ASSESSMENT OF THE HEALTH AND ENVIRONMENTAL BENEFITS OF REACH

ENV.D.3/SER/2011/0027r

Final Report
Part A – Methodology

prepared for
DG Environment

RPA

April 2012

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DG Environment, European Commission

by

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Table of Contents

1. INTRODUCTION 1
1.1 Study Objectives 1
1.2 Structure of this Report 1

2. DEVELOPMENT OF AN ASSESSMENT METHODOLOGY 3
2.1 A General Model for the Assessment 3
2.2 The Benefit Drivers in REACH 4
2.2.1 Mapping of Main REACH Provisions 4
2.2.2 Components to the Assessment Framework 4

3. CRITICAL REVIEW OF METHODOLOGIES AND PREVIOUS ASSESSMENTS 11
3.1 Review of Available Methodologies 11
3.1.1 Overview 11
3.1.2 Commission Impact Assessment Guidelines (2009) 12
3.1.3 ECHA's Guidance on Socio-Economic Analysis 13
3.1.4 RPA et al (2011): Assessing the Health and Environmental Impacts in the Context of Socio-economic Analysis Under REACH 14
3.2 Critical Review of Previous Assessments 15
3.2.1 RPA (2003): Assessment of the Impact of the New Chemicals Policy on Occupational Health 15
3.2.2 Pickvance et al. (2005): The Impact of REACH on Occupational Health 17
3.2.3 Extended Impact Assessment 19
3.2.4 DHI (2005): The Impact of REACH on Environment and Human Health 20
3.2.5 REACH Baseline Study 22
3.3 Summary of Methodologies, Data Requirements and Links to Indicators and Benefits 28

4. THE MODEL FOR ASSESSING THE HUMAN HEALTH AND ENVIRONMENTAL BENEFITS OF REACH 31
4.1 Introduction 31
4.2 General Model for Assessing Health and Environmental Benefits 32
4.2.1 Monetary Valuation Based on the Quantitative Indicators 34

5. SUMMARY OF INDICATORS 37

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 theentry 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 A – has been organised as set out below, with Section 2 of this report overlapping with Section 3 of the Part B report. The aim of

this repetition of information is to help ensure that each Part can be treated as a standalone document.

- Section 2 discusses the approach adopted towards developing the methodology for both the assessment to be carried out as part of this contract and for future evaluations;

- Section 3 presents our review of the assessments undertaken pre-REACH and discusses the extent to which the same types of approach can be applied at this stage in REACH implementation;

- Section 4 sets out the different types of assessment that we have identified as being possible at this point in time, with different approaches linked to the provision of different types of information (quantitative versus qualitative), as well as the potential for monetary valuation; and

- Section 5 provides a summary of the types of indicators of benefits used in the second part of the report.

2. DEVELOPMENT OF AN ASSESSMENT METHODOLOGY

2.1 A General Model for the Assessment

The first task of this study essentially focused on developing the methodological framework to act as the basis for assessing the human health and environmental benefits of REACH, both in relation to its current implementation and for the future. This work comprised a series of sub-tasks, the outputs of which provide much of the material presented in this report. Only a short period of time was available to undertake this work, due to the need to feed the results into the subsequent impact assessment work and the overall REACH Reporting exercise (Article 117 Reporting).

The work started with a detailed review of the REACH Baseline Study methodology[1]. The aim 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[2], with this facilitating interactions between the two studies.

We also reviewed some of the assessments that were undertaken in the past with the aim of predicting the likely health and environmental benefits of REACH. The aim in this case was 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 REACH 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 the impact assessment work (Task 2) was developed. This included identifying how the

1 Eurostat (2009): **The REACH baseline study – A tool to monitor the new EU policy on chemicals**, Luxembourg, Office for Official Publications of the European Communities.

2 *REACH baseline study: 5 years update*, expected in February 2012.

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.

2.2 The Benefit Drivers in REACH

2.2.1 Mapping of Main REACH Provisions

As noted above, a key aspect in the development of the assessment framework was the elaboration of the benefit drivers in REACH and the pathways through which these drivers deliver the benefits. Since the scope of this study is specifically to assess the public health and environmental benefits, the drivers generating business benefits are not included.
In order to identify the main drivers of health and environmental benefits, we reviewed the different provisions within REACH and the corresponding obligations that they placed on the various duty-holders. The starting point for this was a mapping of these key obligations and the functioning of the legislation. Figure 2.1[3] 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.).

The REACH Regulation was 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 also 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.).

2.2.2 Components to the Assessment Framework

Through the mapping of the different obligations and duties, we identified the following key components to the assessment framework:

[3] This figure is also re-presented in the Part B report to enable standalone reading of both documents.

- 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.

As can be seen from Figure 2.1, 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 Enforcementactivities.

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 fulfill 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.

If we then examine each of these drivers in detail, we can establish the pathways through which benefits should be delivered by REACH. Within the scope of the current impact assessment, we have set out a starting hypothesis for each pathway which describes the cause and effect relationships. For each of these, it has then been possible to identify a series of qualitative and/or quantitative indicators which can be used either directly as an indicator of benefits or which can act as a proxy for benefits.

These pathways and indicators are set out in Figures 2.2 to 2.4 for Registration, information through the supply chain, and then Authorisation and Restriction. The hypotheses developed for each of the pathways and the indicators are presented and discussed in the Part B report and are not repeated here for brevity.

However, it is important to note that these Figures acted as the reference for the review of methodologies and the literature which follows in Section 3 to this report and for the "model" set out in Section 4.

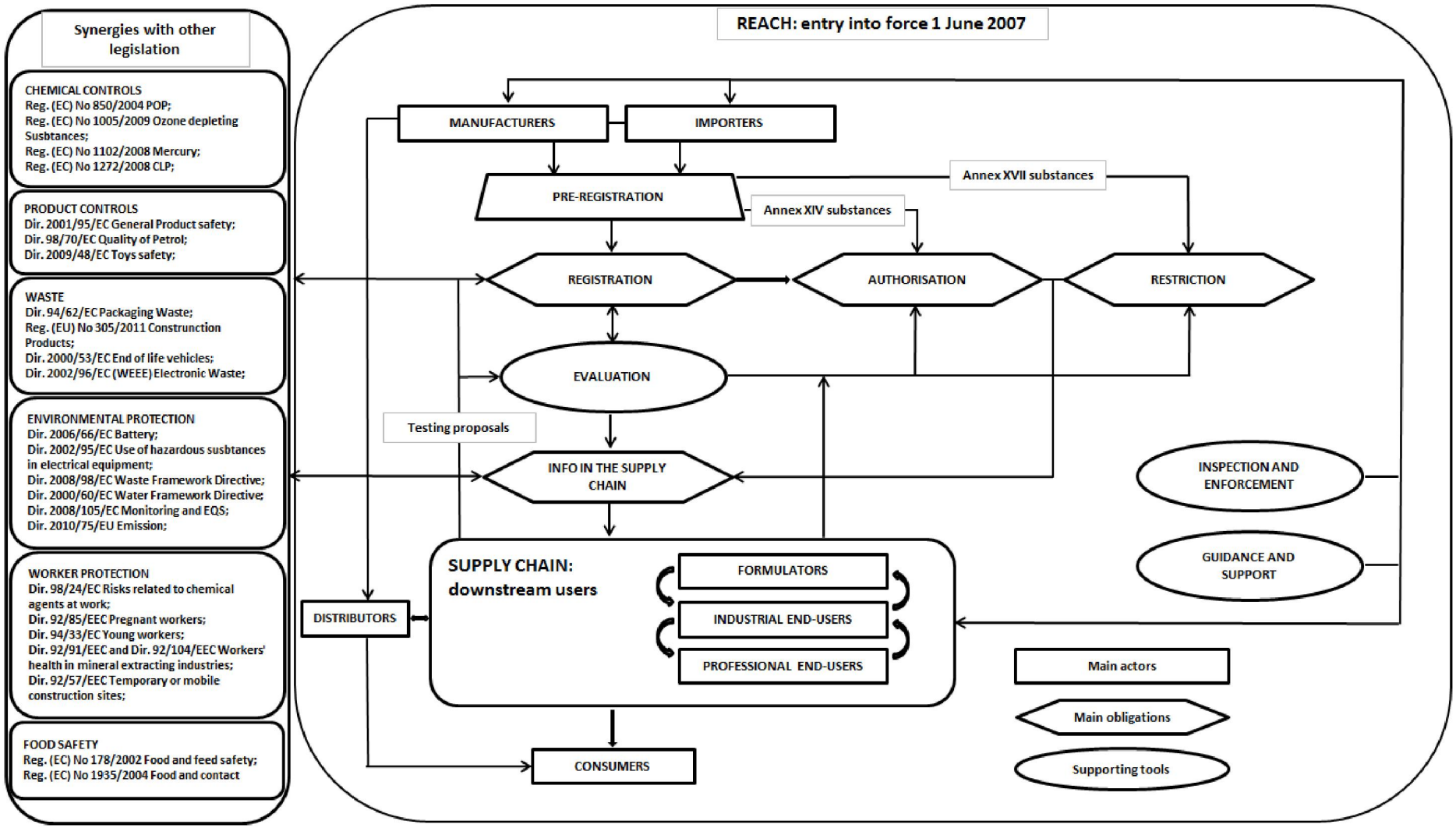

Figure 2.1: Main Actors, Main Obligations, Enhancement Tools and Synergies with Other Legislation

