This includes both decision making by Member States and the Commission in deciding which chemicals should have dossiers prepared, the consultation processes and outcomes from these, and then in how the Commission decides which substances should be prioritised. There is some justification for this view, particularly with respect to the process for identifying SVHC to be considered for prioritisation. This stems to a degree from the fact that many of the substances being considered are already highly regulated. Perhaps it is not unexpected though that in this early stage of REACH implementation, the substances going through authorisation are those already well known to authorities but considered to pose unacceptable risks. It will be important to see if this changes over time, as new information on substance properties comes available through registration, and this leads to currently unregulated or minimally regulated substances being added to the authorisation list.

Interviewees noted that the time available for responding to a listing is too short, with this being a particular issue for complex supply chains where inputs had to be organised across a number of different sectors or actors. There was also concern that prioritising large numbers of substances too quickly could cause real problems for such supply chains, as they would not have the capacity to respond appropriately, particularly where products change on a continual basis. These types of concerns are justified as it takes years for supply chains to react and shift and companies cannot afford to find themselves in a process where they lose products and have to write-off stocks (which in turn has a negative impact on waste streams and implications for the overall resource efficiency of the EU).

Finally, several of the consultees involved in manufacture of formulations noted that they tried to formulate out hazardous substances as a matter of principle. They move away from substances once effective alternatives are found and which are economically viable for both themselves and for their customers. As a result, they did not accept that, based on their experience, there were significant benefits from the announcement effect element of candidate listing.

6.3 Restriction as a Process for Earlier Realisation of Benefits

6.3.1 Pathway to Benefits and Associated Indicators

Restriction helps ensure that EU-wide risks are reduced and triggers benefits by:

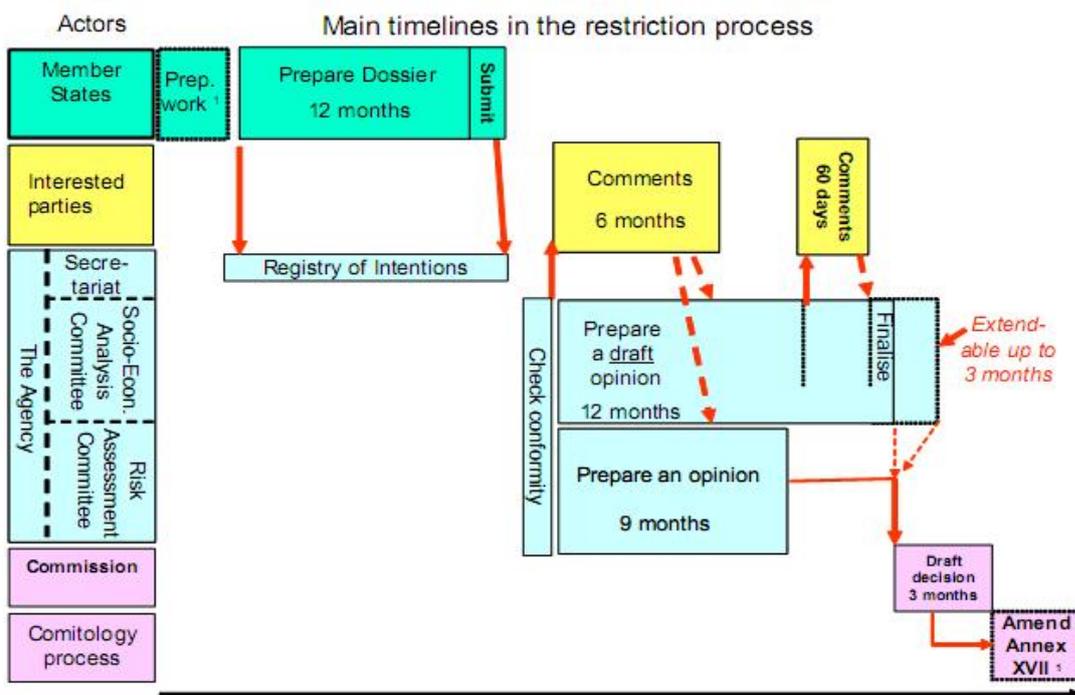
- The registry of intentions acts as a signal to manufacturers and downstream users to consider moving to or developing alternatives, even though restrictions may not take the form of a ban on use; and
- By speeding up the process for risk management, benefits will be delivered more quickly than they were under the Existing Substances Regulation.

The original White Paper referred to “accelerated risk management” (ARM) as the mechanism for taking action at the Community level on substances that are considered to pose unacceptable risks to human health or the environment, and which are not captured by the authorisation process. This was later expanded to act as a more comprehensive process for setting restrictions on the manufacturing, marketing and use of dangerous substances and preparations. However, the general intention for the process was that it acts as an acceleration of that which operated under the Existing Substances Regulation was clear.

The main timeline for the restriction procedure and the preparation of an Annex XV dossier leading to a decision and amendment to Annex XVII is set out in the figure below (taken from the ECHA Guidance document on preparing socio-economic analyses for restrictions). As can be seen from the figure, following preparatory work by a member State or ECHA, the timeline for the procedure should cover a period of around two and a half years, plus the additional time required to amend Annex XVII of the Regulation. This timeline is important as it contrasts greatly to that which was experienced under the Existing Substances Regulation.

Furthermore, REACH also foresees the possibility of a more rapid (fast track procedure) under Article 68(2) applicable to substances either on their own, in a preparation or an article, where they meet the criteria for classification as carcinogenic, mutagenic or toxic to reproduction category 1 or 2, and might be used by consumers. In such as case, the activities required under Articles 69 to 73 would be omitted and Annex XVII would be amended in accordance with Article 133(4).

Figure 2 The main timeline of restriction procedure (a MS preparing the Annex XV dossier) ²



Source: ECHA (2008): Guidance document on preparing socio-economic analyses for restrictions.

6.3.2 Restriction under the Existing Substances Regulation

Data are available from the Joint Research Centre's Online European Risk Assessment Tracking System (ORATS⁴⁵) on various aspects of what was effectively the restriction process under ESR. These show for example that, starting from 1994, a total of 141 substances were prioritized for the production of a detailed Risk Assessment Reports (RAR) to determine if there was a need for risk management (with this process completed for 137 substances prior to REACH coming into force).

Where a need for risk reduction was identified through restrictions on the marketing and use of a substance, these were then implemented through the Marketing and Use Directive (76/769/EEC, also often referred to as the Limitations Directive). Overall, restrictions were introduced for about 100 substances/substance groups over the 30 years in which Directive 76/769/EEC was in operation, with this equating to an average of only 3 per year). Such examples, thus serve to underline the limitations of the earlier restriction process, as recognized by the Commission Working Document (EC, 1998) and the White Paper (EC, 2001).

The length of time it was taking to undertake the risk assessments and subsequent assessments of the advantages and drawbacks of various risk reduction measures, in order to justify action under Directive 76/769/EEC was one of the key factors leading to the creation of REACH. A Commission Working Document produced in 1998 (EC, 1998)⁴⁶ found that, while restrictions had been achieved for 42 substances or groups (900 substances in total, mostly relating to the banning of carcinogenic substances from consumer mixtures) over the 20 years or so of operation of the Directive up to that point in time, there were delays in implementation in several important cases and reaching a co-decision usually requiring at least 18-24 months. Further the Directive was judged overly complex and difficult to interpret and use (EC, 1998).

The subsequent White Paper (EC, 2001)⁴⁷ recognised the need for an improved and accelerated procedure as part of the overall rationale for the introduction of REACH, and these objectives are reflected in the specification of fixed time frames for stages in the processes under REACH. Additional contributory factors to improvements

⁴⁵ ORATS is the Joint Research Centre's Online European Risk Assessment Tracking System, available at Internet site <http://esis.jrc.ec.europa.eu/index.php?PGM=ora>.

⁴⁶ EC (1998): Commission Working Document. Report on the Operation of Directive 67/548/EEC on the approximation of the Laws, Regulations and Administrative Provisions relating to the Classification, Packaging and Labelling of Dangerous Substances, Directive 88/379/EEC on the approximation of the Laws, Regulations and Administrative Provisions relating to the Classification, Packaging and Labelling of Dangerous Preparations, Regulation (EEC) 793/93 on the Evaluation and Control of the Risks of Existing Substances, Directive 76/769/EEC on the approximation of the Laws, Regulations and Administrative Provisions of the Member States relating to Restrictions on the Marketing and Use of Certain Dangerous Substances and Preparations. Brussels, 18.11.1998. SEC(1998)1986 final. European Commission, Brussels, Belgium. Available at Internet site http://ec.europa.eu/environment/chemicals/pdf/report-4-instruments_en.pdf.

⁴⁷ EC (2001): White Paper. Strategy for a future Chemicals Policy (presented by the Commission) Brussels, 27.2.2002. COM(2001) 88 final. European Commission, Brussels, Belgium. Available at Internet site <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2001:0088:FIN:EN:PDF>.

under REACH were the anticipated improvement in quality and quantity of hazard and exposure data from the dossiers prepared under REACH requirements and the inclusion of a requirement of a targeted rather than exhaustive risk assessment since together these should provide for a more robust risk assessment for the uses of concern and, hence, facilitate improved regulatory decision making.

6.3.3 Discussions with Industry

As it currently stands, under REACH, there are 13 substances for which new restriction dossiers have been received to date, and a further 5 substances for which intentions have been indicated. Thus, it is as yet too soon to establish the degree of improvement in the efficiency of the restriction process under REACH.

However, when asked, most interviewees⁴⁸ stated that no differences are felt regarding the restrictions procedure under REACH and pre-REACH (although most were also not affected by any of the proposals to date and may not have been closely following the process). Other interviewees who have been watching how the process has operated to date expressed concern that there is a lack of transparency as to how in practice stakeholder comments are taken into account and what impact they have on the Risk Assessment and Socio-Economic Analysis Committee opinions. Although tables setting out responses to comments are developed, they do not always provide an adequate indication of whether a comment has been taken into account.

There is also a concern from an industry perspective that the process is not operating as intended. In particular, there is concern that dossiers are being accepted as “inconformity” with Annex XV requirements, when their quality is poor and they will clearly need further work as they are being taken through the ECHA Committees (with this additional work being undertaken by the Committee members themselves, including the development of risk assessment models). This gives rise to the concern that formal comments provided by stakeholders on the original proposals are either being used as the basis for improving dossier which should have been of higher quality to start with, and/or the comments are out of date by the time they are submitted and stakeholders are effectively having to respond to a “moving baseline”, with multiple versions of a dossier being prepared. This is both difficult to manage from a timing perspective but is also costly in terms of time efforts. In their view, ECHA and the Commission should take a stronger line on decisions concerning the compliance or non-compliance of dossiers. They argue that from an international perspective it raises questions as to the rigour of the overall decision making processes. It was also noted that, contrary to ECHA’s Guidance, there have been cases where little attempt has been made by the Member State proposing a restriction to consult with industry on costs and other impacts.

⁴⁸ Interviewees were representatives from industry, industry associations and consultants. No Member State representatives were interviewed.

One interviewee mentioned that the procedure according to Article 68(2) (fast track⁴⁹) is regarded as critical because it is not possible to predict which substances will be subject to restriction through this process, reflecting the earlier concerns by industry as to the transparency of the process. This interviewee also suggested that the period allowed for commenting by stakeholders in order to influence the restriction decision was inadequate to allow the preparation of well structured and robust argumentation. In essence, the concern is that under this procedure, industry will have too little time to react to the restrictions in their practical work. Indeed, in 2010, the Commission noted that the procedure had not yet been tested and that there were some concerns over its adequacy; it therefore indicated that it would carry out some further analysis of the adequacy of the procedure⁵⁰. It is of note though that the procedure is currently to be used in relation to CMRs in articles, and it is felt that it may be more predictable in terms of ensuring consumer protection as it will be a direct, one for one, follow up to harmonised classification and labelling.

Some support for the potential benefits of the restriction process came from another consultee who suggested that there was now too great a focus on use of the authorisation process. This respondent indicated that restriction should be regarded as being the more efficient RMM instrument, because it can be targeted at those uses which are considered to be of most concern and risk management measures can be introduced in a shorter time frame. Another argument suggested in favour of restrictions is that it can be applied to the import of articles containing chemicals, helping to ensure that any risks arising from imported products are controlled.

6.3.4 Responses to Other Consultations: Impacts on Competitiveness and Innovation

REACH Competitiveness Survey

In the CSES survey, manufacturers were asked whether any of the substances they produce are included in the list of restricted substances under Annex XVII of the REACH regulation. Out of the 313 responses to this question, 45 manufacturers answered yes, 259 manufacturers answered no and nine manufacturers said they did not know (Table 6.3).

Table 6.3: Are any of the substances you produce included in the list of restricted substances under Annex XVII of the REACH regulation?			
Business size	Yes	No	Don't know
Micro (1-9 employees)	0	13	0
Small (10-49 employees)	2	37	2
Medium (50-249 employees)	9	86	2
Large (more than 250 employees)	34	121	5
Unknown	0	2	0

⁴⁹ Note: This route has not been used extensively to date, with only one group of 8 polycyclic aromatic hydrocarbons have been considered for restriction under this Article, see Internet site http://ec.europa.eu/environment/chemicals/reach/pdf/minutes-100615-17_en.pdf.

⁵⁰ European Commission (2010): Draft Summary Record 5th Meeting of Competent Authorities for REACH and CLP, Doc. CA/77/2010), 15-17 June 2010, Brussels.

When asked in the CSES competitiveness survey what the impact had been of the entry of a substance they produce in the list of restricted substances, 11 manufacturers answered that it had led to the decision by their business to remove the substance from the market and 14 manufacturers said that it had led to the decision to replace the substance with a less hazardous substance. Seventy one manufacturers said it had had no impact (Table 6.4).

Table 6.4: What has been the result of the entry of a substance you produce in the list of restricted substances?			
Business size	No impact	Led to the decision from your business to remove the substance from the market	Led to the decision to replace the substance with a less hazardous substance
Micro (1-9 employees)	5	1	0
Small (10-49 employees)	7	0	2
Medium (50-249 employees)	13	1	4
Large (more than 250 employees)	46	9	8
Unknown	0	0	0

Formulators and Distributors

Formulators were asked by the CSES survey whether any of the substances they produce are included in the list of restricted substances under Annex XVII of the REACH regulation. Out of the 133 formulators who responded, 21 said that they did produce substances included in the list of restricted substances, 101 said they did not and 11 said they did not know (Table 6.5). When asked what the impact had been (Table 6.6), five formulators said that entry of a substance they produce in the list of restricted substances had led to an increase in the production costs due to the need to use different production methods and ten formulators said it had led to a deterioration of the characteristics of the products of their business. No respondents to the survey said that it had to an improvement of the characteristics of the products of their business.

Distributors do not appear to have been asked whether any of the substances they distribute are included in the list of restricted substances under Annex XVII of the REACH regulation and do not appear to have been asked what the result has been of the entry in the list of restricted substances

Table 6.5: Are any of the substances you produce included in the list of restricted substances under Annex XVII of the REACH regulation?			
Business size	Yes	No	Don't know
Micro (1-9 employees)	0	5	0
Small (10-49 employees)	4	31	6
Medium (50-249 employees)	4	37	4
Large (more than 250 employees)	13	28	1
Unknown	0	0	0

Table 6.6: What has been the result of the entry of one or more substances you use in your products in the list of restricted substances? (Formulators)				
Business size	No impact	Led to an increase in the production costs due to the need to use different production methods	Led to an deterioration of the characteristics of the products of your business	Other
Micro (1-9 employees)	0	0	0	0
Small (10-49 employees)	2	1	2	0
Medium (50-249 employees)	5	1	1	3
Large (more than 250 employees)	2	3	7	2
Unknown	0	0	0	0

Notes: No respondents said that it had led to an improvement of the characteristics of the products of their business.

Only seven article producers responded to the question: “are any of the substances you produce included in the list of restricted substances under Annex XVII of the REACH regulation?”. Out of the seven article producers who responded, two article producers said yes, four said no and one said they did not know. Two article man producers said that the result of the entry of one or more substances that they use in their products in the list of restricted substances had led to an increase in the production costs due to the need to use different production methods, while one article producer said that it had led to a deterioration of the characteristics of the articles of their business (Table 6.7).

Table 6.7: What has been the result of the entry of one or more substances you use in your products in the list of restricted substances?				
Business size	No impact	Led to an increase in the production costs due to the need to use different production methods	Led to a deterioration of the characteristics of the articles of your business	Other
Micro (1-9 employees)	0	0	0	0
Small (10-49 employees)	1	0	0	0
Medium (50-249 employees)	1	1	0	0
Large (more than 250 employees)	1	1	1	2
Unknown	0	0	0	0

Notes: No respondents said that it had led to an improvement of the characteristics of the articles of their business.

Table 6.8 shows the number of end users who responded to the question: “are any of the substances included in your products included in the list of restricted substances under Annex XVII of the REACH regulation?”. As shown in the Table, three businesses answered yes, two businesses answered no and one business said that they did not know. Out of the businesses that responded, four agreed that the entry of one or more substances they use in their products in the list of restricted substances had

led to an increase in the production costs due to the need to use different production methods and two agreed that it had led to a deterioration of the characteristics of the products of their business.

Table 6.8: Are any of the substances included in your products included in the list of restricted substances under Annex XVII of the REACH regulation?

Business size	Yes	No	Don't know
Micro (1-9 employees)	0	0	0
Small (10-49 employees)	3	0	1
Medium (50-249 employees)	0	1	0
Large (more than 250 employees)	0	1	0
Unknown	0	0	0

6.3.5 Conclusions

It is currently too soon to comment on whether or not the Registry of Intentions is acting as a signal to manufacturers and downstream users to consider moving to or developing alternatives. From a stakeholder perspective, there are issues with regard to the way in which comments are dealt with and the manner in which the different checks and process requirements are being applied, suggesting these aspects may require further consideration.

Although the process is operating more quickly than that which operated under the combination of the Existing Substances Regulation and the Marketing and Use Directive, the level of activity is disappointing and is lower than was originally anticipated suggesting that the level of benefits expected to be delivered through the restriction provisions is not being achieved.

There are currently only four substances in the Registry of Intentions, with three of these being nonylphenols and their ethoxylates – a group of substances which was already subject to extensive restrictions under the Existing Substances Regulation (EEC 793/93); these intentions have been registered by Sweden and ECHA. In addition to these current intentions, restriction dossiers have been submitted for 13 substances. Only three countries (Denmark, Norway and France) were responsible for dossiers covering 12 of these substances (phthalates, phenylmercury compounds, dimethylfumarate and lead), with the thirteenth dossier submitted by ECHA on behalf of the European Commission.

Overall, the level of activity is lower than was expected. This is true of both the Commission and Member States. It is surprising that more Member States have not either prepared dossiers or registered their intentions to do so. For example, the transitional dossier for medium length chlorinated paraffins identified that the UK government would be taking forward restriction proposals under REACH, however, such intentions have not yet been registered. Other countries that were active under the Existing Substances Regulation but which have not yet submitted intentions

include Germany, Austria and the Netherlands for example. This may in part be due to the need for them to conclude proposals with respect to transitional dossiers, although this should have been achieved within the first few years of REACH implementation. It should be noted though that Austria, Germany, and the Netherlands have been active with respect to the preparation of Annex XV dossiers for SVHC identification, as have other Member States such as Belgium, Poland, and Slovakia.

7. ENHANCERS

7.1 Pathways to the Realisation of Benefits

Throughout the previous sections of this report there has been reference to possible “enhancers” of the benefits that would result from the main drivers within REACH. This includes enhancers in relation to registration, information through the supply chain and authorisation and restrictions.

The key enhancers relate to:

- Evaluation;
- Inspection and enforcement;
- Synergies with other legislation; and
- Guidance and other support, including the dissemination of information to external stakeholders.

The linkages between these and each of the main drivers are illustrated in Figure 7.1.

The role of these pathways to benefits has not been explored through interviews with individual companies or with industry associations, except to ask about inspections in a general sense and the usefulness of guidance and other support. Discussions were held with ECHA, however, and information has been incorporated here from other published or soon to be published sources.