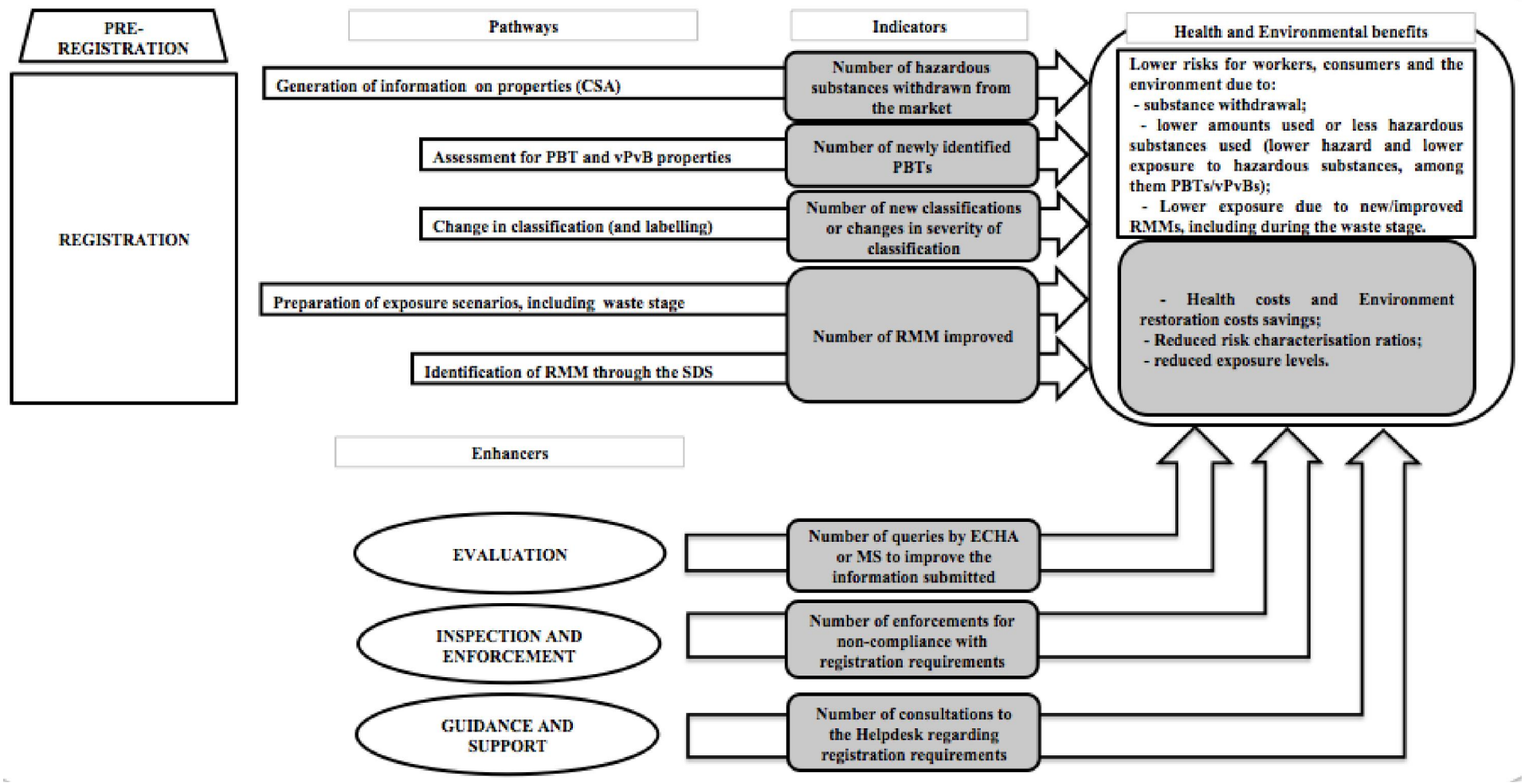

Figure 2.2: The Drivers, Pathways and Indicators of Benefits under Registration

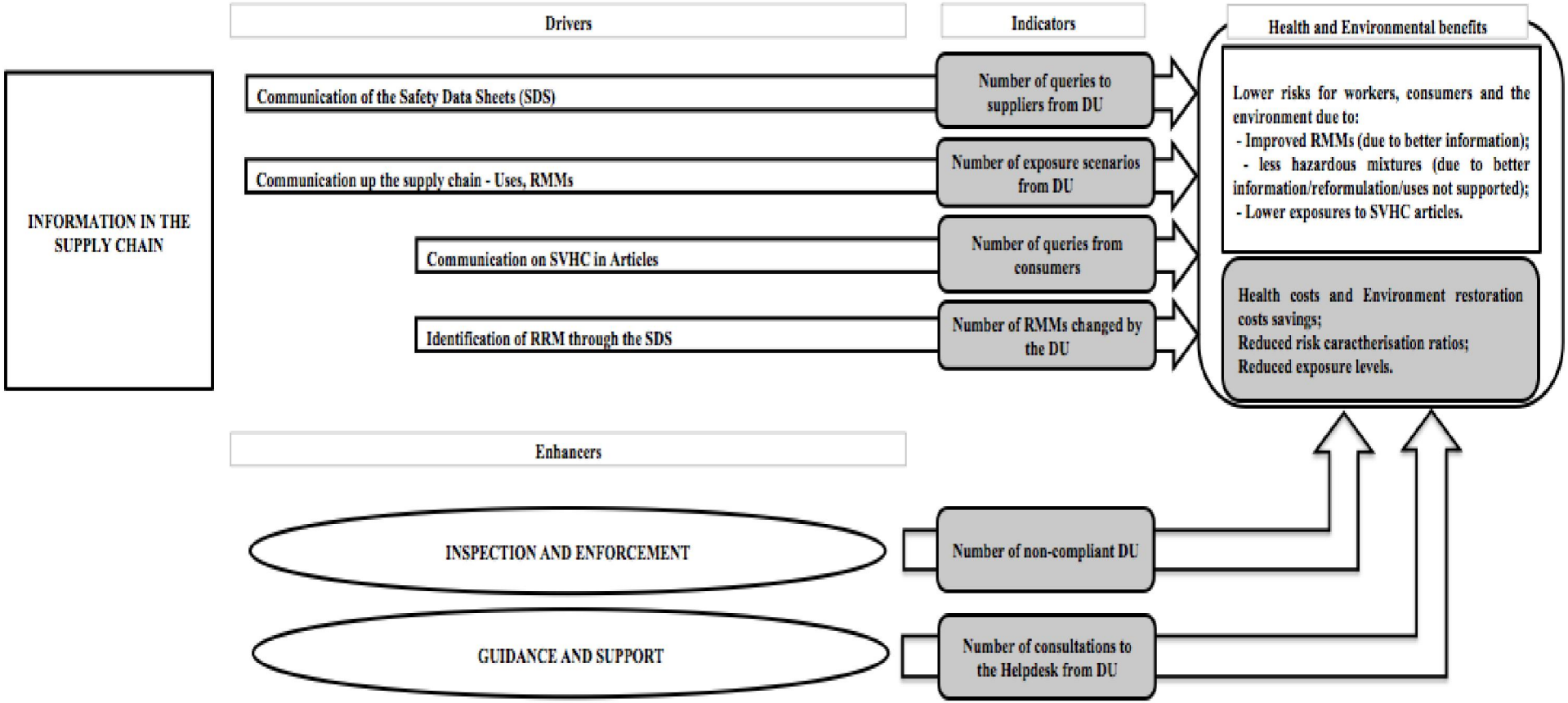

Figure 2.3: The Drivers under Title IV "Information in the Supply Chain" and Title V "Downstream users"