7.2 Dossier Evaluation

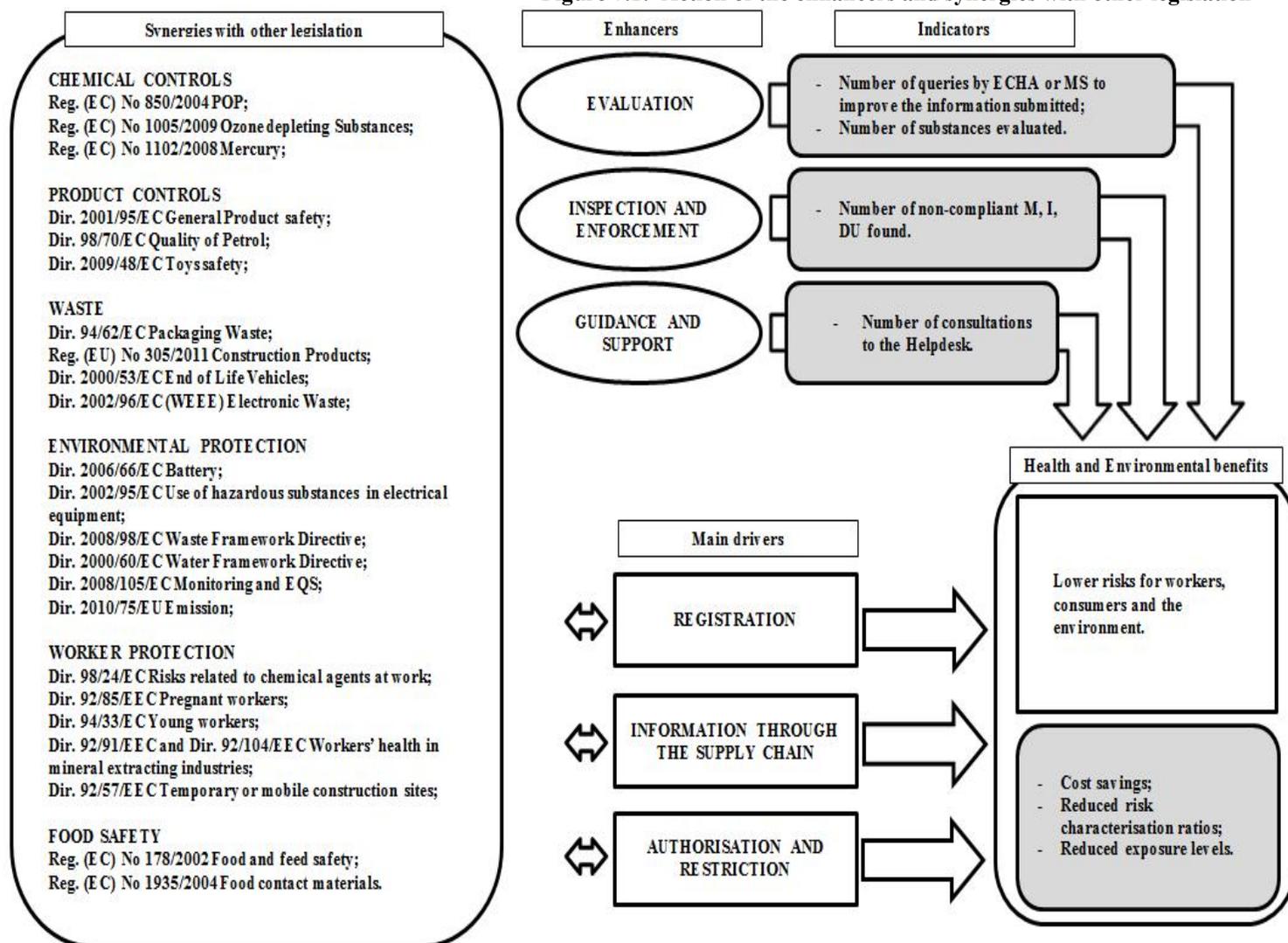
7.2.1 Role as an Enhancer of Benefits

The overall aim of dossier evaluation is to improve the quality of registration dossiers in general by addressing deficits in compliance and testing proposals. The benefits associated with registration as a driver should therefore be enhanced with regard to individual dossiers but more importantly across all dossiers - through communication of the main learning points and the types of general improvements that are needed in dossiers. These may take the form of guidance updates or, as currently performed via the regular evaluation progress reports.

In order to examine the extent to which evaluation may have acted as an enhancer to date, we have looked at statistical information provided by ECHA in its evaluation progress reports (2008, 2009 and 2010) and in its more recent report on the operation of REACH⁵¹. Although interviewees were asked about evaluation, none identified it as a key driver to date; it was recognised, though, as being potentially important with

⁵¹ Unfortunately it was not possible to obtain more recent figures on the evaluation process.

Figure 7.1: Action of the enhancers and synergies with other legislation



respect to acting as the basis for the future up-date of guidance documents and providing feedback to manufacturers and importers on how better to fulfil requirements in the next registration phases.

7.2.2 Evaluation Activities and Challenges

ECHA started dossier evaluation activities in 2008, with an overview of the activity levels provided in Tables 7.1 and Figure 7.2.

	Phase-in	Non-phase-in	Total
Number of Dossiers Opened	111	138	249
Draft Decisions Sent to Registrant	54	28	82
Final Decisions	4	17	21
Quality Observation Letters (QOBLs)	10	34	44
Compliance Check Concluded without Further Action	5	31	36

Source: ECHA report on operation of REACH, Table 8, p. 26.

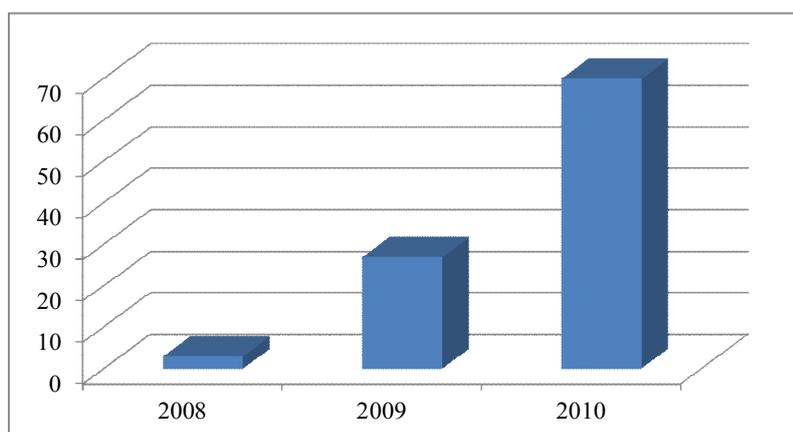


Figure 7.2: Number of Compliance Checks initiated in 2008, 2009 and 2010⁵³

As presented by ECHA in the REACH Implementation Workshop X on 13 December 2011, the total number of concluded compliance checks by November 2011 was 271. Of these, 54 were terminated without administrative action, for 59 cases QOBLs were sent and for 231 dossiers further information was requested.

According to the Evaluation Progress Report of 2010, ECHA “offers the possibility to informally discuss the scientific rationale behind the draft decision. [...] The outcome of the discussion should result in a better understanding of ECHA’s draft decision.”

Evaluation decisions can address shortcomings in the hazard information provided but cannot directly request information on shortcomings in the risk management measures identified. Nevertheless, ECHA may ask for additional information on exposures.

⁵² ECHA will be asked if updated information is available

⁵³ Source: information from ECHA’s General Reports of 2008, 2009 and 2010.

Furthermore, decisions on dossier evaluation can lead to a modification of the conditions of safe use and risk management measures (e.g. if new hazard information leads to more stringent DNELs/PNECs or classification).

The QOBLs may address issues such as classification and labelling or the appropriateness of RMMs. Enforcement of related aspects is to be done by the Member States. In ECHA's report on the operation of REACH, it is stated that it is not clear how to efficiently enforce evaluation decisions.

Figure 7.3 shows a comparison of the outcomes of compliance checks in 2010 with the average of all compliance checks performed so far. Due to the short time of dossier evaluation and the correspondingly low robustness of information, this should not yet be interpreted as lack of improvement in dossier quality through evaluation.

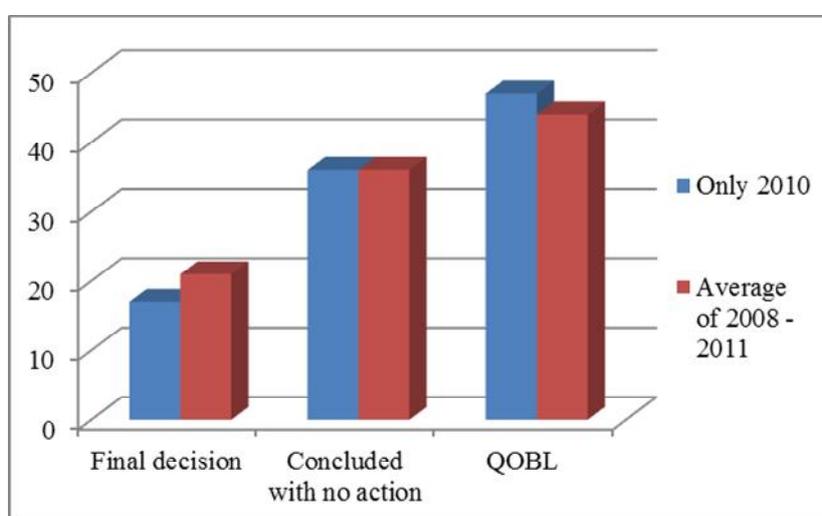


Figure 7.3: Shares of Outcomes of Compliance Checks, Average Compared with 2010⁵⁴

No information is available yet on the response rates for improving dossiers. Some registrants were able to provide the information requested in draft decisions directly, whereas others received the final decisions including a timeline for providing additional information. As these timelines have not all elapsed and respective statistics are not yet available, it is not possible to identify the level of improvement of the individual dossiers that have been updated after an evaluation decision.

The types of evaluation decisions made annually over the three year period indicate no increase in dossier quality between 2008 and beginning of 2011; however, it is not clear whether the same registrants were checked and, hence, it is unclear if there has been an improvement in submissions by individual registrants. Assuming that registrants will bring their dossiers into compliance, the fact that dossier evaluation takes place directly enhances the benefits that should result from the various registration requirements for those dossiers which are actually checked.

⁵⁴ Source: information from ECHA's General Reports of 2008, 2009 and 2010.

7.2.3 General Findings from Dossier Evaluation and Consequences for Guidance Updates

According to the evaluation progress report of 2010 “Many of the dossiers evaluated had at least some quality problems – whether they were selected at random or based on some specific concern. Of course these dossiers were the very first to be submitted and they represent only the tip of the iceberg in terms of numbers. It would therefore be unwise to imagine that they will be representative of dossiers received by the first registration deadline of 30 November 2010.”

Assuming that updates of the registration dossiers will take place, at least in those cases where decisions on non-compliance were taken, a practical enhancement of dossier quality takes place through the dossier evaluation process as such.

The responses to the less binding quality observation letters (QOBL) may shed further light on the motivation of registrants to provide good registration dossiers and consequently also contribute to better information on their substances.

ECHA reports shortcomings related to substance identification in its evaluation progress report and the report on the operation of REACH. These shortcomings have not yet been addressed in the revision of related guidance documents; the current version is that of 2007. ECHA proposes to provide clarification at legislation level.

Observed shortcomings related to the performance and documentation of studies as well as the adaptation of data requirements have not yet been considered in the form of a revision of the respective guidance documents (Sections 7a, b and c⁵⁵). The guidance document Chapter R.5 on exposure based adaptations of information requirements was updated in December 2010 and, hence, was not in time to take effect on the first wave of registration dossiers. The content of revisions indicates that substantial explanation has been added, including methods and approaches for justification and documentation of waiving. These changes would be expected to address shortcomings noted in the registration dossiers submitted to date.

Shortcomings related to the use of available information have not yet lead to an update on the guidance document R3 and R4 on information gathering and evaluation of available information⁵⁶.

All guidance documents on exposure estimation (occupational health, environment and consumers) were revised and published by May 2010. This is considered as too late for the registrants of the first registration deadline to use them extensively in their CSR development. However, the revisions rather take account of new developments (addition of tools) and the need for better structure and clarity and are not so much based on experience from evaluating registration dossiers.

⁵⁵ The revised concise guidance on hazard assessment has only been changed at editorial level.

⁵⁶ The latest updates of December 2011 only concerned editorial changes and revision of references to the CLP-regulation.

In the evaluation of NONS dossiers 53 updates were requested via QOBLs (19 updates received). Following further requests, 27 dossiers were dropped and 26 entered compliance checking. Three conclusions of “no action” were taken. The others concluded either in further information requests or are still on-going⁵⁷. This shows that evaluation does contribute to the dossier quality. Furthermore, the guidance document on registration was updated to clarify the legal situation of NONS.

Checking intermediate status and strictly controlled conditions is a task for the Member States and not in the scope of dossier evaluation. Nevertheless, ECHA screened 303 dossiers for on-site and transported isolated intermediates registered in 2009 and observed that in many cases registrants had provided insufficient information to verify the claimed intermediate status. However, since the guidance on intermediates was published only in December 2010, QOBLs were only sent for the obviously doubtful cases concerning intermediate status. The intermediate guidance was only released close to the registration deadline and was hence most likely not used by the registrants (this was confirmed in the interviews with industry).

ECHA received in total 574 dossiers with testing proposals, covering a total of 1,175 studies. Many of these require public consultation and the evaluation also revealed other shortcomings, which led ECHA to initiate a compliance check (five dossiers). According to the evaluation progress report, four final decisions were taken on testing proposal by the end of 2010. ECHA considers that “one of the most commonly observed noncompliance in the registration dossiers is that testing has been waived without sufficient and valid justification”⁵⁸.

To date, there is insufficient information to interpret the evaluation results with regard to the enhancing effect of evaluation on the benefit driver registration and it is not clear if the quality level of dossiers is significantly higher or lower than expected. However, the fact that the dossier evaluation process is running well should be regarded as a success.

One way in which evaluation could contribute to dossier quality for all registrants is the integration of learning and “good practice” into the guidance documents. The following table shows the updates of guidance documents related to substance registration. In conclusion, only some of the guidance documents relevant for preparing a registration dossier have been updated to date.

R	Title	Date updated	Nature of main updates
2	Information requirements	December 2011	References to CLP updates, editorial changes
3	Information gathering	December 2011	References to CLP updates, editorial changes
4	Evaluation of available information	December 2011	References to CLP updates, editorial changes

⁵⁷ Update of information will be checked with ECHA

⁵⁸ Report on the operation of REACH and CLP, p. 28

Table 7.2: Overview of Guidance Updates (Information Requirements and CSR)			
R	Title	Date updated	Nature of main updates
5	Adaptation of information requirements	December 2010; December 2011	Adaptation to revised Annex XI, revision of workflow and separation of qualitative / quantitative argumentation, guidance on understanding “strictly controlled conditions”, “no release” from article waste stage, streamlining and revision of terminology, harmonisation with intermediate guidance
6	QSARs and grouping of substances	No update (May 2008)	
7a	Endpoint specific guidance	No update (May 2008)	
7b	Endpoint specific guidance	No update (May 2008)	
7c	Endpoint specific guidance	No update (May 2008)	
7.13-2	Env. RA for metals and metal compounds	No update (July 2008)	
8	Characterization of dose-response for human health	December 2010	Addition of new sections and appendices explaining data evaluation and derivation of DNEL/DMELs
9	Physico-chemical hazards	No update (May 2008)	
10	Characterisation of dose-response for the environment	No update (May 2008)	
11	PBT-Assessment	No update (May 2008)	
12	Use descriptor system	March 2010	Addition of categories, streamlining of numbering, clarification of scope, inclusion of examples
13	RMMs and OCs	No update (May 2008)	
14	Occupational exposure estimation	May 2010	Information on other tools added, section on ECETOC TRA revised,
15	Consumer exposure estimation	April 2010	Addition of information on estimation models, revision of section on TRA for consumers, reorganisation of several chapters and addition of explanation as well as product category list, that can be assessed with ECETOC TRA
16	Environmental exposure assessment	May 2010	Redraft of entire workflow, restructuring, detailing assumptions at Tier 1 and Tier 2, revision of local scenarios, adaptation of assessment parameters, limiting ERCs to release factors, revision of ERCs
17	Estimation of exposure from articles	No update (May 2008)	
18	Exposures assessment for the waste life stage	December 2010	Introduction of approach for assessing waste life stage including release factors and structure of waste sector
19	Uncertainty analysis	No update (May 2008)	
20	Terms and abbreviations	No update (May 2008)	

7.2.4 Conclusions

All actors confirmed that dossier evaluation is a useful tool for ensuring the quality of registration dossiers, by identifying missing or incorrect data as well as the poorly justified waiving of data requirements. In addition, the transfer of experience from the evaluations to the evaluation progress report and FAQs, etc. is seen as a helpful and effective way to promote learning. If learning points from the evaluation processes were included in guidance updates as well, this would be an important step in the improvement of registration dossiers in the future. Furthermore, direct contact between ECHA and registrants was also stressed an important opportunity to learn how dossiers could be improved.

However, due to the early stage of REACH implementation, it cannot be determined yet from the evaluation outcomes (decisions, QOBLs), the responses of industry and the related enforcement actions whether these activities have led to a practical improvement of information to date. Therefore, all conclusions point to consideration of the general trend that evaluation does enhance environmental and human health benefits, even if the solid information required to support this is currently lacking.

The success of evaluation may also depend on the existence of a common understanding of quality between ECHA, Member States and industry. Although most feedback shows a generally positive picture, several interviewees noted that the level of transparency in and justification provided to support ECHA decisions are not sufficient and that this is unacceptable to industry. Hence, it should be ensured that the evaluation processes are also used to promote an “agreement on the quality level of registration dossiers” and involve all relevant stakeholders. This “common agreement” could then guide the update of guidance documents and the provision of other, useful information for registrants to develop high quality registration dossiers.

More generally, from the interviews it became obvious that there is a need to further inform registrants about the evaluation process itself, because there still appear to be misunderstandings on its scope and implications.

In addition, it could be helpful for ECHA to provide more detailed information on how the shortcomings observed in compliance checks could be avoided. This might most appropriately be done by publishing “best practice” examples. This should be done as soon as possible so that registrants can use it to inform their registrations for the 2013 deadline.

The inclusion of lessons from compliance checks in the related guidance documents is seen as very important by many consultees; it would ensure that common shortcomings are specifically addressed, increasing the likelihood of avoiding these issues in the next registration phase. This would be an appropriate way of documenting an “agreed understanding” of dossier quality, as well.

There may also be value in allowing companies to “request a dossier evaluation” in order to provide specific feedback on the dossier quality and thus ensure a higher quality level for the next registration phase.

In order to actually measure the effect of dossier evaluation, statistics should be collected on the type of responses to evaluation decisions and in particular to quality observation letters, as the latter are non-binding. Furthermore, it should be ensured that the Member States undertake enforcement of evaluation decisions in order to ensure the credibility of dossier evaluation.

In addition to those used in this report, additional indicators for enhancing the benefit driver of registration could be:

- Number of changes in safe handling / RMMs recommended because of new data generated because of the compliance checks;
- Number of appeals against ECHA evaluation decisions (level of agreement on dossier quality);
- Responses / enforcement actions on QOBLs (level of protection); and
- Number of issues clarified in guidance documents based on experience from dossier evaluation.

7.3 Inspection and Enforcement

7.3.1 Role as an Enhancer of Benefits

The aim of the enforcement system is to verify the compliance of REACH duty holders, with this being important in the context of this study as non-compliance could result in a failure for human health and environmental benefits to be realised. As prescribed by Title XIV of the Regulation, enforcement is a national responsibility and each Member State shall maintain a system of inspections and investigations and lay down provisions on effective, proportionate and dissuasive penalties⁵⁹. In order to strengthen enforcement, recital (105) in the preamble of the Regulation suggests the creation of a Forum for Member States to exchange information and ensure an appropriate coordination between national competent authorities. The tasks of the Forum are provided under article 77(4): it is entrusted to develop enforcement by proposing, coordinating and evaluating harmonised enforcement projects and joint inspections, coordinating exchange of inspectors, identifying enforcement strategies and best practice in enforcement and developing working methods and tools of use to local inspectors.

To harmonise the enforcement systems amongst Member States, the Forum has released documents drawing up guidelines for the development of national strategies and setting up minimum criteria for inspections:

- Strategies for enforcement of REACH and CLP⁶⁰; and

⁵⁹ Articles 125 and 126 of REACH.

⁶⁰ ECHA – Forum for Exchange of Information on Enforcement (2011): Strategies for enforcement of Regulation (EC) no. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and of Regulation (EC) no. 1272/2008 on the classification, labelling and

- Minimum criteria for REACH and CLP inspections⁶¹.

The first document aims at ensuring consistency and compatibility between the different national strategies, suggesting that an effective enforcement strategy should define priorities for enforcement via a risk analysis, looking at the role of the duty holders being targeted and assessing the possible effects of non-compliance. Furthermore, national strategies must:

- Have clear policy objectives and priorities;
- Have the necessary organisation to achieve efficient, transparent and systematic enforcement of the Regulation;
- Actually perform the enforcement measures;
- Develop and implement procedures for periodic progress monitoring and measurement; and
- Develop and implement procedures for review, evaluation and update of the enforcement strategies.