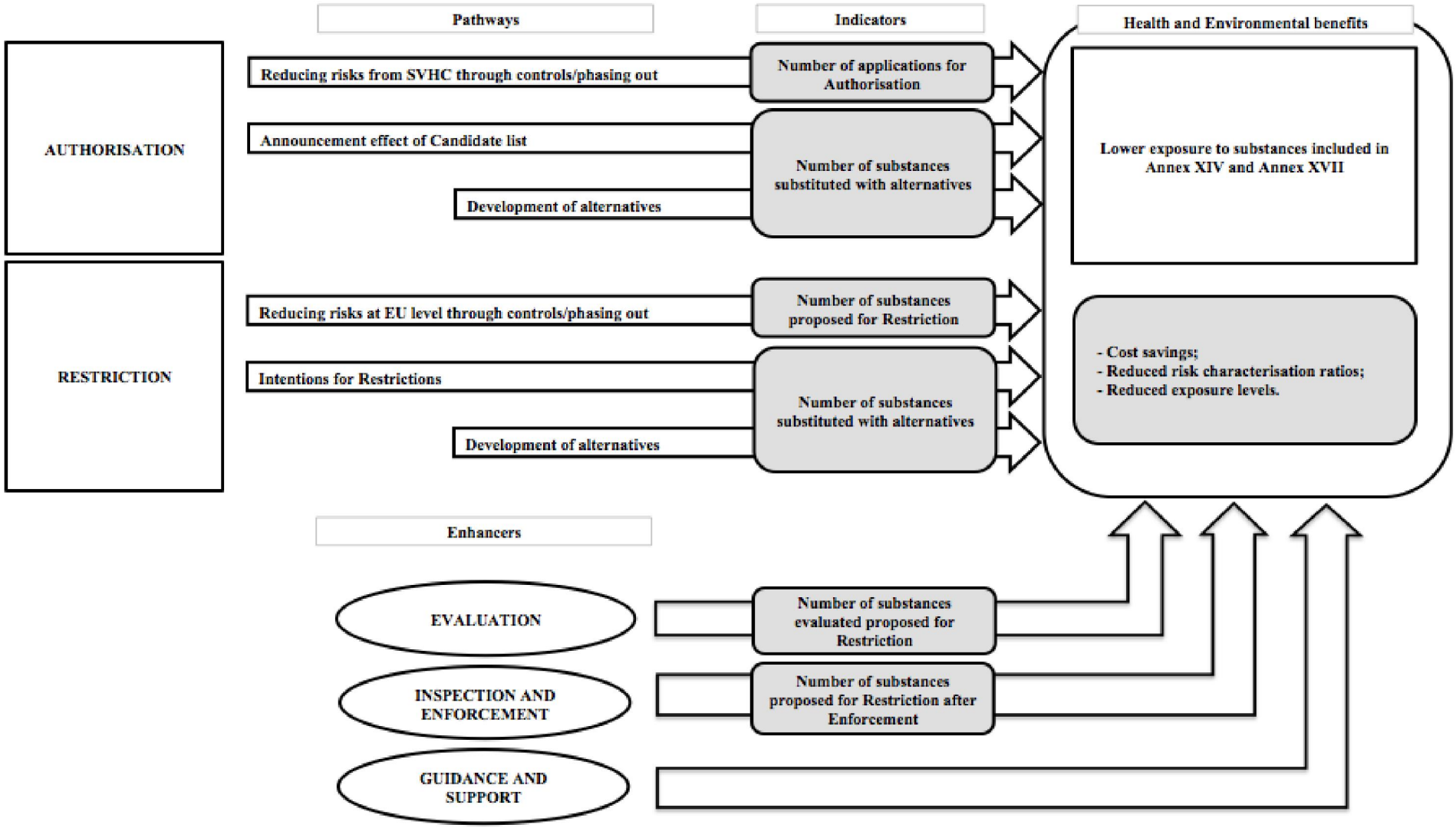

Figure 2.4: The Drivers under Title VII "Authorisation" and Title VIII "Restriction"

3. CRITICAL REVIEW OF METHODOLOGIES AND PREVIOUS ASSESSMENTS

3.1 Review of Available Methodologies

3.1.1 Overview

There is a number of guidance documents available to assist in assessing environmental and human health impacts arising from regulatory proposals. Some of these are not specific to a chemical or health and environment context, such as the Commission's Impact Assessment Guidelines[4]. Others are specific to the chemicals context and have recently been issued in order to aid with the preparation of socio-economic analysis under REACH, such as the ECHA guidance documents and the RPA et al. (2011) "Logic Frameworks" produced for DG Environment. These different guidelines are reviewed below, with a focus on the assessment of the types of environmental and human health impacts that should be delivered by REACH.

In addition, a number of impact assessment related studies have investigated the human health and environmental benefits anticipated from REACH in more detail. Oekopol conducted a review of such studies in 2007[5] (which also included studies covering business benefits but these are not the focus of this current study). The review concluded that studies and assessments of REACH impacts have focused on the determination of costs for industry, with the description and quantification of human health and environmental benefits considered to a much lesser degree. This could be due to the difficulties connected to benefit estimation - such as the dependency of impacts on the behaviour of industry actors, the lack of data on cause-effect linkages, on current chemical-related damages, a gap in baseline information at an enterprise level, etc. However, *the fact that benefits should be created is substantiated at qualitative and/or quantitative level by the studies analysed*.

Table 3.1 presents a summary of the studies examined by Oekopol in their 2007 study and the benefits they identified. Some of the studies are reviewed in more detail below, with a focus on the identification of the pathways, the assumptions and data used for the analysis and the usability of these for assessing the human health and environmental benefits of REACH post implementation.

Table 3.1 Summary of benefits and studies where they were analysed

Benefit	Pathways	Studies discussing benefit
Less environmental damage – less spending for environmental damage	Indirect: better information on substance properties and safe conditions of use Direct: safety assessment before marketing; (quicker) implementation of risk management measures; control of uses through authorisation	EC (2003): Extended Impact Assessment - qualitative RPA & BRE (2003): environmental and human health benefits – qualitative + examples Chemsec (2006): Developing countries – qualitative Chemsec (2005): Surviving REACH – qualitative DHI (2005): environmental and human health impacts – quantitative

[4] For further information see: http://ec.europa.eu/governance/impact/key_docs/key_docs_en.htm

[5] Oekopol (2007): *Analysis of Studies discussing Benefits of REACH*, February 2007

Table 3.1 Summary of benefits and studies where they were analysed		
Benefit	**Pathways**	**Studies discussing benefit**
		ECORYS (2004): summary IA's – qualitative + example PCB clean-up
Reducing risk to the environment from SVHC	Direct: through implementation of RMMs; throughconditions of the authorisation	EC (2003): Extended Impact Assessment – qualitative ECORYS: summary IA's – qualitative DHI (2005): environmental and human health impacts – quantitative
Less public spending to compensate damage	Indirect: better information through registration, authorisation and restrictions procedure	Chemsec: Developing countries – qualitative Pickvance et al. (2005): occupational health – quantitative RPA (2003): occupational health – quantitative UBA (2004): benefits in selected chains - qualitative
Less incidence of occupational diseases	Indirect: better information through registration	Pickvance S et al. (2005): occupational health – quantitative RPA (2003): occupational health – quantitative
Less public spending for public health damage	Direct: control of uses through authorisation Indirect: better information through registration (substance properties and RMMs)	RPA & BRE (2003): environmental and human health benefits – qualitative + quantitative examples
Less incidence of public diseases	Direct: control of SVHC in consumer products through authorisation Indirect: better information through registration	UBA (2004): benefits in selected chains – qualitative + examples WWF (2003): social costs of chemicals - qualitative
Reducing risks / exposure of the general public	Direct: control of SVHC in consumer products through authorisation Indirect: better information through registration (properties and safe use)	EC (2003): Extended Impact Assessment - qualitative DHI (2005): environmental and human health impacts – quantitative ECORYS (2004): summary IA's – qualitative UBA (2004): benefits in selected chains - qualitative

3.1.2 Commission Impact Assessment Guidelines (2009)

The Commission's Impact Assessment (IA) Guidelines, revised in 2009, give general guidance to the Commission services for assessing the potential impacts of different policy options. Public health and safety is included under the Guidelines, including a number of questions aimed at assessing whether there are changes in health risks in the workplace and with respect to the general public via the environment. Furthermore, it also includes public health risks associated with waste disposal and some stages of the life-cycle, like energy use.

In terms of the valuation of health impacts, the Guidelines suggest quantification whenever possible by using the Healthy Life Years indicator[6], or measuring both quality and quantity of life using QALYs (quality adjusted life years) or DALYs (disability adjusted life years). Monetary valuation is also recommended although the

[6] The Healthy Life Years (HLY) indicator is in the core set of the European Structural Indicators as its importance was recognised in the Lisbon Strategy.

guidance acknowledges the problems in so doing. Approaches suggested in Annex 9 to the Guidelines include market based approaches, such as the Cost of Illness (COI) or human capital approach, revealed preferences based approaches, such as Willingness to Pay (WTP) or Willingness to Accept (WTA), and related units based on these, such as Value of Statistical Life (VOSL) and Value of Statistical Life Year (VOLY)[7]. Annex 9 suggests a range of values for different units of measurement, as:

- 50.000 – 80.000 Euros for a QALY (although this could be adjusted for a concrete policy proposal to reflect the specific context);
- 1-2 million Euros for VOSL; and
- 50.000-100.000 Euros for VOLY in Europe.

Life-cycle approaches are also recognised as potentially useful tools to assess the environmental impacts through the different stages of a product's life. As for environmental impacts, monetisation is also recommended. Examples are given of a range of EU-funded environmental impact assessment models, e.g. ECOSENSE; FUND; IMAGE; RAINS; and SMART. These consider environmental and man via the environment health impacts but vary in their focal point, e.g. pollutants to the atmosphere, climate change, acid deposition, etc. Of all the examples given, SMART may be the most applicable to the chemical context, as it focuses on long-term chemical changes and pollution in soil and water but only from atmospheric deposition. Other modules from the models also may be transferable, such as the maps on environmental sensitivities from RAINS.

In summary, although the Impact Assessment Guidelines favour the use of monetisation and go on to suggest some values, the applicability of these values to REACH will always be limited to the extent to which it is possible to quantify the changes in health impacts, e.g. reductions in exposures and hence the burden of certain types of diseases for workers, consumers or the general public. With respect to environmental impacts, the Guidance is in line with the REACH requirement to consider end-of-life stages but is quite general in terms of suggesting specific methods for assessing impacts.

3.1.3 ECHA's Guidance on Socio-Economic Analysis

Guidance on socio-economic analysis (SEA) was issued by ECHA in 2008 and 2011, on restrictions and authorisation, respectively.

Both guidance documents propose a stepwise approach whereby the assessment focuses on those health and environmental impacts that are considered to be significant, with the level of detail and quantification applied determined by the extent to which further information will contribute to developing a robust SEA. Throughout the process, judgements will need to be made (drawing on the expertise of others as appropriate) on what impacts are likely to be significant and how these can best be assessed.

[7] For more discussion on the individual units, please refer to: http://ec.europa.eu/governance/impact/commission_guidelines/docs/iag_2009_annex_en.pdf

The ECHA Guidance documents highlight the importance of moving from qualitative to quantitative assessment and acknowledge the difficulties in quantification when assessing environmental and human health impacts. The units of measurements are similar to those set out in the IA Guidelines.

3.1.4 RPA et al (2011): Assessing the Health and Environmental Impacts in the Context of Socio-economic Analysis Under REACH

This report proposes linked logic frameworks for the assessment of human health and environmental impacts, using the ECHA Guidance on SEA for restrictions as the starting point[8]. The aim of the frameworks was not to invent a new approach but to provide further suggestions and refinements as to how health and environmental impacts in particular could be assessed within the overall SEA process for restriction and authorisation as envisaged by ECHA.

The frameworks set out a step-by-step approach, from impact characterisation to assessment, including valuation and comparison with impacts from the alternatives. The approach is based on a qualitative assessment followed by a more quantitative assessment where appropriate and of value to decision makers. Two case study applications were undertaken of the proposed methods (on TCEP for human health and HBCDD for the environment, two substances of very high concern (SVHC) under REACH).

The study suggests the use of different tools for benchmarking human health impacts as well as proxy indicators for impacts, e.g. changes in exposure level and/or frequency, changes in concentration of a chemical of consumer products, changes in emissions. Fuller quantification may be possible, e.g. where it is possible to use the methods commonly applied as part of health impact assessment to quantify changes in disease cases or disease burden, but should be accompanied by information and the level and sources of uncertainty. The approaches to valuation are those included in the earlier guidelines, namely the use of QALYs or DALYs, the use of VOSL estimates and the use of cost of illness or resource cost estimates.

In comparison with the ECHA guidance for restrictions, the framework suggests use of data from the chemical safety assessment, supported by other information, to infer environmental impacts but highlights that care is needed in doing this, to avoid over-estimating the impacts (as a risk assessment will be generally based on worst-case scenarios). Thus, for example, a smaller sub-set of data may be sufficient to quantify the benefits to the environment. On the other hand, it is recognised that data not included in the CSA may be needed to produce robust information suitable for use by decision makers, e.g. relating to tonnages used, the efficiency of emissions control equipment, local environmental factors (e.g. actual receiving water dilution rates), etc.

[8] At the time of preparation, the ECHA guidance on SEA and authorisation was not yet available.

3.2 Critical Review of Previous Assessments

Although the above types of guidance documents set out model approaches for assessing human health and environmental benefits, the practical problems that can arise are perhaps better illustrated by a review of previous attempts at predicting the benefits that would arise from REACH. Some of the key impact assessment studies are reviewed below, with the aim of identifying those types of approaches that should be considered for future assessments of REACH benefits.

3.2.1 RPA (2003): Assessment of the Impact of the New Chemicals Policy on Occupational Health

Identification of Drivers and Indicators

This study started with an extensive review of the health and safety legislation already in place which would interact with REACH and provide an enhanced level of protection to workers against occupational diseases that may arise from exposure to chemicals. The study highlighted that the health impact reductions and the associated economic benefits will not be delivered by REACH alone, but that REACH is expected to accelerate the introduction of risk management measures, including: improvements in classification and labelling, the adoption of new occupational exposure limits under other legislation, bans on the use of substances of very high concern, etc.

The study identified the generation of new and additional information on the health risks arising from chemicals whose properties are currently poorly understoodas a main driver of benefits. It took as its basis predictions in the White Paper setting out a Strategy for a Future Chemicals Policy that REACH would result in the identification of some 500 new carcinogenic, mutagenic and reproductive (CMRs) toxic substances (the continued use of which would have to be authorised for specific applications). The identification and authorisation of these currently unknown CMRs, together with other chemicals posing human health hazards, as predicted as leading to a reduction in the incidence of work-related occupational health effects in the future and to savings in the economic costs associated with medical treatment and recovery.

Five groups of disease were analysed:

- Skin: eczema, allergic contact dermatitis, irritant contact dermatitis;
- Respiratory System: asthma, allergic rhinitis, and other respiratory illnesses;
- Eyes: conjunctivitis;
- Central Nervous System: CNS disorders; and
- Cancer: various end-points, with a focus on those that stem from general chemicals exposure (as opposed to cancers arising from exposure to known carcinogens).

Availability of Data

The approach adopted in the study identified and reviewed the published data on the numbers of occupational diseases associated with exposure to "specific", "unspecified" and "unknown" chemicals. The availability of data[9] on occupational diseases varied at the Member State level, with a good range being available for Germany, the UK and a few other EU countries. The data also varied in terms of the disease end-points that were covered and the degree to which the data separated chemicals-related cases from other causal agents or activities. As the data became more specific to chemical-related diseases, the number of countries for which detailed figures were available decreased, in particular for data on numbers of occupational diseases associated with "unspecified" or "unknown" chemicals.

Data on exposure to carcinogens across all workers in the EU were provided by the CAREX database (for the years 1990-1993). These data and other estimates of health experts on the number of cancers that are due to occupational exposure reflect cases related to known or suspected carcinogens. No reliable statistical data were found on the numbers of cancers resulting from exposure to unknown carcinogens.

The study also reviewed the literature on the economic costs of ill-health and combined different approaches to economic valuation (direct and indirect resource costs, human costs) considering:

- The costs of medical treatment;
- The value of lost output; and
- The human costs, where these reflect an individual willingness to pay to avoid a particular health effect.

All of the figures for the health care costs, hospital treatment costs for respiratory diseases, the value of a statistical life and the willingness to pay to avoid morbidity related health effects and to reduce the risk of fatality were taken from different studies, among them: Pearce (2000)[10] and the values from the European project ExternE (1997).

Assumptions in the Study

The study combined information from different sources and generalised at EU level the validity of data coming from specific countries with the help of adjustment factors. The approach that was adopted for extrapolation was based on estimating incidence rates amongst the worker population for individual countries and then using the average figure to predict the number of cases at the EU level.

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[9] Annex I to the study reports a large list of statistical data sources to the date (2003), among them Eurostat, the World Health Organisation and the International Labour Organisation databases, plus the Health and Safety Authorities datasets across the EU.

[10] Pearce (2000): *Valuing Risks to Life and Health, Towards Consistent Transfer Estimates in the European Union and Accession States*, paper prepared for the EuropeanCommission (DGXI), Workshop on Valuing Mortality and Valuing Morbidity,November 13, 2000, Revised December 2000, Brussels.

In order to account for uncertainty as to the impacts of REACH, varying assumptions were made resulting in benefit estimates under low to high scenarios. For example, assumptions were made regarding the effectiveness of REACH (1/3 to 2/3 decrease of health effects by unknown chemicals) and the value of a human life (low and best value):

- Lower bound: one third of the diseases can be avoided. For cancer this is 2,167 cases, which is 0.23 % of the total cancer deaths per year in the EU;
- Upper bound: two thirds of the diseases can be avoided. For cancer this is 4,333 cases or 0.47% of the total cancer deaths per year in the EU.

Once the estimates of the number of disease cases avoided for worker populations were developed, the study then valued these in money terms. It used as its lower estimate €0.65 million (based on the willingness of individuals to pay to avoid the risk of fatality, no medical costs are included in this estimate) with the best estimate being €1.0 million (human costs and some elements of medical costs and lost output).

The resulting estimates of the benefits for occupational health were that these would fall between €18 billion and €54 billion, depending on assumptions concerning the number of disease cases avoided and the choice of the estimate as to the value of a statistical life. These are not the total benefits of REACH, because other potential benefits in relation to consumer and public health and the environment have not been taken into account.

The estimates assumed that the benefits would be realised over a 30-year time period, with the time when reductions in diseases would begin to occur linked to the nature of the end-point. A 3% discount rate was assumed for consistency with the Business Impact Assessment carried out for REACH (RPA and Statistics Sweden, 2002).

3.2.2 Pickvance et al. (2005): The Impact of REACH on Occupational Health

Identification of Drivers and Indicators

The aim of the study carried out by the University of Sheffield for the ETUI was to complement the set of estimates produced by the above RPA study on occupational health benefits. As a result, it did not cover cancers but focused on two broad groups of occupational diseases: non-malignant diseases of the skin (dermatitis) and diseases of the respiratory system (asthma and chronic obstructive pulmonary disease).

The authors combined a range of techniques to calculate the direct and/or indirect health benefits of REACH, calculating the burden of occupational disease from the information obtained on incidence rates, estimating the proportion of cases attributable to exposure to substances affected by the Regulation and using this estimate to calculate preventable disease for the EU-25 workforce (200 million). The authors then analysed the costs associated with skin and respiratory diseases in terms of the associated health service costs, productivity costs, and the value of the lost health-related quality of life to the individual using QALYs.