Enforcement decisions should be taken by the national authorities on a case-by-case basis, considering a range of factors listed in the document⁶².

The document setting up minimum criteria for REACH inspections was developed by the Forum to ensure a level playing field within the internal market. Such criteria should be applied as a common basis for the performance of inspection activities, to enforce the Regulation in an effective way while trying to minimise the administrative burden placed on duty holders. Four different elements of inspections are covered: the organisation, the planning, the implementation (including the actual inspections and the follow-up), and the review of the arrangements for a strategy. Each one of these elements should take into account the resources available for inspections, the number and size of duty holders, the information available on the likelihood of the hazards occurring, and the vulnerability of those who could be affected (workers, the general public, the environment).

Firms have an incentive to comply with REACH (and CLP) due to the risk of punitive measures, criminal sanctions and the risk of damage to their corporate reputation. Should a company be found to be non-compliant, they are likely to be subject to more rigorous investigation in the future, due to the risk-based approach to inspections used in most Member States. As a result, it is likely that they would face additional

packaging of substances and mixtures (CLP), first edition adopted in December 2008, updated in March 2011.

⁶¹ ECHA – Forum for Exchange of Information on Enforcement (2011): Minimum criteria for REACH and CLP inspections, first edition adopted in December 2009, updated in March 2011.

⁶² ECHA – Forum for Exchange of Information on Enforcement (2011): Strategies for enforcement of Regulation (EC) no. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and of Regulation (EC) no. 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP), first edition adopted in December 2008, updated in March 2011, p.12.

administrative costs associated with further dealings with the enforcing authority (potentially including further inspections) and potentially prosecution.

In order to analyse the extent to which Enforcement may have acted as an enhancer to date, we have looked to the findings of the REACH-EN-FORCE-1 project⁶³ run across Europe in the second semester of 2009 and to the preliminary results coming from the analysis of the Member States reports on the operation of REACH⁶⁴.

7.3.2 REACH-EN-FORCE-1 Project's Results

REACH-EN-FORCE-1 project was designed to enforce the core principle of REACH: “no data, no market”. Inspections were addressed mainly to manufacturers and importers of substances with REACH obligations on the (pre)registration and Safety Data Sheets (SDSs). During the period May – December 2009, 1,600 companies were inspected in 25 Member States, selected on the basis of different criteria and selection methods and representing different duty holders and areas of activity. Non-compliance with REACH obligations was observed in 24% (378) of the inspected companies with the majority of such cases concerning SDS provisions (293).⁶⁵

Figure 7.4 shows the measures undertaken as result of non-compliance found during the inspections. By “others” is meant a written advice, a letter with additional information or an announcement that a company got more time to address the problems.

The results of the project showed that there are signals that especially SMEs will not be able to fully comply with registration obligations due to the lack of material resources and information. Compliance regarding SDSs was checked only basically, looking at the formal requirements, since the scope of SDS check in the project was quite limited. Inspectors promoted the knowledge and understanding of duty holders, while ensured compliance by formal enforcement where appropriate.

Beyond the statistical data, it was concluded that the execution of such projects contributes to the harmonization of the enforcement systems and it was suggested that stakeholder organisations should intensify their support and information on the obligations of the Regulation especially towards SMEs.

REACH-EN-FORCE-2 project, started in 2011, is targeting downstream users, especially formulators of mixtures, such as paints, dyes and industrial compounds. Inspections are checking compliance with the information through the supply chain requirements and inspectors are raising awareness of the future obligations for downstream users with relation to the extended safety data sheet.

⁶³ ECHA – Forum for Exchange of Information on Enforcement (2010): REACH-EN-FORCE-1, Results of the Forum coordinated REACH enforcement project on registration, pre-registration and safety data sheets, August 2010.

⁶⁴ RPA (2012): Technical Assistance to prepare the Commission report on the operation of REACH, prepared for DG Environment, Draft Final Report, January 2012.

⁶⁵ *Ibid*, p.2 and 6.

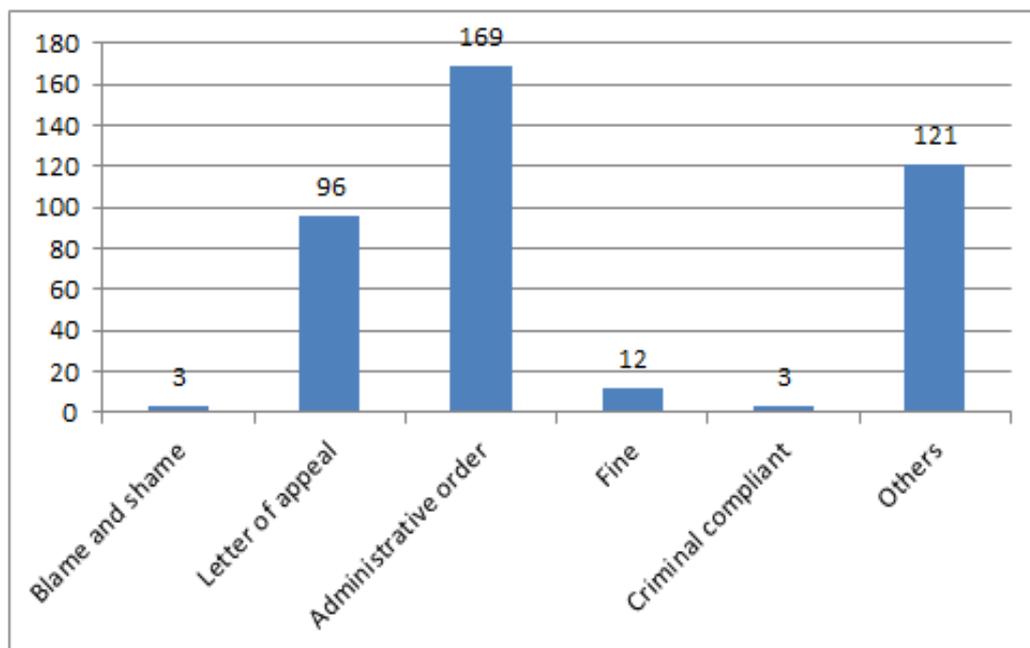


Figure 7.4 Overview of the measures due to non-compliance

7.3.3 Preliminary Results of the Analysis of Member States' Reports

Despite the guidelines provided by the Forum, when examining the national enforcement strategies followed by all the Member States, it was found that the data provided by the different Competent Authorities could not be subject to any robust statistical analysis due to a lack of consistency. For example, Germany provided a figure of over 300,000 duty holders existing nationally, while France (with a comparable size of the chemical industry), provided a figure of 3,000 duty holders. This suggests that further work may be needed by the Forum to clarify definitions and to ensure that Competent Authorities understand and use the same terminology.

ECHA also observed that to harmonise enforcement of REACH across the Member States was proving very difficult and suggested that it should be empowered to enforce compliance following submission of non-compliant registration dossiers.

From their perspective, some of the Competent Authorities indicated that the lack of access to the data held by the Agency is an obstacle to the effective planning and implementation of enforcement activities.

7.3.4 Conclusions

In this first phase of the implementation of the REACH, inspections were more focused on ensuring a broad understanding of the Regulation by the duty holders, with resources allocated so as to provide guidance to companies to increase levels of compliance. Compliance was checked in order to suggest improvements and identify best practices, and formal enforcement was undertaken only in the presence of serious non-compliances.

Although one of our interviewees stated that only big actors are the subject of inspections and investigations, the data reported by the different Member States highlight that most of the enforcement activities (between 80 and 90%) are on small and medium enterprises. Another interviewee appreciated the role played by the Forum in the harmonisation of the system and called for more effort in this sense.

Discussions with interviewees (e.g. as set out in Sections 4 and 5) highlight the fact that there are concerns regarding compliance with obligations regarding Safety Data Sheets and information being passed down the supply chain. In terms of enforcement, this is an issue that should be considered further following publication of the results of REACH-EN-FORCE-2 project focused on formulators of mixtures.

In order to facilitate the analysis of the system, a more harmonised and systematic approach to the collection of data on the number and type of duty holders should be implemented and the Competent Authorities should keep records on more specific classes of non-compliance found.

7.4 Synergies Between REACH and Sectoral Legislation

7.4.1 Introduction

The project conducted on the scope of REACH and other relevant EU legislation (Milieu 2011) has identified many synergies between REACH and other legislation. Sometimes these synergies are the result of in-built mechanisms expressly provided for in REACH or in the other legislation, such as cross-references. In other cases the synergy is by providing a better information base for the regulation. Such synergies include the use of information, e.g. classification, risk assessments or risk management measures provided for under other legislation, under REACH. Another example would be the use of data from REACH risk assessments when selecting substances subject to regulation or control under sectoral legislation or when implementing such provisions. Specific examples are given below in a non-exhaustive list.

This information is based on Milieu (2011): *Technical assistance related to the scope of REACH and other relevant EU legislation to assess overlaps.*

7.4.2 Chemical Controls

Examples of synergies where the information from REACH could be applied under other specific chemicals legislation, includes:

- The PBT assessment conducted by registrants under REACH could be used by authorities to help to identify potential POP substances under the Regulation (EC) No 850/2004 on persistent organic pollutants; and
- The regulation on Ozone Depleting Substances (Regulation (EC) No 1005/2009 on substances that deplete the ozone layer, recast) could benefit

from the assessment done under REACH CSA in order to identify new candidates for inclusion in the Montreal Protocol.

- REACH registrants could on the other hand benefit from the information collected and shared under the Mercury Regulation on the banning of exports of metallic mercury (Regulation (EC) No 1102/2008), in particular the safety assessment for the disposal of metallic mercury.

7.4.3 Product Controls

Synergy has been identified between REACH and several EU legislation related to product control where the information or risk assessments provided in REACH could be useful.

- According to the General product safety Directive (Directive 2001/95/EC) producers are required to identify any risks which their products might pose to consumers. The information provided by REACH on how to control risks of uses including in consumer products could support this type of assessments.
- According to the Quality of Petrol Directive (Directive 98/70/EC) the producer is required to assess metal additives, and the assessments made in the REACH registration of these metals could be re-used in this context.
- The Directive on Toys safety (Directive 2009/48/EC) will benefit from information generated under REACH as the Directive require SDSs to be communicated for substances contained as well as a list of components and materials used in the toy.
- In the Packaging waste Directive (Directive 94/62/EC) information provided in REACH registration dossiers (CSA) could be used in setting standards for packaging and for checking compliance with essential requirements set out in Annex II of the Packaging waste Directive, and in the support the process of developing technical standards in the Directive on explosives for civil use (Directive 93/15/EEC).
- The Directive on Construction Products (Regulation (EU) No 305/2011) refers directly to the communication of information required in Articles 31 and 33 of REACH to be provided together with the declaration of performance.