Availability of Data

To determine the disease burden, three databases - PubMed, NIOSHTIC, and CISDOC - were searched for relevant peer-reviewed publications using a range of search terms including: occupational dermatitis/eczema, asthma, chronic obstructive lung/pulmonary/airways disease, burden, prevalence, incidence, compensation, cost, outcome, name of EU state. All reference citations were also followed up and all these data were compared with the information from the public health organisations in the EU Member States and with occupational disease data coming from the EODs, EUROSTAT[11], MISSCEEC[12], EUROGIP[13] and RIDDOR[14] databases.

Health service costs were calculated using evidence from other studies in the published literature (Pickvance*et al*, 2005). For valuing production losses, two alternative methods were used: the human capital approach (the traditional approach) and the friction-cost method. The monetary values of the prevention of reductions in health-related quality of life for individuals with occupational asthma, COPD, and dermatitis was approximated by multiplying an estimated utility decrement over an assumed duration of symptoms by the value of a QALY (assumed to be between €28,000 - €43,000, see also discussion below under cost-benefit analysis). The mid-point estimates of costs incurred due to productivity losses, health care costs, and monetary valuations of the impact of lost health relating to chemicals covered by REACH were calculated for 10-year and 30-year time horizons following implementation of REACH, compared to a scenario in which REACH has not been implemented.

The data regarding the chemical substances produced and marketed in the EU were collected from the EINECS, ELINCS and IUCLID databases.

Assumptions in the Study

The approach adopted by the authors required several assumptions to be made by the analysts. In contrast with the approach followed by RPA, it was assumed that the effects of REACH are likely to be proportional to the theoretical and actual effects of chemical substances wherever they fit into the existing framework of chemical legislation. Given the impact of the assumptions built into the estimates of the number of cases of disease, the authors preferred to set upper and lower bounds based on a range of estimates for the burden of disease rather than for the scope of REACH. These estimates of burden took into account both the case count and the case severity for each disease.

11 http://europa.eu.int/comm/eurostat/newcronos/reference/sdds/en/health/occ_dis_base.htm

12 http://europa.eu.int/comm/employment_social/missceec/index_en.html

13 http://www.eurogip.fr/en/bref/index.htm

14 http://www.riddor.gov.uk

3.2.3 Extended Impact Assessment

Identification of Drivers and Indicators

The Commission's Extended Impact Assessment focused on the quantification of the costs of REACH for the Chemical Industry, providing just a qualitative description of the potential health and environmental benefits and some illustrative quantitative figures. It identified four benefit drivers[15]:

- The generation of information about the properties of the chemicals and the potential risks which they may pose for health and the environment, and to develop strategies to manage these risks;
- The availability and accessibility to this information to downstream users, the authorities and the general public;
- The replacement of the substances of very high concern by new substances less dangerous for health and the environment; and
- The faster action of the authorities when risk reduction measures are needed.

The testing and registration costs could lead to the withdrawal of some substances that the manufacturers or importers think their production is no longer profitable. In the light of the information gathered risk management measures will be taken aiming to reduce risk of exposure to hazardous chemicals.

Availability of Data

The Extended Impact Assessment recognised that a comprehensive quantitative assessment of the health and environmental impacts of REACH would be impossible. This was mainly due to the lack of basic information about the effects of the chemicals that REACH was being introduced to regulate. It noted the complications arising from cocktail effects, non-linear dose-response functions, poor aggregate data and underreported health problems. Notwithstanding, it concluded that the evidence available to support the conclusion that the health burden related to chemicals was considerable, and that the four main drivers within REACH should help reduce this health burden.

The inability to provide a comprehensive quantitative assessment of current impacts meant that it was also impossible to apportion environmental impacts between historical and on-going emissions and to establish how much of the benefits would be delivered by REACH and how much from the existing legislation. For example, regarding the occupational health impacts, the Extended IA stated that the benefits would be delivered in synergy with the existing legislation, e.g. the Chemical Agents Directive 98/24/EC and/or Directive 2004/37/EC on the Protection of Workers from Occupational Exposure to Carcinogens or Mutagens.

[15] EC (2003): *Extended Impact Assessment,* Commission staff working paper, SEC (2003) 1171/3, 29/10/2003.

Assumptions in the Study

The Extended IA noted that estimating the benefits of REACH requires assumptions about:

- The amount of disease that is due to chemicals;
- The proportion of this unknown amount of disease that will be identified by REACH;
- The proportion that will be tackled through risk management measures after socio-economic assessments have been carried out;
- The number of lives subsequently saved and other health improvements; and
- The monetary value attached to these.

Given the current lack of information, the Impact Assessment adopted a conservative figure of 1% as representing the proportion of all diseases (measured in Disability Adjusted Life Years - DALYs) due to agro-industrial chemicals and chemical pollution from diffuse sources; this was based on the estimated range of 0.6% to 2.5% by Murray and Lopez (1996)[16]. The proportion of diseases that will be identified and tackled by REACH was then assumed to be 10%[17]. It was then further assumed that 10 DALYs are equivalent to 1 life saved[18] with the value of a statistical life assumed to be €1 million. It was also assumed that REACH would start to deliver benefits after 10 years of implementation and that these would continue for another 20 years. The magnitude of the estimated benefits from this assessment is similar to that derived by RPA (2003) at €50 billion.

3.2.4 DHI (2005): The Impact of REACH on Environment and Human Health

Identification of Drivers and Indicators

The DHI study identified three approaches for assessing the potential benefits of REACH on the environment and humans exposed via the environment. The aim of applying all three approaches was to circumvent the lack of suitable data. The three approaches were:

- Use of WTP estimates – with this based on benefits transfer of willingness to pay among the broad population for avoiding impacts of chemicals (weaker approach);
- Damage function approach (weakest approach) with this applied to four specific cases. Then, through a system of scoring, the amount of substances with a higher score was estimated and an assumed benefit of 10% of the costs was calculated; and
- Avoided or saved costs approach (most robust approach).

16 Murray and Lopez (1996): *The global burden of disease,* World Health Organisation, 1996.

17 RPA (2003): *Assessment of the impact of the new Chemical Policy on Occupational Health*, 2003.

18 WHO (2002): *World Health Report,* 2002.

Although the use of WTP estimates was considered the theoretically correct approach to assessing benefits, its application was limited by a lack of relevant studies, with only estimates of benefits in relation to drinking water quality derived.

The damage function approach was applied using a risk ranking type of system based on the EURAM[19] method to provide the basis for assessing the likely changes in exposure to hazardous substances, which could then be linked to valuation. The scores which were estimated are measures of environmental exposure (EEX-values), of environmental effects (EEF-values) or measures combining exposure and the toxic properties of the chemicals (environmental scores, ES-values). Persistent toxic substances that are produced in large amounts were ranked very high. Although the method resulted in a very high number of substances being ranked similarly (DHI, 2004), and the DHI study team urged caution in the use of the results, the approach provided a means of benchmarking substances in terms of their relative risks which could be used to develop an overall indicator of more general shifts in risks.

The DHI study (2004) also used the avoided costs approach (as a form of market-based approaches) to estimate the benefits from chemicals regulation. Saved costs included the costs of water purification, sludge and dredged sediment disposal and cleaning of fish. The starting point was that excess levels of chemicals in a specific environmental compartment would restrict the possibilities of using it, thereby implying a loss of potential future income or value and/or costs for treatment or cleaning. The avoided costs approach generated the smallest estimates of environmental benefits but was also considered the most robust of the methods applied (as opposed to WTP values where only limited studies were available).

The benefit drivers discussed in the study were ranked in order of decreasing importance:

- Industry introduces additional Risk Management Measures (RMM) as a consequence of either having re-classified substances as a result of additional information on substance properties leading to additional S-phrases, or having identified risks by preparing a Chemical Safety Assessment (CSA) in relation to Registration of their chemicals;
- Use conditions are imposed as a result of an Authorisation obtained for certain uses of prioritised substances of very high concern; and
- Restrictions on manufacturing, marketing and/or use as a result of the Restriction procedure.

The DHI study (2004) viewed the restriction procedure as essentially a continuation of the Marketing and Use Directive (76/769/EEC), so they assumed that REACH will have no or only minor influence on releases to the environment through this instrument. The main benefits of REACH were then assumed to be related to registration of phase-in (existing) substances manufactured or imported in a quantity of more than 10 tonnes per year and meeting the criteria for classification as dangerous or the PBT/vPvB criteria.

[19] European Union Risk Ranking Method, which was developed for prioritising EU high production volume chemicals for risk assessment.

Availability of Data

The input data for the study were obtained from the European Commission's IUCLID database and from the Danish EPA QSAR2 database. The information from the IUCLID database was restricted to substances manufactured or imported in quantities above 10 tonnes/year and information on properties and amounts was collated for 8,031 substances. The following data were extracted:

- CAS numbers;
- DSN number coding for the registrant;
- Quantities manufactured or imported per year;
- Main Categories of use (per entry); and
- Hazard classification.

All of the input data were uncertain and the authors noted that it could only be used with caution.

Assumptions in the Study

The study highlighted the level of uncertainty associated with all of the data which it relied upon:

- The majority of the information in IUCLID submitted by industry on the quantity of chemicals manufactured or imported was for the years 1991-1995 although some entries have been updated since then;
- Information on main categories of use was on the one hand based on information available to the registrant and on the other hand specified by a number of main categories of uses, which are a weak basis for estimating releases;
- The QSAR models used for estimating biodegradation and aquatic toxicity had not been subject to an external validation and peer review (although a comprehensive internal validation has taken place).

Assumptions regarding the efficiency of REACH in reducing the burden of chemicals were the same as in the Extended IA, fixed at a level of 10% (with the justification for this referenced to RPA (2003) although we note that this 10% figure is not an assumption within RPA (2003); instead it is an interpolation of the average percentage reduction between the low and high scenarios).

3.2.5 REACH Baseline Study

Identification of Drivers and Indicators

The 2008 REACH Baseline Study[20] led by Eurostat set out a system of indicators to monitor the impact of REACH on human health and the environment over time based

[20] http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-RA-09-003/EN/KS-RA-09-003-EN.PDF

on a series of specifically-developed surrogate markers, and other indicators related to the quality of the information available for risk assessment purposes. Theserepresent:

- **Administrative indicators:** used to monitor the REACH process. These refer to the registration, evaluation, authorisation and restriction steps defined by REACH and include, for example, the numbers of substances registered and of chemical safety reports documented by ECHA;

- **Risk and quality indicators:** intended to link two of the main aims of REACH, the reduction in nominal risks of chemicals for humans and the environment and the improvement in the quality of publicly available data. These indicators are assessed on the basis of a defined sub-set of 237 substances; and

- **Supplementary indicators:** these relate to those REACH objectives not covered by the other two indicator types, including increase in the quality of safety data sheets and the use of alternative test methods.

The Risk and Quality Indicator System, the core part of the Eurostat methodology, was developed to determine not the "real" but a "nominal" risk, as the real risk is currently not known (and will only partially be known after the implementation of REACH). The quality indicators define the quality of the calculation of the nominal risk in terms of number of assumptions that have to be included for the determination of the risk. The value of the Risk and Quality Indicator System was designed so as to grow with the repetition of the exercise over the years as new data for a larger subset of substances becomes available. However, the study acknowledged that these indicators could not be easily used by other studies. Instead, it was proposed that the administrative and supplementary indicators could be used to develop an alternative methodology for the quantification of the environmental and human health benefits delivered by REACH.

Thus, only a subset of the overall indicator set developed for the Baseline Study is therefore of relevance to the assessment to be carried out for this study, although the full set of indicators is likely to be of value to future evaluations of the health and environmental benefits of REACH. The potential value of the indicators considered under each pillar with respect to this study is summarised below.

Administrative Indicators

The administrative indicators are aimed at monitoring progress with REACH implementation, and in particular as regards registration (including total numbers of registrations and within different production classes), evaluation (e.g. numbers of testing proposals examined, registration dossiers evaluated and substances evaluated), and progress in authorisation and restriction (e.g. number of substances placed on the candidate list, number of Annex XV dossiers, number included in Annex XIV, number of authorisations granted, etc.). While these measures do not directly inform on either health or environmental impacts, they may be of value in establishing changes in the extent of the use of chemicals of various toxicities against which changes in health and environmental burdens should be measured.

Risk and Quality Indicators

Indicators included in the Eurostat baseline study under this pillar should be those of greatest value to this study, since the system developed by Eurostat is intended to provide information on:

- impacts on workers;
- direct impacts on consumers;
- impacts on the environment; and
- impacts on humans via the environment.

The problem with these indicators lies with the assumptions and data sources needed to derive a measure of the real change in risk, as explained in above. Because of this, it is suggested that as part of future evaluations, it may be easier to gather information on the supplementary indicators listed below.

Supplementary Indicators

A number of 'supplementary' indicators were identified in the Baseline study that could be derived from existing statistics and other data sources that may be available at the Member State (rather than EU) level. Those of potential relevance to thisstudyinclude:

- Relating to protection of human health (workers and consumers) and the environment:
  - changes in quality of safety data sheets;
  - dangerous (toxic) chemicals in households;
  - production of toxicchemicals;
  - cross-border transport of toxic chemicals;
  - occupational skin diseases; and
  - changes in chemical use patterns in Scandinavia and Germany based on information from their product registers.
- Improvement in knowledge of chemical properties and their safe use:
  - availability of hazard data;
  - availability of use and exposure data;
  - changes in classification and labelling.
  - assessment of existing and new chemicals within a single, coherent system:
  - registration of new chemicals as a proxy.

Availability of Data

A problem with some of the above indicators is that supporting data were not available at the time the first baseline report was written in order to establish a baseline for the current or future evaluations. These data still remain unavailable and

thus could not be used for the purposes of this assessment. This includes for instance the number of dangerous substances in the household. It remains unclear whether some of the information will become available in the future (e.g. post December 2011), e.g. whether a formal agreement between Eurostat and the German Federal Ministry for the Environment can be established to obtain output from the BfR[21] database to inform on the 'dangerous chemicals in households' indicator.

Assumptions in the Study

Eurostat started the development of its approach to assessing the impacts of REACH with the commissioning of a study to develop a 'snap shot' of data for the year 2007. The intention was that this would provide the baseline against which future comparisons could be made (Eurostat, 2008 & 2009).

The system is based on the premise that neither the calculation of risk, nor the understanding of changes in data quality and provision, are manageable for all (approximately 30,000) substances falling within the scope of REACH. Instead, the impact assessment system focuses on the detailed statistical analysis of only a very small subset of the chemicals on the European market, with these acting as a surrogate of the wider chemical use situation across Europe. Thus, a stratified subset of 237 substances was randomly selected from approximately 10,000 existing substances considered to be of high, medium or low production volume, as well as the selective inclusion of some Substances of Very High Concern (SVHC).

For each selected reference substance, a "Risk Score" (of between 1 and 1000 or greater) was calculated using criteria specifically developed for the baseline study; this draws on estimates of exposure and toxicity. The toxicity assessment for worker scenarios draws on occupational exposure limit (OEL) values and, for other scenarios, on tolerable daily intake (TDI)-type values or derived no-effect levels (DNELs) where these were available. Where such estimates were not readily available, analogous values were developed for the chemical. Characterisation of environmental effects was similarly achieved by using actual or surrogate values for predicted no effect concentration (PNEC) or no-observed-effect-concentration (NOEC) values for relevant media. Exposure was based upon an exposure assessment that sought to define the 90^{th} or 95^{th} percentile exposure for a given scenario, i.e. a "reasonable worst case". Data gaps were addressed through use of assessment factors (AFs) to address data uncertainty or route-to-route extrapolations or adoption of the medium hazard category via the oral route from the GLEV or OIRIS datasets for non-carcinogens or CMR (Category 1 and 2) substances respectively.

The exposure and toxicity metrics were then used to derive a Risk Score, i.e. a weighted risk characterisation ratio through multiplication of a risk characterisation ratio (RCR) by a population risk modifier and an optional severity of effect modifier. It should be noted that any shift in the level of modelled risk thus derived does not

[21] BundesinstitutfürRisikobewertung, German Federal Institute for Risk Assessment which operations the poisoning information center in Germany and manages a database of classified chemical consumer product to which manufactures and importers need to notify their receipts

represent a change in "real-world" risk but in the "nominal" risk based on the changes in the pattern of the set of Risk Scores.

The degree of uncertainty surrounding the available datasets was also assessed for each chemical and used to derive a "Quality Score". This was based upon consideration of the extent (size of database) and nature (use of robust studies, reliance of QSARs, etc.) of the available toxicity and environmental toxicity datasets. Consideration of the quality of the exposure data encompassed both human and environmental aspects.

The data thus derived were used to construct a series of 'snapshots' of each of the proposed indicators as of the year 2007, with each sample chemical assigned to one of four categories: High Production Volume Chemicals (more than 1 000 tonnes/year; HPV); Medium Production Volume Chemicals (1 000 >> 100 tonnes/year; MPV); Low Production Volume Chemicals; (100 >> 10 tonnes/year; LPV); or Substances of Very High Concern (SVHC). Modelling was conducted for each of the impact classes of interest. The intention was thus to characterise the 'baseline' situation as the basis for future comparison.

The assumption underlying the Baseline study model is that, as REACH implementation progresses, the quality of data will improve leading to more informed knowledge and awareness of the risks relating to chemicals and consequently changes in industry practice regarding the use of chemicals. It is therefore intended that comparisons over time against the 2007 baseline estimates for the subset of chemicals might enable prediction of changes in the overall pattern of the Risk Scores across the chemicals used by industry (i.e. a progressive move away from the use of toxic substances to less harmful alternatives and gradual improvement in quality of data available). The intention is to complement the assessment of changes in Risk Scores by comparison to changes in other metrics relating to workers and consumers over time by reference to data from pre-existing reporting systems in Germany (BfR consumer products database) and Scandinavia (SPIN data).

The baseline study approach was therefore developed to indirectly inform on the degree of REACH's success in ensuring a high level of protection through information provision throughout the supply chain. The Risk and Quality indicator system constitutes the core element of the assessment but – importantly – provides a mechanism for the future prediction of impacts using surrogates of real-world risk (based on scientific approximation and agreed conventions relating to uncertainty) rather than directly measuring 'real' changes in burdens.