7.4.4 Waste

Several synergy possibilities exist between REACH and the waste legislation. Some are mentioned here:

- Sector legislation on waste streams could draw on the information held by ECHA in the process of identifying additional substances for management e.g. under the End of Live Vehicles (Directive 2000/53/EC), the Directive on electronic waste (Directive 2002/96/EC (WEEE)), the Battery Directive (Directive 2006/66/EC) and the Directive on the use of hazardous substances in electrical equipment (Directive 2002/95/EC (ROHS)); and

- Furthermore the Waste Framework Directive (Directive 2008/98/EC) provides a synergy option from the Directive to REACH because the identification of wastes can be used as an input to the preparation of the parts of the CSA focussing on waste, i.e. the suitable waste codes from the List of Waste as established in the Commission Decision 2000/532/EC including subsequent amendments.

7.4.5 Environmental Protection

In environmental protection, there are several links and possible synergies, e.g. to the Water Framework Directive and related regulation, as well as to the regulation of industry.

- Data generated through the implementation of the Water Framework Directive (Directive 2000/60/EC) and other water-related directives (monitoring and EQS (Directive 2008/105/EC) can be used in carrying out REACH assessments or when considering possible authorisation or restriction of a substance. Conversely, data from REACH registration process and substance evaluations can be used when implementing the Water Framework Directive e.g. in permitting of installations or use of data on the intrinsic hazard of substance for prioritising substances or datasets used to generate DNEL and PNECs and assessing PBT properties as an essential starting point for EQS development.
- In the Industrial Emission Directive (Directive 2010/75/EU) information on the uses, releases and hazards of substances provided in REACH registrations or Annex XV dossiers can support the development of reference documents on industrial sectors (BREF). Vice versa permits issued under this directive can ensure implementation and functioning of RMM that are recommended in REACH exposure scenarios and are also mentioned in the permit

7.4.6 Worker Protection

With respect to the legislation on worker protection, examples of synergies are:

- The risk assessment carried out under the Directive on the risks related to chemical agents at work (Directive 98/24/EC (CAD)) relies on the information transmitted down the supply chain as required in REACH, i.e. the SDS and attached exposure scenarios. Also the identification of carcinogen and mutagen substances under the Directive on the risks related to exposure to carcinogens or mutagens at work (Directive 2004/37/EC (CMD)) relies (indirectly) on the information generated under REACH;
- The information generated under REACH and the CSA could be used under the Pregnant Workers and Young Workers Directives (Directive 92/85/EEC and Directive 94/33/EC) to help assess risks from chemical agents to safety or health; and

- Finally the information on use conditions and risk management measures generated in the REACH CSA and communicated in SDS and the attached exposure scenarios can provide useful information for the assessments of substances for health effects related for workers in mineral-extracting industries (Directive 92/91/EEC and Directive 92/104/EEC) and requirements at temporary or mobile construction sites (Directive 92/57/EEC).

7.4.7 Food Safety

In the food safety area, the following synergies are identified:

- There is a possible synergy between the restrictions manufacturing and use of certain substances as specified in REACH Annex XVII and the legislation on food contaminants. (e.g. cadmium, arsenic, lead and mercury) because these restrictions indirectly can reduce the levels in feedingstuffs and food (Regulation (EC) No 178/2002); and
- Furthermore some information on substances required under REACH is also required for the authorisation of the use of these substances in food contact materials (Regulation (EC) No 1935/2004).

8. CONCLUSIONS AND RECOMMENDATIONS

8.1 Summary of Aims and Approach

The overall aim of the work reported above has been to provide a better understanding of the benefits to human health and the environment following the current implementation of REACH and to propose recommendations on how to improve the level of protection of human health and the environment. These recommendations are to relate, in the first instance, to modifications in the implementation and enforcement of REACH, with consideration then given to changes in the development of guidance and in providing interpretation. As a last resort, the recommendations might consider changes in the legal provisions of REACH.

In order to assess the functioning of the different mechanisms of the Regulation and the extent of the realisation of the expected human health and environmental benefits to date, we have combined different types of analyses. This has included approaches to capture any quantitative evidence of benefits, as well as more qualitative and perception based approaches. This work has included:

- A literature review of the previous impact assessments and of the reports produced by ECHA and a range of other organisations;
- An analysis of the statistical data produced by ECHA and other relevant data sets, including the available outputs from the REACH Baseline study;
- Analysis of the raw data collated by CSES through the surveys they conducted for DG Enterprise and Industry on the competitiveness and innovation impacts of REACH⁶⁶; and
- Direct consultation by RPA and Oekopol with industry representatives (companies and associations – a total of 60 interviews) covering different relevant sectors and all the roles under REACH, e.g. manufacturer, importer, formulator, downstream user and article producer.

The interviews with industry were based on a series of “work hypotheses”, which set out the pathways through which the Regulation’s drivers are expected to deliver benefits. The aim of the interviews was then to discuss their experience with the first phase of REACH, and to gather their opinions on the hypothesized pathways for the generation of benefits in order to understand if the Regulation is effectively working (especially referring to recital (1) of REACH “...ensure a high level of protection of human health and the environment...”). Interviewees were also asked for any recommendations for its improvement.

However, it is too soon to have a complete picture of the extent of the impacts: databases are still being set up and all the relevant stakeholders (from the chemical companies to the Agency and the Commission) are in the “learning by doing” process, familiarising themselves with the duties imposed by this ambitious Regulation.

⁶⁶ CSES (2011): Impact of REACH on single market and competitiveness, draft report for DG Enterprise and Industry. And CSES (2011): Impact of REACH on Innovation, draft report for DG Enterprise and Industry.

Nevertheless, the assessment carried out for this study provides an indication of areas where improvements should be made if the expected benefits of REACH are to materialise. It also verifies the general hypothesis that REACH will deliver human health and environmental benefits. Although the extent to which it has done so to date is limited, this is much as expected for the first round of phase-in substances to be Registered. As problems in implementation are ironed out and more and better information is generated for those substances where the lowest levels were available prior to REACH, benefits can be expected to improve and for many of these to have a last impact in relation to human health and the environment (for example, the identification and then control of newly identified CMRs).

The remainder of this section sets out for each of the work hypothesis explored in the preceding sections our conclusions, the identified issues and recommendations for potential measures to address them.

8.2 Registration

8.2.1 Key Findings

The first phase-in deadline of the Regulation was 1st December 2010. As of 19th December 2011, 23,857 registration dossiers were submitted resulting in 4,136 registered substances⁶⁷.

All of the following substances should have been registered by this date: the substances manufactured or imported in quantities of 1,000 tonnes or more per year; carcinogens, mutagens and reprotoxicants categorised 1a or 1b under the CLP Regulation (EC) No 1272/2008 manufactured or imported in quantities of 1 tonne or more per year; and phase-in substances classified as very toxic to aquatic organisms which may cause long term adverse health effects manufactured in greater than 100 tonnes or more per year. In addition, non phase-in substances must be registered before they can be manufactured or placed on the market, when registration would be required under Title II of REACH.

In order to understand if registration is acting as a driver for the generation of benefits, four main work hypotheses were:

- The generation of new (test) data will lead to improved information on the properties of chemicals, improved reliability of classifications and thus improved information on safe use and handling. It will also improve the information base for the implementation and enforcement of other legislation;
- The preparation of chemical safety assessments for substances registered at greater than 10 t/y and which have hazardous properties should create benefits through a reduction in unsafe uses;
- The requirement to carry out a PBT assessment as part of the Chemical Safety Assessment should help ensure that substances of Very High Concern are

⁶⁷

<http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances>

identified and can be subject to more detailed evaluation and potentially authorisation (or restriction); and

- The requirement to register substances will create benefits for human health and the environment where a substance is no longer supported by registrants due to its hazardous properties and is thus withdrawn from the market.

The realisation of benefits expected from the registration driver through these four pathways is limited to date but expected to have a greater impact in the future. This is because the substances registered in the first round of REACH have been those for which the greatest level of data was already available. However, there is a fear that some of the benefits arising from changes in recommended RMMs may be lost due to problems surrounding SDS (see Section 5).

In addition, the evaluation of dossiers should act as an enhancer of benefits if it helps registrants learn how to improve their registration dossiers. Guidance should also act as an enhancer by providing tools for assessing safe use. Similarly, inspection and enforcement should act as enhancers by ensuring there is an incentive to comply with the registration provisions within the Regulation.

Changes in Classification

From an analysis carried out for this study of substances being monitored as part of the REACH Baseline Study⁶⁸, it is clear that the information being generated by REACH is resulting in changes in classification, with the majority of these being more restrictive classifications. This is particularly noticeable for endpoints such as acute toxicity, sensitisation, reproductive toxicity and aquatic toxicity (acute and chronic). Overall, the percentages classified after registration increased across all of the endpoints being considered. This suggests that classifications are becoming more reliable as more and improved information on substances properties is generated and as registrants harmonise classifications. These findings are important as classifications drive the need for a Chemical Safety Assessment, for the development of exposure scenarios and, in response to these, for registrants to put forward recommended risk management measures in their extended Safety Data Sheets (SDS). There are some outstanding issues, such as the continued existence of multiple self-classifications which is giving rise to problems for formulators, but these should reduce over time as more substances go through registration.

Chemical Safety Assessments

With respect to the duty to prepare a Chemical Safety Assessment, the findings support the hypothesis that this should lead to safer use as new or more stringent risk management measures than those currently in place are being recommended by registrants to their downstream supply chains. This should lead to benefits for workers, to the environment (through reduced emissions) and to the general public through reductions in exposures, particularly as the lower tonnage substances go

⁶⁸ Oko-Institut, FoBiG, DHI and INERIS (2011): REACH Baseline Study: 5 Years Update, Progress Report IV, Eurostat study Reference No 2010/S 167-255573, Freiburg, December.

through registration. However, there are also concerns that registrants are carrying out exposure modelling using default assumptions only and that this is resulting in some cases to overly stringent recommendations on operating conditions and risk management measures.

ECHA, through its guidance, should encourage registrants to consider more fully the use of detailed downstream user data on how substances are used in practice (volumes, operating conditions, frequency, duration, temperature, etc.) so as to ensure that the exposure assessments undertaken in the CSA are realistic and hence provide a reliable basis for recommending risk management measures. This is important to the generation of benefits because better targeted measures will help ensure that downstream users actually (being able to) implement the operating conditions set out in exposure scenarios and increase the overall credibility of the CSA process. For example, this could include stronger recommendations for the use of existing methods and approaches for exposure assessment, in particular in the field of workers protection, such as control banding, exposure modelling and standardised operating procedures to ensure the development of realistic exposure scenarios.

Guidance and tools to develop Chemicals Safety Assessments should be further adapted, made easier to install and use and made more specific with regard to the possibilities to modify conditions of use. The enhancing function of these tools for the conduction of CSAs is particularly important for the next registration phase due to the expected higher number of SMEs registering.

PBT Assessments

An analysis of selected substances registered in the first phase-in period suggests that registrants have not yet fully responded to the need to provide a clear assessment of PBT and vPvB properties. More work on this aspect may be required across the first tranche of registration dossiers; such assessments are likely to become more important in the next registration phase, as the lower volume substances are likely to have had less data available on their properties prior to registration under REACH than the higher volume substances had pre-REACH.

Substance Withdrawal

One of the objectives of REACH is to progressively replace hazardous substances with less hazardous alternatives. Substance withdrawal is therefore expected to create benefits to human health and the environment, if the substitution results in reduced exposure and/or emissions of hazardous substances.

There is evidence that substances have been “dropped” from the market or otherwise not registered due to their properties (in particular CMRs) and the potential costs of supporting them through authorisation as well as registration. It is also clear though that substance withdrawal may be taking place as part of the rationalisation of product portfolios. It is less clear that, where substances have been withdrawn, they have been replaced by a less hazardous alternative as, in some cases, manufacturers are offering instead alternative substances of a similar hazard profile. This is an issue that should be investigated again in future research.

Much concern on substance withdrawal is based on the expectation that less experienced companies with fewer resources would register in the next two registration phases. ECHA and the COM may wish to consider increasing their efforts for supporting SME registrants in order to avoid unwanted withdrawal of substances that would lead to no additional benefits to human health and the environment.

8.2.2 Recommendations

Main Recommendations

There is a need for ECHA, MS and the Commission to support the continued learning of all actors as to what constitutes a good registration dossier. Ensuring the better fulfilment of existing rules should be given priority over improving the rules.

- 1) The evaluation of registration dossiers shows that the quality of information is not sufficient and it is expected that this problem will be more pronounced with the lower volume substances. For its part, it is essential that industry increases its effort to provide high quality dossiers which would ensure the safety of substances placed on the market. It is also important that ECHA effectively communicates its learnings from the first phase in easy to use and concise guidance documents as well as illustrative best practice examples. This communication should be accompanied by (separate) documentation of the reasons for requesting additional information from registrants, including a justification for how this contributes to proper risk management. The aim should be to ensure that dossiers are brought into compliance with REACH requirements. Member States should focus enforcement activities on addressing those quality aspects that result in registration dossiers being non compliant.
- 2) Industry should increase its efforts with respect to the requirements for a PBT assessment. Annex XIII prescribes that if a substance at a screening level is found to be either P, B or T or vB or vP it should be subject to further testing by the registrant, unless sufficient RMM are implemented. ECHA may want to consider providing further guidance on the need for these assessments and Member States should take actions to check on such assessments as part of evaluation and enforcement activities.
- 3) Support tools to facilitate information generation and transmission should be further developed and optimised in cooperation with industry. ECHA should continue to offer training, in particular for the use of CHESAR and conducting chemical safety assessments. The further development of CHESAR should consider integrating available assessment tools and risk management measures from other legal areas.

Lower Priority Recommendations

- 4) Existing methods and approaches for exposure assessment, in particular in the field of workers protection, such as control banding, exposure modelling and

standardised operating procedures, should be applied to develop realistic exposure scenarios. Where possible monitored values should be used where modelled values cannot be generated or are not precise enough. Registrants should also make better use of downstream user information on RMMs already in place, rather than recommending more generic measures that conflict with what industry has adopted over time and is agreed with national health and safety and environmental protection authorities. ECHA should further emphasise the value of these approaches in its guidance; industry associations should organise events for experience exchange and discussion between “new” and “old” registrants.

- 5) ECHA and the Commission may wish to consider increasing their efforts for supporting SME registrants in order to avoid unwanted withdrawal of substances that would lead to no additional benefits to human health and the environment.

8.3 Information through the Supply Chain

8.3.1 Key Findings

Effective supply chain communication is essential for the functioning of REACH both in terms of registrants relying on information for the assessment of risks and of downstream users relying on good information to implement safe use. Manufacturers and importers of hazardous substances are required to provide hazard, exposure and risk management information to their recipients, primarily via an extended SDS (eSDS). In addition, suppliers of articles that contain chemicals identified as Substances of Very High Concern (SVHCs) have obligations (under Art 33) to provide information available down the supply chain and to consumers, to enable the safe use of those articles.

For these provisions, three main work hypotheses were examined which can be summarised as follows:

- The communication of information through SDS and eSDS creates benefits because new information is passed to downstream users to enable them to check their handling and use of chemicals;
- The requirement to communicate information upstream on operating conditions or risk management measures creates benefits because new and appropriate RMMs are identified and included in up-dated safety assessments and the overall quality of safety data sheets is improved; and
- The need for article producers to communicate the presence of an SVHC on the candidate list within an article leads to benefits by helping to ensure the safe use of articles; triggering requests from retailers for the phase-out of SVHCs in articles; and enabling consumers to take the presence of an SVHC into account in their purchasing decisions.

The obligation on registrants to set out safe operating conditions (OCs) and RMMs and to provide such information to downstream users is new. It should therefore have

generated benefits during this first phase but is likely to be even more important for those substances about which there is currently less knowledge.

With respect to the quality and value of SDS and eSDS, the findings are mixed. The quality of SDS will have improved because the information on classification (and hence labeling) contained within them is regarded as more reliable. In addition, the information being provided on DNELs is useful for workplace safety assessments (as a substitute for an OEL) and can contribute to better targeted RMMs. However, communication of information on PNECs would appear of less value given the difficulties in linking environmental emissions at a particular site to environmental concentrations; in this respect they are of more value to authorities than to downstream users.

However, there are clear problems with regard to the content and format of current eSDS. The role of these in delivering health and environmental benefits can only be fulfilled if the information being provided to downstream users is in a more usable format than is the case for many of the current eSDS. The fear is that unless the quality of these improves, there may be a reduction in the usefulness of the documents to downstream users. Many consultees noted that due to the large amount of information contained in the eSDS that is either not relevant, not useful or confusing, the information needed to ensure safe use can be “hidden” or “diluted”. As a result, some actors are not circulating eSDS if they believe that they will not be understood by downstream users, and thus that basic safety information could be ignored.

Thus, until eSDS for substances are understandable and concise, enforcement authorities may wish to stress that formulators should focus on including the most prominent information in mixture SDS (e.g. uses advised against, RMMs which are known to not have existed before). This should prevent formulators from forwarding “useless and extensive” information in order to ensure legal compliance. They should also be encouraged to communicate with suppliers on the improvement of their information. Linked to the above, there may be value in research which looks into the details of changes in risk management measures arising from the chemical safety assessment in comparison to the risk management measures triggered by classification alone. An open discussion of what information from the exposure scenario is of most value should be identified so that this can be communicated.

Despite the above, players at the bottom of the supply chain, such as article producers, have benefited from an increased level of knowledge on the properties and/or the possible uses of chemical substances. This can only have been the result of supply chain communication requirements. The same is true for end-users, who’s responses to the CSES surveys indicate that REACH had increased their level of knowledge on the properties and/or the possible uses of chemicals.

With respect to communication on SVHCs through the supply chain, the starting hypothesis was that human health and environmental benefits would be delivered through the “announcement effect” associated with the candidate listing of SVHC. It was also hypothesised that the requirement for the provision of information on SVHCs in articles contained in concentrations above 0.1% to end-users of articles

could lead article recipients (e.g. retailers) to avoid articles containing SVHCs or, as a minimum, would ensure the communication of information on safe use and disposal.

Both of these propositions would appear to be supported. Candidate listing is leading to early action towards substitution by formulators and demands for substitution within their supply chains by article producers. Thus, it is expected that SVHCs will gradually be withdrawn from use, particularly from supply chains that produce end-consumer goods. It is less clear that substitution is taking place to the same extent where use of the SVHC is in an industrial process and where the substance is not present in the final good. There are concerns, though, that the substitutes are not necessarily always better from a human health or environmental perspective. In this respect, there may be value in considering groups of substances with similar properties together when assessing substances for entry onto the candidate list.

It can also be concluded that the need to communicate on SVHCs has delivered benefits, in that it has made companies more aware of raw materials in their products. In the longer term, this will lead to much greater awareness throughout the supply chain of chemicals management issues and the replacement of SVHCs in articles; however, in the short term, it is proving difficult for EU article producers and retailers to put in place the necessary information management systems. Although work has started to put in place the necessary information systems to manage supply chain communication and to undertake the necessary compliance checks, they are worried that, as the candidate list increases in size, it will become more difficult for them to manage these activities. It is therefore important that they increase efforts in this regard.

There is a problem with the interpretation of the 0.1% concentration threshold in articles, with there being inconsistencies across the EU as to how an article is being defined. While most countries have adopted the Commission and ECHA's definition, some Member States have adopted an alternative approach. The Commission's interpretation means that, in many "final" articles, the 0.1% will not be exceeded although the article may be composed of (exposure relevant) parts with high SVHC amounts. This interpretation means that information on the presence of SVHCs in those parts does not reach the user of the article, potentially reducing the benefits of these communication requirements. These differing interpretations also give rise to problems with regard to the internal market.