Summary

While seeking to establish a wider set of metrics than just the impact of chemicals on human health and the environment, the Eurostat baseline system was never intended as a comprehensive tool to address **all** potential benefits that could arise from REACH implementation. Rather, it sought to establish a number of metrics which could be grouped under the three different types (or 'pillars' as described in Eurostat, 2009) of indicators.

The study is currently being updated and, as can be seen from the Part B report, data on the 71 out of the 237 in total substances that were registered in the first phase-in period has been used in the assessment carried out as part of this study. As more chemicals go through registration under REACH, more information will become available and it will be possible to undertake a broader analysis of the health and environmental benefits arising from REACH.

Even for this subset of 71 substances, caution is needed in translating the predictions of changes in impacts as the Risk Scores to date have been driven by the quality of data factors as much as they have by toxicity and exposure considerations. This means that it is important that this study considers other possible approaches to the benefits assessment than the ones included in the Baseline study.

Table 3.2 sets out the indicators being developed by the Baseline study and compares them to the drivers identified for the purposes of this study. While many of the indicators and supporting datasets for the Baseline study are well established, a number of issues have been identified that might impact on the availability and value of the proposed indicator sets. Those particularly highlighted by Eurostat (2009b) and that are of relevance here include:

- identified data limitations and gaps have cast doubt on the suitability of the proposed indicator on occupational skin disease, so alternative approaches need to be sought;
- a formal agreement between Eurostat and the Nordic Council of Ministers, Chemicals Group had yet to be established to enable access to output from the SPIN database for the 'use patterns in Scandinavia' indicator; and
- further work on indicators to inform on endocrine disrupting chemicals and persistent or bioaccumulative chemicals may be necessary.

While noting that REACH is expected to result in an increased number of substances classified as dangerous, Eurostat (2009b) also recognised that changes arising from CLP will have an influence.

Table 3.2: Eurostat Baseline Study, Drivers and Indicators

Baseline Study Indicator System	Drivers for this Study		
	Direct effect	Indirect effect	Pathway
Administrative indicators			
Registration of chemicals		✓	Better information through registration
Evaluation of chemicals		✓	Enhancement of registration; better information (substance evaluation)
Authorisation and restriction of chemicals	✓	✓	Control of uses through authorisation and restriction.
Establishment of a central agency		✓	Consolidated way of gathering data and assessment
R&Q indicator system			
Protection of human health and the environment	✓		Implementation of risk management measures and control of uses through authorisation and restriction

Table 3.2: Eurostat Baseline Study, Drivers and Indicators			
Baseline Study Indicator System	**Drivers for this Study**		
	Direct effect	**Indirect effect**	**Pathway**
Improvement of knowledge on properties and safe uses of chemicals	✓		Reclassification, effects through (new) coverage by downstream legislation, improved information for safe use and potential re-formulation
Assessment of existing and new chemicals in a single, coherent system	✓		✓
Increased transparency and consumer awareness			(✓)
Promotion of alternative methods for assessment of hazards of chemicals			✓
Supplementary indicators			
Changes in quality of safety data sheets		✓	Better information on substance properties and safe conditions of use
Toxic chemicals in households		✓	Reduced exposure through reduction of toxic chemicals – health benefits through the environment
Production of toxic chemicals	✓		Reduced exposure through reduction of toxic chemicals and benefits to the environment from reduced emissions
Cross-border transport of toxic chemicals	✓		
Occupational skin diseases	✓		Reduced skin exposure from RMM
Changes in use patterns in Scandinavia and Germany	✓	✓	
Availability of hazard data		✓	Better information on substance properties and safe conditions of use
Availability of use and exposure data *Total number (and percentages) of substances with information on use pattern;* *Total number (and percentages) of substances with a CSR;* *Total number (and percentages) of substances with a CSR including exposure assessment and risk characterisation*		✓	Better information on substance properties and safe conditions of use
Changes in classification and labelling	✓		Effects on coverage by downstream legislation and for use in (consumer) mixtures
Registration of new chemicals as a proxy		✓	

3.3 Summary of Methodologies, Data Requirements and Links to Indicators and Benefits

Table 3.3 below summarises the different methodologies available to describe quantitatively the impacts of REACH, the data requirements for each methodology

and the subsequent limitations. It highlights also the fact that the previous relevant assessments tried to combine the different approaches to obviate to the lack of data.

Table 3.3: Summary of Methods for Assessing Health Impacts

Methodology	Underlying Data	Metrics and End-Points	Limitations	Study
Risk Ranking	- Classification - Dose-response	- Qualitative assessment of severity - Likelihood of effect	Does not require quantification of the number of cases of a disease nor take into account the social costs associated with impacts	DHI (2005) Eurostat Baseline study (2009)
Benchmarking	- Hazard data, including persistence - Exposure data (e.g. intake)	- Qualitative comparison of risk vis a vis other substances	Does not provide an estimate of number of cases of a disease nor take into account the social costs associated with impacts	Eurostat Baseline study (2009)
Physical Measure of Disease Cases	- Dose-response - Risk or Odds ratio and Attributable Fraction - Prevalence - Incidence - Exposure data	- Lives saved – cancer effects - Life years saved – cancer effects - Disease cases avoided – mutagenic effects, reprotoxic effects, morbidity effects	Secondary health effects not captured – may be an issue with e.g. carcinogens where exposure may also lead to other chronic or acute effects. Does not take into account health care costs, lost productivity nor social costs. Does not readily allow consideration of benefits related to both morbidity and fatality effects	RPA (2003) Pickvance (2005)
Utility based measure using QALY or DALY	- Dose-response - Risk or Odds ratio and Attributable Fraction - Prevalence - Incidence - Exposure data	- QALYs or DALYs for: - Fatality effects - Life years lost - Morbidity effects taking into account impacts on quality of life	Does not take into account health care costs nor social costs, included costs to carers; may overlap to some degree with lost productivity estimates.	Extended Impact Assessment (2003) RPA (2003) Pickvance et al. (2005)
Cost of Illness	- Dose-response - Attributable Fraction - Prevalence - Incidence - Exposure data	- € Health care or medical costs - € Lost productivity	Does not take into account the social costs associated with impacts on the quality of life. Calculations required data on the average length of a disease event and other observed data that may not be available.	RPA (2003) Pickvance et al. (2005
Revealed Preferences	- Dose-response data to link change in risk to wage premia - Relative risk or similar to assess € per unit risk avoided for avertive expenditure - Exposure data	- € Wage risk premia -> Value of a statistical life - € Avertive expenditure	Does not take into account the social costs associated with impacts on the quality of life nor impacts on other carers. Avertive expenditure method does not provide a true valuation of economic benefits.	No studies use this directly but it will indirectly underlie estimates of the value of a statistical life and there are issues regarding the appropriateness of valuing occupational health benefits related to it in practice
Stated Preferences	- Data on prevalence (?), starting risk levels and after policy risk level -> could be linked to NOAEL, LOAEL and related statistics, together with exposure data	- € WTP for fatality - Value of a statistical life (VOSL) or value of a life year lost (VOLY) - € WTP to avoid a morbidity effect – a disease or disease event	Does not take into account health care costs, but may incorporate a measure of lost productivity and will capture social costs to individual and can capture those to carer.	DHI (2005)

4. THE MODEL FOR ASSESSING THE HUMAN HEALTH AND ENVIRONMENTAL BENEFITS OF REACH

4.1 Introduction

As discussed in Section 3, in 2003, the Commission prepared an Extended Impact Assessment of the then current proposals for the REACH Regulation, with this including an assessment of the potential health and environmental benefits that would arise from the implementation of its various provisions. Based on conservative assumptions, the estimated economic value of the benefits to human health were given as being in the order of magnitude of EUR 50 billion over the next 30 years, although the assessment also made it clear though that this was not an estimate of the benefits of REACH, but rather an indication of their potential scale. The follow-up DHI study found it more difficult to derive a reliable indicator of the potential environmental benefits due to methodological and data issues.

It is important for the Commission to have a model or framework which can improve on these estimates looking into the future. This would help the Commission to:

- monitor the performance of the REACH regulation in terms of reduced risks to human health and the environment;
- provide a means of linking changes in benefits to changes in the Regulation;
- continue to identify possible improvements to the implementation of REACH and to specific provisions of the Regulation which would lead to increases in its efficiency and effectiveness in ensuring a high level of protection to human health and the environment.

As noted in Pearce and Koundouri (2004), due to informational deficiencies and to the large number of chemicals involved, it is impossible to adopt an "ideal" methodology for a rigorous benefits appraisal. For "ideal", the authors intend "*a conceptually sound model, but which ignores the availability or otherwise of the relevant data*"[22]. This approach would require identifying exposure-response functions for each chemical, both in terms of human health and environmental effects. Then it would require estimating the effects of REACH in reducing exposure levels and translating those into reduced effects levels, so that it would be possible to value them in monetary terms using economic valuation procedures. To be strictly rigorous, the methodology should also involve careful selection of an appropriate discount rate and consideration of the distribution of the impacts.

Data on chemical properties, dose-response relationships and exposures are needed however to undertake such an ideal analysis. Although REACH has the aim of providing such information, there are still significant gaps in knowledge. As a result, the impact assessments conducted during the period prior to REACH introduction adopted reasonable assumptions about some of the key variables and parameters.

[22] Pearce D, Koundouri P (2004): *Regulatory assessment for chemicals: a rapid appraisal cost-benefit approach*, Environmental Science & Policy 7, 2004, pp. 435-449

4.2 General Model for Assessing Health and Environmental Benefits

Objective of the model is to find out whether and to what extent REACH and"*all the possible changes in the specific provisions and improvements of the Regulation that the Commission might consider*" generated and will generate human health and environmental benefits. To meet this objective, a seven step assessment tool has been developed. This kind of assessment tool has the advantage to be able to be repeated in time and improved in every single step of the process, as new information and data become available.

First step of the process and essential preliminary task is the review of the relevant literature at the date. Literature review is a fundamental part of every research process and can bring "value" to every operational step, providing new and different glances that could enhance the methodology and broaden the knowledge of the topic.

After the identification of the useful publications among the general guidance documents available to assist in assessing environmental and human health impacts arising from regulatory proposals and the more specific studies to the chemicals context, the review should be performed following a theoretical framework of themes. For this model, we propose that the critical review of the literature should carefully look at:

- The identified and analysed mechanisms (called in this study *drivers*) that link the provisions of the Regulation with the human and environmental benefits generated;
- The assumptions made by the studies in order to overcome the data gaps;
- The data used and their availability;
- The findings and conclusions.

Second step of the process is the identification of the drivers and related pathways through the analysis of the Regulation and its modifications and on the basis of the literature review. If the repeated application of this assessment tool should not identify new drivers or enhancers in the original legal body of REACH, it might find that successive amendments to the Regulation have introduced modifications (and, potentially, totally new drivers or enhancers) to them. In this case the following step should focus on the impacts of the changes in the obligations.

Third step is the formulation of work hypotheses which set out the pathways and associated mechanisms through which the Regulation is expected to deliver benefits. In the case of modifications to the Regulation, new work hypotheses should be formulated to enable the analysis of such changes. The work hypotheses need to be tested through the analysis of the information and data collected.

Forth step is the collection of primary and secondary data, where with primary data we intend data collected for the first time and with secondary data those ones which have already been collected (and possibly analysed) by someone else. For the collection of primary data, a structured survey should be addressed to the Chemical Industry actors, submitting the work hypotheses to the analysis of all the respondents. This approach allows to find out the problems in the functioning of the Regulation,

that in the moment of its formulation where impossible to be identified by the policy-makers. For the collection of secondary data, ECHA is the main source of raw datasets and of preliminary analyses of those datasets. Other data sources could be available at national level or provided by other studies identified for the literature review.

Fifth step is the definition and analysis of indicators in order to quantify the human health and environmental benefits generated by REACH. The analysis of the indicators should provide a quantitative description of the cause-effect link between drivers and benefits, estimating the effects of the Regulation in reducing the exposure levels to harmful chemicals. Essential part of this step is the identification of the baseline or the establishment of one (for a discussion on the difficulties to identify/establish a baseline, please see Pearce and Koundouri, 2004[23]).

Sixth step is the translation of the reduced exposure levels and of the reduced human health and environmental effect levels associated in monetary values. Table 3.3 above provides a review of the valuation methodologies and their limitations.

Seventh and last step is the combination of the information gained across the different assessment techniques to develop more holistic conclusions on benefits generated either from on-going implementation or from proposed changes and the identification of potential recommendations as appropriate to aim of the assessment.

The assessment of the current human health and environmental benefits presented in the second part of the report follows the general model set up above, and evolved over the course of the project in order 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, trying to overcome the data gaps at the present stage of the implementation of REACH. In the future, it should be possible to improve the fifth and sixth step of the assessment tool proposed, undertaking a greater level of statistical and quantitative analysis, as more data should be available from ECHA to facilitate analysis of the impacts of chemicals e.g. the withdrawal from the market, the classification and labelling changes, etc.

The adopted approach 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 REACH Baseline Study;

[23] Pearce D, Koundouri P (2004): *Regulatory assessment for chemicals: a rapid appraisal cost-benefit approach*, Environmental Science & Policy 7, 2004, pp. 437.

- Analysis of the raw survey data collated on the impacts of REACH on the Competitiveness and Innovation of EU companies as well as on the Single Market[24]; and

- 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 implementation in the first phase of REACH, and 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.

4.2.1 Monetary Valuation Based on the Quantitative Indicators

None of the quantitative indicators provided by the Eurostat Baseline Study, as set out in Table 3.2, will enable a robust monetary valuation of the benefits of REACH. Nevertheless, once the database of registered substances and the C&L inventory will be fully available, an analysis of the substance withdrawal from the market due to hazard properties or less hazardous substances added to the market and an assessment of changes in classification could provide a basis for a monetary valuation exercise.

With respect to substance withdrawal, if it is found that substances with CMR, high acute aquatic toxicity or PBT properties have not been registered then a follow-up assessment will be undertaken to determine whether or not it is possible to quantify changes in either disease cases or in environmental presence. If withdrawal is of a carcinogen, then it may be possible to repeat the type of assessment carried out in RPA (2003) or using the approaches described in the Human Health Logic Framework for SEAs under REACH[25] to quantify changes in future cancer burdens; this would be more difficult for mutagens or reproductive toxins but some valuation of the avoidance of future disease cases may be feasible depending on the chemical substance and the ready availability of toxicity and dose-response data.

Where substance withdrawal of substances having acute aquatic toxic or PBT properties, quantification would have to be based on information on environmental hot spots (e.g. from the literature), data on key uses and the likely geographical distribution of these combined with for example consideration of persistence, and/or environmental monitoring data. Although we believe it is unlikely, there may be sufficient information on past problems associated with a particular substance to develop valuations of damage costs avoided resulting from substance withdrawal. Again, the type of assessment that would be carried out here would draw on the range of approaches set out in the Environment Logic Framework for SEAs under REACH.

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[24] 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.

[25] RPA (2011): Assessing the health and environmental impacts in the context of socio-economic analysis under REACH - Part 2: the proposed logic framework and supporting case studies, prepared for DG Environment. Available at Internet site: http://ec.europa.eu/environment/chemicals/reach/pdf/REACH%20SEA%20Part%202%20LogicFrame%20Final%20publ.pdf

Similarly with respect to changes in classification, it may be possible to examine the implications of these in more detail. This will be particularly relevant where the changes relate to classifications on human health hazards and where it is possible to link a substance to use in particular occupational settings. For example, if a substance is newly identified as a respiratory or dermal sensitiser, then it may be possible to follow the type of approach applied in RPA (2003) and Pickvance*et al* (2005) to predict the change in disease cases that would arise from reduced exposures due to increased worker protection. One approach to doing this would be to look at UK and German data on diseases linked to unidentified or unknown chemical agents for the sectors of concern. If data on use for a substance suggests this would be widespread within a sector (e.g. it is a commonly used substance in the processes/activities undertaken) then it may be possible to attribute some proportion of such disease cases to previous exposures. Any such analysis would have to take into account the degree to which personal protective equipment or other measures would be taken in any event to protect against exposures to other substances which were already classified as posing health hazards.

5. SUMMARY OF INDICATORS

Table 5.1 provides a summary of the types of indicators of benefits used in the second part of the report.

Table 5.1: Summary of indicators		
Drivers and enhancers	**Pathways**	**Indicators identified**
Registration	**Chemical Assessment as part of the Chemical Safety Report**	Changes in DNELs, PNECs Number of new RMMs of increased stringency No. of "uses advised against"
	New classification and data quality	No. of new classifications Changes in severity of classification due to the availability of new data Changes in self-classification of substances by manufacturer as given in IUCLID 4 or elsewhere Increase in the level of harmonisation (proxy: No. of SIEFs)
	Assessment of PBTs and vPvBs	No. of newly identified PBTs or vPvBs
	Substance withdrawal for hazard properties reasons	No. of substances withdrawn from the market due to hazard properties or less hazardous substances added to the market
Information in the Supply Chain	**Safety Data Sheets and Communication through the Supply Chain**	Level of feedback communication on SDS quality and feedback / proactive communication on conditions of use (ES) to suppliers from downstream users No. of exposure scenarios generated by DUs No. of RMMs applied to processes changed by the DUs because of REACH information No. of ES for registered substances Quality of ESs at formulators level and usefulness for downstream communication
	Communication on SVHC in articles	No. of hazardous substances removed from articles due to "announcement effect" Number of queries from consumers on candidate SVHC in articles
Authorisation	**Listing of SVHC on candidate list**	No. of applications: adequate control route applications versus SEA route applications; number of approvals; number of exemptions in Annex XIV Decisions to phase out substances or to not-support uses because of listing on candidate list (predictive character of the candidate list) No. of substances replaced with alternatives
Restriction	**Restriction as a process for earlier realisation of benefits**	No. of substances proposed for Restriction Percentage of applications covered and risk reduction assumed to be achieved by restriction No. of substances replaced with alternatives
Evaluation		Feedback by registrants on helpfulness of evaluation given by ECHA No. of queries by ECHA or MS to improve the

		information submitted No. of substances evaluated
Inspection and Enforcement		No. of enforcements for non-compliance with registration requirements No. of non-compliant manufacturers, importers, downstream users in the implementation of ESs
Guidance and Support		No. of consultations to the Helpdesk regarding registration requirements No. of consultations to the Helpdesk by downstream users.