8.3.2 Recommendations

Main Recommendations

- 1) The first step in supply chain communication is the basis of all further communication and therefore has to be improved first:
 - ECHA (in cooperation with industry) should progress their work on CHESAR and derive from that the core information structure for communication on uses in order to facilitate respective supply chain communication;
 - ECHA should prepare a revised ES Format for supply chain communication as soon as possible, based on a review of best practice. A standardised IT format

should also be developed; a harmonised IT template is required so that processing (merging and scaling) can be done through the use of software (e.g. CHESAR);

- Industry should use the CHESAR information structure to develop their software tools to provide safety data sheets;
 - Industry's work on standard phrases for conditions of use and risk management measures should be continued; however, it appears that more commitment is needed as well as stringency in meeting internal deadlines and targets as trust that such tools will be developed in time has been lost; and
 - Downstream users should (be encouraged to) provide information on conditions of use in ECHA's information structure in a targeted way. Standardised sector tools like spERCs should be further developed to comprehensive assessment support instruments.
- 2) Formulators have an essential role in the supply chain communication with regard to the information on safe use, because they have to provide their safety data sheet in a way that it gives orientation to the downstream user on what to actually do. Although not legally required, a consolidation of information is necessary and respective guidance is (still) not available, except for the concept of DPD⁺ by CEFIC. ECHA should work with industry to develop specific guidance for formulators on how to identify and process information that should be forwarded to the customers and information that should not.
- 3) Communication on the presence of candidate list substances in articles is being hampered by the different interpretations of the legal text between the COM and Member States. This issue should be clarified and a legally binding interpretation should be found.
- 4) Challenges in the communication on candidate substances have two aspects: a) identification of the content and b) what to communicate if a candidate substance is contained above 0.1%. Industry should consider building up electronic systems which allow identifying candidate substances in articles and article parts (such as the IMDS material management system of the automotive industry). This would support the implementation of all article related requirements. The content of communications on SVHC should be further explained to avoid only the name of the substance being communicated (with this being of little benefit).

Lower Priority Recommendations

- 5) Consideration should be given to assessing groups of substances on the candidate list to avoid formulators and downstream users shifting to unsuitable alternatives. As part of this, ECHA and the Competent Authorities of the Member States should ensure greater transparency on how substances are identified for candidate listing. These processes may also benefit from early consultation with industry experts and registrants.

8.4 Authorisation and Restrictions

8.4.1 Key Findings

The authorisation provisions within REACH are aimed at assuring that risks from substances with properties of very high concern (SVHCs) are properly controlled, with this including the progressive phasing out of their use. It is a hazard based concept, although the prioritisation of SVHCs does take into account factors such as production volumes and whether there is wide-dispersive use of the substance as proxies for potential risks.

REACH also includes a separate provision allowing restrictions to be placed on the manufacture (or import), placing on the market or specific uses of either a substance, mixtures and/or articles (subject to some exemptions), where these can be shown to pose an unacceptable risk to human health or the environment that should be addressed on an EU-wide basis. The restriction provisions are not dissimilar to those established under the earlier combination of the Existing Substances Regulation and the Marketing and Use Directive. However, the restriction process under REACH is expected to speed up the time taken for measures to be adopted and implemented and to allow for more targeted assessments.

The two work hypotheses were tested in relation to these provisions.

- Candidate listing and the possibility of a future authorisation requirement trigger benefits because they provide incentives for the substitution of SVHCs. This is achieved by: discouraging manufacturers from the registration of listed substances; triggering requests for phase-out by article producers; triggering the reformulation of mixtures; and triggering the promotion/ identification of alternatives by manufacturers (and may trigger innovation).
- Restriction triggers benefits by placing controls on activities giving rise to risks and, through the registry of intentions, by providing an incentive to substitute away from the substance of concern.

At the time of writing, 73 substances had been entered onto the candidate list, with 36 substances prioritised for authorisation. From the above information, it is clear that both Annex XIV Listing and candidate listing are having their desired effect: substances placed on the lists are being withdrawn from use (whether all uses or only partially across some uses) and downstream users are moving to substitutes where possible. Thus, these instruments are beginning to deliver their intended benefits of removing substances of very high concern from use in the EU.

As anticipated, substance withdrawal is taking place because manufacturers and importers are reluctant to bear the risks of registering a substance that may be subject to authorisation, which would lead to further costs associated with having to make applications for continued use. Where the use of a substance is considered justifiable or important, manufacturers are less willing to withdraw it from the market and downstream users also appear to be willing to support critical substances through the authorisation process. There is concern though amongst downstream users over the

loss of substances which deliver particular performance characteristics for which there are no good substitutes at present. This may impact on processing requirements (higher resource use and thus emissions of other substances to the environment), on product quality (which could lead to increased maintenance, frequency of replacement and wastes), or on product availability, with all of these having potentially negative health and environmental implications.

At the same time, there is a need for transparency in the judgements underlying the decision making by Member States and the Commission when deciding which chemicals should have dossiers prepared and then on deciding those which should be prioritised. Further explanation and justification could help address this issue and build understanding and trust.

Companies have also indicated though that there are difficulties in handling information on the presence of a SVHC following candidate listing within the timeframes allowed under the Regulation, with this being a particular issue for complex supply chains where inputs have to be organised across a number of different sectors or actors. The current requirement is for such communication to take place immediately, which is impractical; extending the timeframe briefly after listing would ensure that complex supply chains were able to fulfil their obligations and reduce the likelihood that suppliers make false declarations (thereby negating the intended benefits).

With regard to the restriction provisions, it is currently too soon to comment on whether or not the Registry of Intentions is acting as a signal to manufacturers and downstream users to consider developing or moving to alternatives. The processing of individual substances through the restriction is operating more quickly than took place under the Existing Substances Regulation and Marketing and Use Directive. However, it is of note that not many substances have been processed in total, with this aspect disappointing as it is limiting the human health and environmental benefits observed so far. More proposals were expected by this point in REACH implementation from both Member States and the Commission.

8.4.2 Recommendations

- 1) In order to protect against substitution with similarly hazardous substances the following actions should be taken:
 - Consideration of listing substance groups, where it is likely that substitution with a substance within the same group is likely (ECHA and MS);
 - Development of guidance and training on alternatives assessment (Industry);
 - Compilation of information on possible alternatives to the use of the SVHC from commenting and other information sources (Industry, Member States, ECHA), as well as “exclusion” of substances known to be preferred alternatives but also having problematic properties; and

- Research to determine whether or not substitution takes place with less hazardous substances and the impact that candidate listing is having in this respect.

8.5 Enhancers

We identified four main enhancers within REACH, with these being:

- Evaluation;
- Inspection and enforcement;
- Synergies with other legislation; and
- Guidance and other support, including the dissemination of information to external stakeholders.

The role of these pathways to benefits was not been explored through interviews with individual companies or with industry associations, except to ask about inspections in a general sense and the usefulness of guidance and other support. Discussions were held with ECHA, however, and other information from published or soon to be published sources has been drawn upon.

Dossier Evaluation

Dossier evaluation undoubtedly has the potential to ensure that the health and environmental benefits that should arise from the proper fulfillment of the main provisions of REACH are in fact achieved. It is essential to ensuring the quality (through a quality control function) of registration dossiers and that this improves over time. In particular, ECHA may want to check carefully the claimed status of a substance (if it is effectively an intermediate or not, with repercussions on the information requirements and on the evaluation process⁶⁹), the plausibility of the suggested RMM and the reliability of default assumptions used in the exposure scenarios (as industry consultees highlighted issues in this respect). ECHA may also want to consider including additional prioritisation criteria for dossier evaluation to those already prescribed under art.41(5) of the Regulation, e.g. dossiers of substances classified for chronic aquatic toxicity end-point, that may suggest persistent and/or bio-accumulation properties, given that this appears to be an aspect needing attention more generally. Such dossiers might then feed into the substance evaluation process.

The transfer of experience from the evaluations to the evaluation progress report and FAQs, etc. is seen as a helpful and effective way to promote learning. If learning points from the evaluation processes were included in guidance updates as well, this would be an important step in the improvement of registration dossiers in the future. Furthermore, direct contact between ECHA and registrants was also stressed as an important opportunity to learn how dossiers could be improved.

⁶⁹ Art. 49: “For on-site isolated intermediates that are used in strictly controlled conditions, neither dossier nor substance evaluation shall apply”.

The success of evaluation may also depend on the existence of a common understanding of quality between ECHA, Member States and industry. Although most feedback shows a generally positive picture, ECHA's decisions do not always appear to be well supported by technical or scientific justifications (with this highlighted as an issue with regard to testing proposals and queries over the use of read across methods). More generally, it is clear that there is a need to further inform registrants about the evaluation process itself, because there still appear to be misunderstandings on its scope and implications.

The inclusion of lessons from compliance checks in the related guidance documents is important; it ensures that common shortcomings are specifically addressed, increasing the likelihood of avoiding such issues in the next registration phase. This would also be an appropriate way of documenting an "agreed understanding" of dossier quality. In order to actually measure the effect of dossier evaluation, statistics could be collected on the type of responses to evaluation decisions and in particular to quality observation letters, as the latter are non-binding. Furthermore, it should be ensured that the Member States undertake enforcement of evaluation decisions in order to ensure the credibility of dossier evaluation.

Inspection and Enforcement

In this first phase of the implementation of REACH, inspections were more focused on ensuring a broad understanding of the Regulation by the duty holders, with resources allocated so as to provide guidance to companies to increase levels of compliance. This type of approach should help ensure that the obligations placed on different actors are met and that registration and the other requirements are carried out to an adequate quality. It is likely therefore to act as an enhancer to the benefits delivered through the main drivers.

As reported above, interviewees highlighted the concerns that they have regarding the fact that extended Safety Data Sheets do not yet appear to be being produced in the numbers expected, with this resulting in a lack of exposure scenario information being passed down the supply chain. In terms of enforcement, the failure for eSDS (even if in a simplified form as suggested above) to be provided downstream is an issue that should be considered further following publication of the results of the REACH-ENFORCE-2 project focused on formulators of mixtures.

It has been suggested that conformity statements on the absence of SVHC are being signed by suppliers even though they lack knowledge of the actual SVHC content, passing the burden of compliance down to retailers. This non-compliance is in part due to chemical impurities, use of different batches of input materials, etc. combined with a lack of sufficiently high penalties and a fairly low probability of being caught. Member States and enforcement authorities should consider increasing penalties for improper declarations and increasing inspection activities on this aspect.

Similarly, increased inspections of imported articles would help ensure a level playing field for EU producers as well as importers. The Forum should consider if the current

arrangements are adequate and set out an EU-wide strategy on random checking of importer articles.

Synergies between REACH and Sectoral Legislation

A project conducted on the scope of REACH and other relevant EU legislation (Milieu, 2011) has identified many synergies between REACH and other legislation, with these being the result of in-built mechanisms expressly provided for in REACH or in the other legislation, such as cross-references. In other cases the synergy is by providing a better information base for the regulation. The existence of such synergies highlights the enhancing effect that the information being generated under REACH is having and will continue to have on delivering human health and environmental benefits more generally.

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